

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women

Protocol summary

Summary

This study will be done with aim to survey the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women. This is a non-blinded clinical trial. The study population will included 20-24 weeks pregnant women who referred to health centers of Sanandaj city. A total of 70 eligible pregnant women will be selected in available method and randomly will be assigned in to two experimental and control groups. Baseline, health promoting lifestyle questionnaire will be provided to both groups, height and weight is measured and body mass index will be calculated. The intervention group will receive cognitive behavioral group counseling eight sessions (if necessary up to 10 sessions) of 60-90 minutes for a session in week. The control group only will receive the usual centers care. The end of the study and one month after the end of the study lifestyle questionnaire will be provided to both groups, the body mass index will be measured and both groups will be compared. Inclusion criteria: Age between 19 and 50 years; 20-24 weeks gestational age; Literacy, Wanted pregnancy; Singleton pregnancy; No mental illness; No known fetal illness; No history of drug addiction; Lack of sleep medication use and Neurological drugs; Having a BMI underweight, normal, overweight and obese. Exclusion criteria: Abortion; Childbirth or hospitalization during the study; No participation in the two or more sessions of meetings.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041014333N72**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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+98 83 1821 4653

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women

Public title

The effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in

pregnant women.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 19 years; 20-24 weeks gestational age; Literacy, Wanted pregnancy; No underlying disease or complications labeled in pregnancy (pre-eclampsia, gestational diabetes, a history of giving birth to infants and IUGR,...); Singleton pregnancy; No mental illness; No known fetal illness; No history of drug addiction; Lack of sleep medication use and Neurological drugs; Having a BMI underweight, normal, overweight and obese. Exclusion criteria: Abortion; Childbirth or hospitalization during the study; No participation in the two or more sessions of meetings.

Age

From **19 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Simple randomly sampling, using encoded on the card

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

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

City

Kermanshah

Postal code

Approval date

2017-03-08, 1395/12/18

Ethics committee reference number

kums.rec.1395.763

Health conditions studied

1

Description of health condition studied

pregnancy

ICD-10 code

Z34.8

ICD-10 code description

Supervision of other normal pregnancy

Primary outcomes

1

Description

Life style

Timepoint

The beginning of the study, after study and one month after the end of the study

Method of measurement

Based on lifestyle questionnaire Walker (HPLP)

2

Description

Weight gain

Timepoint

The beginning of the study, after study and one month after the end of the study

Method of measurement

Weighbridge branded Seca

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive cognitive behavioral group counseling eight sessions (if necessary up to 10 sessions) of 60-90 minutes for a session in week.

Category

Lifestyle

2

Description

The control group only will receive the usual centers care.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers
Full name of responsible person
Mahnaz Farhoodi
Street address
Abidar Street
City
Sanandaj

Fax
Email
iclddoctor12@Gmail.com
Web page address

Person responsible for scientific inquiries

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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
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Contact

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Person responsible for updating data

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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