

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of group counseling with a positivist approach on postpartum depression in adolescent mothers

Protocol summary

Study aim

Determining the effect of counseling with a positivist approach on postpartum depression in adolescent pregnant women

Design

A clinical trial with a control group, with parallel, randomized groups, will be performed on 46 patients.

Settings and conduct

The study population will be selected from adolescent pregnant mothers referring to comprehensive health centers in Zanjan. There is no blinding in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adolescent pregnant mothers under 19 (19-13 years); Having an education, at least first guidance; First pregnancy; 28 weeks of pregnancy; A living fetus with no abnormalities; Single pregnancy; Mothers' consent to participate in the research project; Internet and Android phone access. Non-inclusion criteria: History of drug use; Pregnancy problems (bleeding - placenta previa, preeclampsia); Existence of psychiatric disorders in adolescent pregnant mothers.

Intervention groups

Intervention group: In the 26th to 28th weeks of pregnancy, positivism counseling sessions will be held individually using the telephone and cyberspace through 8 60-90 minute sessions once a week for 8 weeks. Control group: routine pregnancy care will be provided.

Main outcome variables

Postpartum Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027994N8**

Registration date: **2021-07-20, 1400/04/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-20, 1400/04/29**

Update count: **0**

Registration date

2021-07-20, 1400/04/29

Registrant information

Name

Taraneh Emamgholi khooshehchin

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8318

Email address

khoosheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling with a positivist approach on postpartum depression in adolescent mothers

Public title

The effect of counseling on postpartum depression

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Adolescent pregnant mothers under 19 (19-13 years)
 Having an education, at least first guidance First
 pregnancy 28 weeks of pregnancy A living fetus with no
 abnormalities Single pregnancy Mothers' consent to
 participate in the research project Internet and Android
 phone access

Exclusion criteria:
 History of drug use Pregnancy problems (bleeding -
 placenta previa, preeclampsia) Existence of psychiatric
 disorders in adolescent pregnant mothers (individuals
 who earn score 9 or lower on the General Health
 Instrument (GHQ-12). Incidence of stressful events
 (accidents, death of a loved one, separation from a
 spouse, bankruptcy, severe disputes, immigration), in
 the last 6 months Underlying disease (including diabetes
 mellitus, cardiovascular and other chronic diseases)

Age
 From **13 years** old to **19 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **46**

Randomization (investigator's opinion)
 Randomized

Randomization description
 In this study, first, the easy sampling method will be
 used and then individuals with inclusion criteria will be
 divided into two groups of intervention and control using
 random block division. In this way, first, using blocks of
 size 4, the arrangement of people next to each other in
 each block will be determined, and then a number will be
 assigned to each block, and 12 blocks will be determined
 to provide the required number of samples. Then, using
 the table of random numbers, the sequence of using the
 blocks will be determined. Entering to each group will be
 done by the number of selected blocks and the
 arrangement inside the block, respectively. The number
 of people in each group will be 23.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Zanjan University of Medical Sciences

Street address
 Zanjan University of Medical Sciences, Azadi square

City
 Zanjan

Province
 Zanjan

Postal code
 4513956113

Approval date
 2021-06-16, 1400/03/26

Ethics committee reference number
 IR.ZUMS.REC.1400.111

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

F53

ICD-10 code description

Puerperal psychosis

Primary outcomes

1

Description

Postpartum depression

Timepoint

Before intervention and four weeks after delivery

Method of measurement

Edinburgh Postpartum Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Counseling with a positive
 psychology approach for the intervention group will be
 held once a week through 8 60-90 minute sessions, and
 at the end of each session, participants will be given
 homework.

Category

Other

2

Description

Control group: For the control group, routine pregnancy
 care will be performed. Finally, after the intervention, if
 desired, the members of the control group will be
 provided with a description of counseling sessions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive urban health centers

Full name of responsible person

Samira Esmaeili

Street address

Azadi square

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4513665758

Phone

+98 24 3344 4280

Email

samirasmaeeli71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Zanjan University of Medical Sciences; Azadi Square

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shoghli@xums.ac.ir

Grant name

thesis

Grant code / Reference number

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

No

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Samira Esmaeili

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery; Karmandan Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

taraneh emamgholi khooshehchin

Position

faculty

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samira Esmaeili

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Email

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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

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

make this available

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

Title and more details about the data/document

The release schedule is not yet known

When the data will become available and for how long

The release schedule is not yet known

To whom data/document is available

The release schedule is not yet known

Under which criteria data/document could be used

The release schedule is not yet known

From where data/document is obtainable

The release schedule is not yet known

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

The release schedule is not yet known

Comments