

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation the Effect of Psychological Immunization Strategy on Depression Anxiety and Stress of Pregnant Mothers

Protocol summary

Study aim

Determine the Effect of Immunization Training on the Depression, Anxiety and Stress of Pregnant Mothers

Design

Non-randomized clinical trial, control group, parallel groups, non-blind, pre-test and post-test Sampling using available sampling method With 60 pregnant women

Settings and conduct

A sample of 60 pregnant women referred to the clinics in the city of Dare_shahr is selected by means of a mild to moderate scorecard. Sampling is done non-randomly. In the test group, the samples are divided into 5 groups of 6, and each group has six sessions of immunization training each week for two 90-minute sessions. One and two months later, both groups are re-examined with a questionnaire. The data collection method is a demographic questionnaire and DASS-21.

Participants/Inclusion and exclusion criteria

Inclination to participate in the study gestational age from 16 to 24 weeks lack of mental illness in the individual and the first-degree family having a higher education level or higher healthy fetus in ultra sonographi surveys single-strike pregnancy, no complications Pregnancy no chronic diseases Outcome criteria preterm delivery anxiety disorder during the study (Death of loved ones, separation from a spouse ...) failure to attend 20% of psycho-immunization sessions

Intervention groups

Pregnant Mothers

Main outcome variables

Improve mental status of mothers with mental disorders.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012440N6**

Registration date: **2018-11-09, 1397/08/18**

Registration timing: **prospective**

Last update: **2018-11-09, 1397/08/18**

Update count: **0**

Registration date

2018-11-09, 1397/08/18

Registrant information

Name

Ziba Taghizade

Name of organization / entity

Tehran University of Medical Sciences school of nursing and midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 8824 4694

Email address

taghizad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the Effect of Psychological Immunization Strategy on Depression Anxiety and Stress of Pregnant Mothers

Public title

The Effect of Psychological Immunization Strategy on Depression, Anxiety and Stress of Pregnant Mothers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Pregnant women referred to health centers in the city of Darreh_shahr city who have criteria for entry into the study and have been selected randomly Criteria for entering the study: The desire to participate in the study Gestational age between 16 and 24 weeks, Having no mental illness in the first person and family, Have a guidance level or higher Healthy fetus in ultrasound examination, Single pregnancy pregnancy, no pregnancy complications, Lack of chronic diseases
Exclusion criteria:
 Outcome criteria include preterm delivery, anxiety disorder during the study (Death of loved ones, separation from a spouse ...), failure to attend 20% of psycho-immunization sessions

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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

Ethics committee of Tehran University of Medical science

Street address

Tehran University of Science, keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-10-15, 1397/07/23

Ethics committee reference number

IR.TUMS.VCR.REC.1397.470

Health conditions studied

1

Description of health condition studied

Depression, anxiety, stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression

Timepoint

Before the Intervention and One and Two Months After the Intervention

Method of measurement

Dass_21 Questionnaire

2

Description

Anxiety

Timepoint

Before the Intervention and One and Two Months After the Intervention

Method of measurement

Dass_21 Questionnaire

3

Description

Stress

Timepoint

Before the Intervention and One and Two Months After the Intervention

Method of measurement

Dass_21 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Pregnant Mothers

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Moayeri clinic

Full name of responsible person

Masoomeh Teymouri

Street address

Republican Street opposite Mellat Bank

City

Dare_shahr

Province

Ilam

Postal code

12345678

Phone

+98 84 3522 2424

Email

masiteymouri1369@gmail.com

2

Recruitment center

Name of recruitment center

Taleghani Clinic

Full name of responsible person

masoomeh Teymouri

Street address

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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Cheraghi

Street address

Vice Chancellor for Research, Tehran University of
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Masoomeh teymouri

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Phd in Reproduction Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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

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Full name of responsible person

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Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

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Street address

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Tehran

Province

Tehran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available