

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effectiveness of psychological intervention in the first semester on some health parameters at the end of the second trimester

Protocol summary

Study aim

Determination of the effect of psychological intervention in the first trimester on some health indicators at the end of the second trimester in women undergoing pregnancy care in private centers in Kerman, 2023-2024

Design

Clinical trial work with control group, with parallel groups, without blinding, randomized, is performed on 60 pregnant women. Available sampling and limited randomization method according to the law of random allocation in two similar groups (each group of 30 people) will be intervention and control. For this purpose, using random allocation software, a random sequence will be generated based on two intervention and control groups, then based on this generated sequence, people will be allocated to two intervention and control groups.

Settings and conduct

Available sampling, intervention in first-trimester primigravida pregnant women, in Mehrgan Hospital meeting hall

Participants/Inclusion and exclusion criteria

primigravida pregnant women up to 9 weeks gestational age, age 18-45 years, singleton pregnancy, non-participation in other psychotherapy sessions, unwanted pregnancy, people fluent in Farsi language, absence of any underlying and chronic diseases and not taking sedative drugs and not being infected to other psychological diseases before starting the intervention

Intervention groups

Psychological intervention in 3 sessions (60-90 minutes) during 3 weeks (once a week) for the intervention group in Mehrgan Hospital meeting hall by a master's student in counseling in midwifery and trained and proficient to implement psychological intervention. The control group did not receive any intervention and received routine pregnancy care.

Main outcome variables

Reducing anxiety and stress, improving sleep quality, blood pressure, thyroid, fasting blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034452N17**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of psychological intervention in the first semester on some health parameters at the end of the second trimester

Public title

Investigating the effectiveness of psychological intervention on some health factors of pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

primigravida pregnant women up to 9 weeks gestational age 18-45 years singleton pregnancy non-participation in other psychotherapy sessions unwanted pregnancy fluency in persian language absence of any underlying and chronic diseases non-use of sedatives non-infection of Other psychological diseases before starting the intervention

Exclusion criteria:

Loss of pregnancy during the intervention occurrence of a traumatizing event such as the loss of loved ones absence from a session of the intervention

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

In this intervention, 60 pregnant women who meet the inclusion criteria for entering the study from among the referrals to two gynecologists of private centers in Kerman in the time period until the sample size is reached (available sampling) with the limited randomization method according to the law of random allocation in two similar group (each group of 30 people) is placed in intervention and control. For this purpose, using random allocation software, a random sequence is generated based on two intervention and control groups, then based on this generated sequence, people are allocated to two intervention and control groups.

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

Research Ethics Committees of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University campus. Haft. Bagh Highway, Kerman, Iran Kerman

City

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Province

Kerman

Postal code

7616913555

Approval date

2023-11-04, 1402/08/13

Ethics committee reference number

IR.KMU.REC.1402.290

Health conditions studied

1

Description of health condition studied

Psychological intervention in primigravida pregnant women without underlying disease

ICD-10 code

O09.31

ICD-10 code description

Supervision of pregnancy with insufficient antenatal care, first trimester

Primary outcomes

1

Description

Anxiety state of people

Timepoint

Before the intervention in the first trimester of pregnancy and the second trimester of pregnancy

Method of measurement

Pregnancy-related anxiety questionnaire and Penn State worry questionnaire

2

Description

sleep quality

Timepoint

Before the intervention in the first trimester of pregnancy and the second trimester of pregnancy

Method of measurement

PSQI sleep quality questionnaire

3

Description

blood pressure

Timepoint

Before the intervention in the first trimester of pregnancy and the second trimester of pregnancy

Method of measurement

Sphygmomanometer

4

Description

FBS

Timepoint

Before the intervention in the first trimester of pregnancy and the second trimester of pregnancy

Method of measurement

Blood samples from people and in the laboratory

5

Description

Thyroid disorders

Timepoint

Before the intervention in the first trimester of pregnancy and the second trimester of pregnancy

Method of measurement

Blood samples from people and in the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 pregnant women who meet the inclusion criteria in the first trimester receive three sessions of psychological intervention, each session lasting 60-90 minutes and one session per week.

Category

Behavior

2

Description

Control group: 30 pregnant women who are in the control group do not receive any psychological intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan hospital

Full name of responsible person

Fereshte Mohseni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

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Web page address

<http://vresearch.kmu.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

associate prof

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

with previous agreement with the corresponding author

From where data/document is obtainable

email address

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

email address

Comments