

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effectiveness of cognitive - behavioral group counseling on pregnancy's worries and stress in pregnant women

Protocol summary

Summary

1)Objectives, this study conducted as effectiveness of cognitive - behavioral group counseling on pregnancy's worries and stress in pregnant women.2)Design, this is a randomized clinical trial without blinding.The sample size will be 70 pregnant women in multi selected center.3) Setting and conduct, Data were collected using a pregnancy-specific stress questionnaire(PWSQ)4) Participants (including major eligibility criteria),Women in the study were 18 to 35 years old with at least education diploma and without history of mental illness5)Intervention contain group counseling and 6)main outcome measures (primary and secondary outcome variables) is pregnancy's worries and stress in pregnant women

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052527728N2**

Registration date: **2016-06-27, 1395/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-27, 1395/04/07

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

zohrehmahmoodi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Alborz University Medical Sciences and Health Services

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of cognitive - behavioral group counseling on pregnancy's worries and stress in pregnant women

Public title

Effectiveness of group counseling on pregnancy's worries and stress in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian women; 18 to 35 years old; 20 to 32 week by LMP or Sonography under 12 week; single pregnancy; Primi Gravida; at least Diploma; Women with stress by pregnancy's worries and stress questionnaire; Lack of mental illnesses and depression disorders According to patient; Do not use antidepressants and anti anxiety and anti stress drugs Exclusion criteria: Unwillingness to continue participation in the study; If they have unfortunate accidents in the past 6 months for example (Death of a spouse, a relative preference , Divorce. The imprisonment of husband..)

Age

No age limit

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

Block sampling with random numeral

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz.University of Medical Sciences

Street address

Alborz University Of Medical Saiances,Karaj,IRAN

City

Karaj

Postal code

561-31452

Approval date

2016-05-08, 1395/02/19

Ethics committee reference number

Abzums.Rec.1395,19

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

cognitive behaviour disorder

ICD-10 code

F43.0

ICD-10 code description

A transient disorder that develops in an individual without any other apparent mental disorder in response to exceptional physical and mental stress and that usually subsides within hours or days. Individual vulnerability and coping capacity play a role i

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

Pregnancy's worries and stress

Timepoint

Before intervention _ Immediately after the intervention - two weeks after intervention

Method of measurement

Quetionnaire

Secondary outcomes

empty

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

intervention1: in case group, In addition to the Routine consultation, they have 6 session cognitive behavioral treatment. in2 session (90 minute) in week

Category

Behavior

2**Description**

Control group: educational package with routine consultant.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kamali,Alborz and Bamonar Hospitals

Full name of responsible person

Dr Zohreh Mahmoodi

Street address

Kamali Hospital,Kamali Allay,Tillegani street,Karaj.Iran

City

Karaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Alborz University of Medical Sciences,Vice chancellor for Research

Full name of responsible person

Dr Mohammad Javad Gharavi

Street address

Alborz University of Medical Sciences,Golestan1,Karaj,IRAN.

City
Karaj

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Alborz University of Medical Sciences,Vice chancellor for Research

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
Alborz University of Medical Sciences

Full name of responsible person
DrZohreh Mahmoodi

Position
PhD

Other areas of specialty/work

Street address
Department of Nursing., Alborz University of Medical Science., Eshteraki St., Baghestan Blv

City
Karaj

Postal code
561-31452

Phone
+98 26 3455 1034

Fax
+98 26343336007

Email
Zohrehmahmoodi2011@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person

Dr zohrehmahmoodi

Position
PhD

Other areas of specialty/work

Street address
Department of Nursing., Alborz University of Medical Science., Eshteraki St., Baghestan Blv

City
Karaj

Postal code

Phone
+98 26 3455 1034

Fax

Email
zohrehmahmoodi2011@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
Dr zohrehmahmoodi

Position
PhD

Other areas of specialty/work

Street address
Department of Nursing., Alborz University of Medical Science., Eshteraki St., Baghestan Blv

City
Karaj

Postal code

Phone
+98 26343336007

Fax

Email
zohrehmahmoodi@abzums.ac.irzohrehmahmoodi2011@gmail.com

Web page address

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