

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of acceptance and commitment group counseling on anxiety and quality of life in pregnant women with hypertensive disorders

Protocol summary

Anxiety and Quality of Life

Study aim

Determining the effect of acceptance and commitment group counseling on anxiety and quality of life in pregnant women with hypertensive disorders

Design

Random Allocation software will be used for randomization with a control group, with parallel groups, no blinding , randomized.

Settings and conduct

Quasi-experimental with pre-test-post-test design and with control group that will be performed on eligible women referring to comprehensive health centers in Mashhad. Available sampling will be available from eligible women and then randomly assigned to two groups of 30 intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Iranian Having at least a cycle of education Non-smoking and alcohol Having a smartphone with Android operating system or IOS system Get a score less than 26 from the Beck Anxiety Questionnaire Pregnancy age 24-26 weeks Pregnancy or preterm hypertension Non-severe eclampsia (based on patient records) Single pregnancies Exclusion criteria: No chronic underlying diseases and medical and obstetric complications No history of mental disorders and no hospitalization during recent pregnancy Failure to participate in more than two sessions of counseling medical and obstetric complications during research that requires pharmacological medical interventions Existence of family disputes during the study Occurrence of adverse events during the study

Intervention groups

In the intervention group, eight group counseling sessions (the first session will be held in person and the other 7 sessions will be held virtually) based on acceptance and commitment and focusing on anxiety and quality of life of women with hypertensive disorders of pregnancy.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210218050401N1**

Registration date: **2021-07-31, 1400/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-31, 1400/05/09**

Update count: **0**

Registration date

2021-07-31, 1400/05/09

Registrant information

Name

Samanea خزاعی

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

khazaeifs981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-08-05, 1400/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acceptance and commitment group counseling on anxiety and quality of life in pregnant women with hypertensive disorders

Public title

Effect of acceptance and commitment group counseling on anxiety and quality of life in pregnant women with hypertensive disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Having at least a cycle of education Non-smoking and alcohol Having a smartphone with Android operating system or IOS system Get a score less than 26 from the Beck Anxiety Questionnaire Pregnancy age 24-26 weeks Pregnancy hypertension or Non-severe preeclampsia (based on patient records) Single pregnancies No chronic underlying diseases and medical and obstetric complications No history of mental disorders and no hospitalization during recent pregnancy

Exclusion criteria:

Reluctance to participate in research Failure to participate in more than two sessions of counseling medical and obstetric complications during research that requires pharmacological medical interventions Existence of family disputes during the study Occurrence of adverse events during the study

Age

From **15 years** old

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

This study will be performed on 60 pregnant women with a gestational age of 24-26 weeks with preeclampsia and gestational hypertension referred to Health Center 2. From this center, two comprehensive health service centers were selected from the total comprehensive health centers covered by it. They will be. The two centers will be allocated to intervention (control counseling) and control groups by lottery method. Patients with preeclampsia and gestational hypertension are identified and listed under those centers using the Sina system. Sampling will be done by available methods

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 Mashhad University of Medical Sciences

Street address

Mashhad Ibn Sina St., School of Nursing and Midwifery

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.104

Health conditions studied

1

Description of health condition studied

on anxiety and quality of life in pregnant women with hypertensive disorders

ICD-10 code

O10- O16

ICD-10 code description

edema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Pregnancy Related Anxiety Questionnaire score

Timepoint

Before starting the information, end of intervention and One month later

Method of measurement

Vandenberg Pregnancy Related Anxiety Questionnaire

2

Description

WHO Quality of Life BREF Questionnaire Score

Timepoint

Before starting the information, end of intervention and One month later

Method of measurement

WHO Quality of Life BREF Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Participants in the intervention group are first asked to complete the Personal and Midwifery Profile Form and the Zemen Social Support, Beck Anxiety, Vandenberg Pregnancy Anxiety, and Quality of Life (WHOQOL-BREF) questionnaires. For the intervention group, eight group counseling sessions (three groups of 10 people) are held by the researcher at intervals of two sessions per week in the form of questions and answers, a dynamic and active relationship between the counselor and the participants. The duration of each session will be 45-60 minutes. . The first counseling session is held in person in the center's classroom, and the next seven sessions are conducted virtually via Skyroom. The first session includes group members getting to know each other and greeting each other, explaining the group rules, explaining about pregnancy, getting acquainted with the counseling approach, explaining suffering, the second session: living in the present and mindfulness, the third session: avoiding experience Session 4: Acceptance, Session 5: Failure, Session 6: Self as context, Session 7: Values, Session 8: Commitment and mindfulness practice focusing on the end of counseling and finally the questionnaires completed by pregnant women Be. A file of summary sessions for practice at home is also provided. Training and routine intervention intervention group (assessment of blood pressure, weight, fetal heart rate and fetal growth monitoring from uterine height. Training and routine follow-up according to gynecologist feedback or Maternity hospitals will receive telephone follow-up if not referred by health care providers and midwives. One month after the intervention, the Vandenberg Pregnancy Anxiety Questionnaire (WHOQOL-BREF quality of life questionnaire) will be completed for intervention group

Category

Prevention

2

Description

Control group: Participants in the control group are asked to complete the Personal and Midwifery Profile Form and the Siemens Social Support, Beck Anxiety, Vandenberg Pregnancy Anxiety, and Quality of Life (WHOQOL-BREF) questionnaires. Routine training and care (assessment of blood pressure, weight, fetal heartbeat and fetal growth monitoring from uterine height, routine training and follow-up according to gynecologist or maternity ward feedback if telephone follow-up is not provided) by health care providers and midwives One month after the intervention, the Vandenberg Pregnancy Anxiety Questionnaire (WHOQOL-BREF) will be completed for the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 2 of Mashhad

Full name of responsible person

Jahani Shoorab Nahid

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School of Nursing and Midwifery, Ibn Sina St, Mashhad

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Email

Jahanishn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

chool of Nursing and Midwifery, Ibn Sina St, Mashhad

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TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

991788

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Samane Khazaei Fadafan

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Ibn Sina St,
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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Jahani Shoorab

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Jahanishn@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samanea Khazaei fadafan

Position

Counseling student in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers and students of academic institutions

Under which criteria data/document could be used

Based on the present study and without changes in the data

From where data/document is obtainable

Contact the author responsible for responding via email
or phone khazaey1270@gmail.com Phone:
00989158200204

What processes are involved for a request to access**data/document**

The request for access to data / documents will be
reviewed by the research team

Comments