

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Effectiveness of Relaxation and Cognitive Counseling Intervention on Hypertension and Quality of Life in Pregnant Women with Hypertension

Protocol summary

Study aim

Study and comparison of the effectiveness of relaxation and cognitive intervention on blood pressure and quality of life in pregnant women with hypertension

Design

A randomized, controlled, one blind, placebo-controlled clinical trial

Settings and conduct

This study will be conducted in Fasa city. Sixty pregnant women will be selected from the offices of Fasa urban family physicians and randomly assigned into three groups of intervention, Cognitive counseling relaxation training and control groups. The study is a one blinded, meaning that participants are not aware of the interventions of other groups. Quality of life and blood pressure of pregnant women before and after the intervention will be measured for all groups and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with hypertension in the second 3 months of pregnancy

Intervention groups

Intervention group 1: Relaxation counseling group;
Intervention group 2: Cognitive counseling group and
Control group receiving no intervention

Main outcome variables

Hypertension and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191028045259N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Sanaz Atef

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

sa.atef68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Relaxation and Cognitive Counseling Intervention on Hypertension and Quality of Life in Pregnant Women with Hypertension

Public title

Comparison of the Effectiveness of Relaxation and Cognitive Counseling Intervention on Hypertension and Quality of Life in Pregnant Women with Hypertension

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The women under study should be pregnant and hypertensive Be literate.

Exclusion criteria:

disabling diseases

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

for randomization we prepare 60 cards and divide into 3 groups of 20. The first 20 cards of number 1 are written. The second card of number 2 and the Third 20 cards of number 3 are written ad put in the envelope. We ask the pregnant woman with hypertension to choose one of the cards. Finally, the number on the selected card represents the group where the patient will be placed.

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 Kerman University of Medical Sciences

Street address

Ebnsina Ave., Jahad Blvd., Kerman city

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-11-02, 1398/08/11

Ethics committee reference number

IR.KMU.REC.1398.344

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I11

ICD-10 code description

Hypertensive heart disease

Primary outcomes

1

Description

Hypertension

Timepoint

Before and after intervention

Method of measurement

Mercury barometer

2

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

WHOQOL-Bref Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: "Relaxation" In this method, the intervention is performed in 4 90-minute sessions. In These sessions explain the impact of relaxation on maternal mental health, improvement of sleep, maternal nutrition, and its effect on the process of delivery and on postpartum recovery, and on being effective in breastfeeding and reducing postpartum depression. At each session, the target group is practicing relaxation. and will repeat at intervals between intervention sessions at home.

Category

Behavior

2

Description

Intervention group 2: Cognitive counseling Cognitive counseling is provided in 8 to 10 one-hour sessions. 8 group sessions and 2 individual sessions to discuss specific topics. In this way the following will be taught to the participants. -Definition and Importance of Cognitive Therapy -The Cognitive Discovery Method of Pregnancy-

Related Cognitive Disorders -Patients' Cognitive Evaluation of the Effectiveness of Cognitive Techniques on Cognition's and Their Changes -Reviewing future thinking and behavior change programs

Category

Behavior

3

Description

Control group: There is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Family doctors' offices in Fasa city

Full name of responsible person

Firouzeh Mirzaei

Street address

Ibn Sina Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Firouzeh Mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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Other areas of specialty/work
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Kerman
Province
Kerman

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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