

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of cognitive behavioral counseling on mental health and quality of life nulliparous pregnant women

Protocol summary

Summary

This study is an interventional study. The statistical population includes all pregnant women under the age of 20 weeks who are referred to Kamyaran city health centers. After obtaining the necessary permissions, the researcher will refer eligible pregnant women to the appropriate health care centers of Kamyaran City using the available sampling. Then a simple randomization method will be used to implement random assignment. This is done by a research fellow 60 consecutive sheets per sheet and placed in a container. Choice of even numbers will be grouped into group A and odd numbers will be grouped into group B. The groups A and B are non-randomly assigned to the intervention group or the control will be. The intervention group (30 people), in addition to the routine care of clinics for pregnant women, 8 sessions (if necessary, will increase to 10 sessions) 90 to 70 minutes Cognitive-behavioral group counseling conducted weekly by the researcher in the hall of the health center of Kamyaran city. The control group (30 people) will also receive routine care. First, the goals of the research are explained to the participants and written informed consent will be obtained. Then, the demographic form, general health questionnaire (28 questions) and short form (sf-36) quality of life questionnaire will be completed by both groups. In the next step, the intervention team will conduct 8 sessions once a week, 90 to 70 minutes, a cognitive-behavioral group counseling session for the intervention group. One month after the last cognitive behavioral group counseling session, the questionnaires will be completed again by the individuals in both groups and the scores will be compared. In all stages of the distribution and collection of questionnaires will be done by someone else who is not in the research. After completing the research, the control group will also receive a consultation for ethical reasons. The statistical analyst does not know which groups are assigned.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030532900N1**

Registration date: **2017-09-29, 1396/07/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-29, 1396/07/07

Registrant information

Name

Sousan Heydarpour

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3823 2679

Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-08-05, 1396/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive behavioral counseling on mental health and quality of life nulliparous pregnant women

Public title

The effect of cognitive behavioral counseling on mental health and quality of life nulliparous pregnant women referred to health centers in Kamyaran

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Primal pregnant women; Pregnancy under 20 weeks old; Being literate; fluent in Persian; Without history of infertility; aged over 18; uncomplicated pregnancy; intended pregnancy; being Iranian. Exclusion criteria: Abortion or preterm labor during the study; admission to the hospital during the study; incidence of fetal or maternal complications during the study; the occurrence of any mental illness requiring drug use during the intervention; not attending more than 2 sessions of counseling sessions (up to 25% No more sessions); an unexpected stress during counseling; a person's dissatisfaction with the continuation of the study; the presence of a known disease in the fetus; separation or divorce; Mental or physical disorder; the use of anxiolytic and antidepressant drugs; participation in class relaxation, yoga and others like them; incident or loss of family members during the past three months.

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)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Shahid Beheshti Boulvar, Kermanshah

City

Kermanshah

Postal code

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

KUMS.REC.1395.718

Health conditions studied

1

Description of health condition studied

quality of life

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Mental Health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mental Health

Timepoint

Before and one month after the intervention

Method of measurement

General Health Questionnaire (GHQ)

2

Description

quality of life

Timepoint

Before and one month after the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire - short form (sf-36)

Secondary outcomes

empty

Intervention groups

1

Description

Eight sessions of cognitive-behavioral group counseling (if necessary, increase to 10 sessions) 70 to 90 minutes per week, conducted by the researcher.

Category

Other

2

Description

Root care is provided for health care centers for the control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Kamyaram city

Full name of responsible person

Street address

City

Kamyaran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences,

Full name of responsible person

Dr. behrooz.hamzeh

Street address

Vice Chancellor for Research and Technology, Building No. 2, Shahid Beheshti Boulvar

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences,

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Sousan Heydarpour

Position

phD in Reproductive Health

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty