Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

assessment of the Effect of Cognitive Behavioral Counseling on self-efficacy in pregnant Women with chronic Hypertension in Kurdistan province

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of cognitive-behavioral counseling on self-efficacy in pregnant women with chronic hypertension.

Design

A clinical trial with a control group with parallel, single-blind, randomized groups on 100 patients. A random block of even and odd numbers was used for possession.

Settings and conduct

The study population included all pregnant women with chronic hypertension who referred to health centers, gynecologists' offices and hospitals in Kurdistan province. If they have the criteria to enter and sign the consent form, they will enter the intervention. The intervention sessions will be held online and individually. With the preparation of even and odd cards by the clinic colleague, the researcher and the samples will not know about the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: pregnant women up to 32 weeks, single pregnancy, no history of infertility and no diagnosis of anomaly, chronic hypertension and drug treatment, minimum literacy Reading and writing, not attending relaxation and yoga classes, no severe underlying disease, no neurological problems and anxiety disorder, no symptoms of preeclampsia, no major depression (grade 12 or higher on the Edinburgh scale) and giving informed written consent to Participants. Dissatisfaction of the samples to continue participating in the study, the need to use another treatment method during the study and diagnosis of preeclampsia will be the exclusion criteria.

Intervention groups

Participants are randomly assigned to two groups of 50, including a control group and an intervention group. The control group will receive only routine care and the intervention group will receive six 90-minute sessions of cognitive-behavioral counseling (two sessions per week) online and individually, in addition to routine care.

Main outcome variables

self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151028024753N4**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Mitra Kolivand

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-01, 1399/08/11

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
assessment of the Effect of Cognitive Behavioral Counseling on self-efficacy in pregnant Women with chronic Hypertension in Kurdistan province

Public title
assessment of the Effect of Cognitive Behavioral Counseling on self-efficacy in pregnant Women with chronic Hypertension in Kurdistan province
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
pregnant women up to 32 weeks of gestation singleton pregnancy no history of infertility no diagnosis of anomaly with chronic hypertension and undergoing drug treatment minimum literacy Reading and writing not attending relaxation and yoga classes no severe underlying disease no neurological problems and anxiety disorder no symptoms of preeclampsia no major depression giving informed written consent to Admission
Exclusion criteria:
Dissatisfaction of the samples to continue participating in the study diagnosis of preeclampsia the need to use another treatment method during the study
Age
From **15 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, samples will be easily or accessible and then randomly assigned to the intervention and control groups. To perform random allocation, the "random block" method, which consists of a large block for the entire sample volume, will be used. Thus, after determining the sample size by the researcher, in the first stage, this specified number will be selected from among the people who meet the inclusion criteria and have signed the informed consent form, if desired. In the next step, we assign a number from one to 100 to each of these selected people to participate in the study. In the next step, by one of the softwares, we determine 100 random numbers without repetition between one to 100, so that each of these numbers corresponds to the number assigned to each of the people that we have specified in the initial list of 100 selected. We will consider even numbers for the control group and odd numbers for the intervention group. This will not be obvious to the participants before random allocation is performed, and random sequencing will be performed by a separate individual from the other researchers.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher and participants are unaware of their place in the intervention or control group. Samples will be placed in the intervention or control group by selecting random blocks as even or odd numbers that the researcher is unaware of
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
Kermanshah University of Medical Sciences, Eisar Square, Kermanshah, IRAN Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Approval date
2020-05-11, 1399/02/22
Ethics committee reference number
IR.KUMS.REC.1399.145

Health conditions studied

1

Description of health condition studied
Chronic Hypertension
ICD-10 code
O10-O11, O
ICD-10 code description
Hypertensive disease complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Self-efficacy

Timepoint

The beginning of the study, immediately and one month after intervention

Method of measurement

Self-efficacy questionnaire in patients with hypertension

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 sessions of cognitive-behavioral counseling ... Cognitive-behavioral counseling is an approach in which more correct thoughts replace dysfunctional thoughts and will change behavioral consequences ... The duration of the course is three weeks, two sessions of 90 minutes each week Will be held.

Category

Behavior

2

Description

Control group: This group will only receive routine care for high-risk pregnancies such as: controlling blood pressure, weight and symptoms of preeclampsia, listening to the fetal heartbeat, controlling danger signs such as dehydration, reduced fetal movements, pain and bleeding.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

High-risk pregnancy clinic of Besat Hospital in Sanandaj

Full name of responsible person

Shamsi Zare

Street address

Vakil Street

City

Sanandaj

Province

Kurdistan

Postal code

6619956745

Phone

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Email

besat@muk.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Shahid Beheshti Blvd., Building No. 2, Deputy of Research and Technology

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mitra Kolivand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Professor

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Other areas of specialty/work
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Person responsible for updating data

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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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