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

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
Anxiety and Quality of Life

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, Mashhad
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Person responsible for scientific inquiries

Contact
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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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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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khazaeifs981@mums.ac.ir

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