

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The effect of distance self-compassion education on depression in pregnant women

Protocol summary

Study aim

The effect of distance self-compassion education on depression in pregnant women

Design

This randomized clinical trial is a non-blinded study with a control group and parallel design. This randomized, phase 2-3 study will be performed on 72 pregnant women with a diagnosis of depression. Simple randomization is used for randomization and participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at Motazedi comprehensive urban health service center, is not blinded. At the beginning of the study, the Edinburgh Depression Inventory will be provided for the participants and if they get a score of 7-19 and other inclusion criteria, they will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 14-26weeks; 3 depressive symptoms based on DSM5; Single pregnancy
Exclusion criteria: History of mental disorders; History of infertility; History of experiencing accidents over the past year

Intervention groups

In addition to routine pregnancy care, the intervention group will receive 8 sessions (one session per week for 45 minutes) of compassion-based training virtually through WhatsApp. In this research, the first session will be done individually (to get acquainted with the audience and get their psychological history) and other sessions in groups of 3 people will be done through WhatsApp virtual network video call. The control group will receive routine prenatal care.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N174**

Registration date: **2021-09-11, 1400/06/20**

Registration timing: **prospective**

Last update: **2021-09-11, 1400/06/20**

Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of distance self-compassion education on depression in pregnant women

Public title

The effect of self-compassion education on depression in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women 20-35 years old Gestational age 14-26weeks 3 depressive symptoms based on DSM5 Single pregnancy

Exclusion criteria:

History of mental disorders History of infertility History of experiencing accidents over the past year

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method. 72 cards are selected and numbers from 1-72 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group.

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.KUMS.REC.1400.096

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

Depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

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

Depression

Timepoint

Before the intervention, end of the intervention, one month after the intervention

Method of measurement

Using the Edinburgh Depression Inventory (EPDS):

Secondary outcomes

empty

Intervention groups**1****Description**

In addition to routine pregnancy care, the intervention group will receive 8 sessions (one session per week for 45 minutes) of compassion-based training virtually through WhatsApp. In this research, the first session will be done individually (to get acquainted with the audience and get their psychological history) and other sessions in groups of 3 people will be done through WhatsApp virtual network video call.

Category

Behavior

2**Description**

The control group will receive routine prenatal care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motazedi Comprehensive Urban Health Service Center

Full name of responsible person

Bitra Ashabi

Street address

Hafezieh Street, 45 meters second

City

Kermanshah

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671581340

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Bitra Ashabi

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mastaneh Kamravamanesh

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Bitā Ashabi

Position

Master student of counseling in midwifery

Latest degree

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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

There is no more information

Study Protocol

No - There is not 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

No - There is not 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