Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of self-care counseling on quality of life and self-care behaviors in pregnant women with hypertension

Protocol summary

Study aim
Determining the effect of self-care counseling on quality of life and self-care behaviors in pregnant women with gestational hypertension referred to teaching hospitals in Mashhad

Design
Clinical trial with control group, with parallel, randomized groups, intervention on 90 pregnant women. A random number table will be used for randomization using the site www.randomization.com.

Settings and conduct
This is a randomized quasi-experimental study in two groups. Sampling of pregnant women referring to medical centers and gynecological hospitals in Mashhad and Sabzevar was first available by method and then pregnant women by stratified random allocation in two groups of control and Intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: Medical diagnosis of gestational hypertension by measuring systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than 90 mm Hg more than twice or mild preeclampsia in the 20th week of pregnancy Medical diagnosis of chronic hypertension by measuring systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than 90 mm Hg more than twice measured before pregnancy Inclusion criteria: Severe preeclampsia and eclampsia Having a serious medical and midwifery complication that requires medical and pharmaceutical interventions, Hospitalization and termination of pregnancy due to high blood pressure,

Intervention groups
Women in the intervention group will receive 4 sessions of self-care counseling based on the GATHER counseling steps for 45 to 60 minutes per week for 24 to 32 weeks of pregnancy. The control group will also receive routine care.

Main outcome variables
Quality of life and self-care behaviors in pregnant women with hypertension

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201117049426N1**
Registration date: **2021-03-22, 1400/01/02**
Registration timing: **prospective**

Last update: **2021-03-22, 1400/01/02**
Update count: **0**

Registration date
2021-03-22, 1400/01/02

Registrant information

Name
golnaz sadat ahmadinezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-12, 1400/02/22

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-care counseling on quality of life and self-care behaviors in pregnant women with hypertension

Public title
The effect of counseling on quality of life and self-care behaviors of pregnant women with hypertension

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Written informed consent to participate in the research Being a pregnant woman Being Iranian and living in Mashhad Age over 18 years Medical diagnosis of gestational hypertension by measuring systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than 90 mm Hg more than twice or mild preeclampsia in the 20th week of pregnancy Diagnosis of mild preeclampsia or gestational hypertension above 140/90 mm Hg without serious complications Medical diagnosis of chronic hypertension by measuring systolic blood pressure greater than or equal to 140 mm Hg or diastolic blood pressure greater than 90 mm Hg more than twice measured before pregnancy No drug addiction No serious medical and obstetric problems and complications No underlying illnesses that require constant medication Ability to communicate verbally, have a minimum literacy Having a phone number to call and want to participate in the study

Exclusion criteria:
Having serious medical and midwifery complications that require medical and pharmacological interventions Hospitalization and termination of pregnancy due to high blood pressure Severe preeclampsia and eclampsia

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample allocation to two classes (gestational hypertension - chronic hypertension) is using double blocks. Random allocation in each class will be by using the site www.randomization.com and using double blocks 45 The sample (separated by half of the sample size in the control and intervention group for each of the cities of Mashhad and Sabzevar) is randomly assigned to both intervention and control groups. The numbers of individuals and the relevant group are specified. We put the name of the related group in the envelope and the numbers related to it on the envelope. The numbered envelopes are then sorted from one to n, and the individuals remove the envelope entry, respectively, and to the group inside the envelope marked with the letters A (intervention) and B (control), the Allocation Concealment allocation method: Sealed envelopes

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
Khorasan Razavi, Mashhad, Daneshgah St., Ph.D. Intersection, Ibn Sina St., School of Nursing and Midwifery

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Mashhad

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Razavi Khorasan

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Approval date
2021-02-23, 1399/12/05

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.091

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

2

Description of health condition studied
Hypertension in pregnancy

ICD-10 code
O13

ICD-10 code description
Gestational [pregnancy-induced] hypertension without significant proteinuria

Primary outcomes

1

Description

Quality of life: The meaning of quality of life in this study is the score obtained from the quality of life questionnaire (sf-36) which has 36 questions and consists of 8 subscales and each subscale consists of 2 to 10 items. The eight subscales of this questionnaire are: Physical Function (PF), Role for Physical Health (RP), Role for Emotional Health (RE), Energy / Fatigue (EF), Emotional Well-Being (EW), Social Function (SF), Pain (P) and general health (GH). Also, from the integration of subscales, two general subscales are obtained, namely physical health and mental health. In this questionnaire, a lower score indicates a lower quality of life and vice versa.

Timepoint

The time periods for measuring the quality of life variable score at the beginning of the study and 2 weeks after the end of the weekly self-care counseling.

Method of measurement

Quality of Life Questionnaire (SF-36): It has 36 questions and consists of 8 subscales and each subscale consists of 2 to 10 items. The eight subscales of this questionnaire are: Physical Function (PF), Role for Physical Health (RP), Role for Emotional Health (RE), Energy / Fatigue (EF), Emotional Well-Being (EW), Social Function (SF), Pain (P) and general health (GH). Also, by merging the subscales, two general subscales with the names of physical health and mental health are obtained. In this questionnaire, a lower score indicates a lower quality of life and vice versa. How to score in this questionnaire is as follows: physical function with 10 3-choice questions, role disorder due to physical health with 4 2-choice questions, role disorder due to mental health with 3 two-choice questions, feeling of vitality with 4 6-choice questions O, mental function or 5 6-choice questions, social functioning with 2 5-choice questions, feeling of pain and disability with 2 5-choice questions, and general health feeling with 5 5-choice questions and a question related to emotion There is also a health change that is not included in any of the dimensions of the questionnaire and is only added to the total score. The scale score of the items in this questionnaire is between 1 and 5. The range of scores of this questionnaire is between 0 and 100, and a higher score indicates a better quality of life.

2

Description

Self-care behaviors: Self-care behaviors are the sum of conscious, learned and purposeful actions and activities that a person does to maintain life and promote the health of himself and his family.

Timepoint

Periods of self-care behavioral scores were measured at the beginning of the study and 2 weeks after the end of the weekly self-care consultation to evaluate the success of the intervention.

Method of measurement

Self-care questionnaire in patients with hypertension (HTN-SCP): will have 20 items in 4 areas of diet with 8 items, medication diet 5 items, attention to food label 2 items and disease management 5 items. Answers in the form of four-point Likert will always be (score 4), often (score 3), sometimes (score 2) and very little / never (score 1). The maximum score of the items will be 80 and the minimum will be 20. A higher score indicates better self-care behavior and a lower score indicates poor self-care behavior.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the intervention group, patients with a gestational age of 24 to 32 weeks participate in the intervention group in 4 group counseling sessions that will be held by the researcher every week in health centers. Each session will be held for 45 to 60 minutes. Counseling sessions will be held in groups with 4 to 6 pregnant mothers, mothers in the same group in the first counseling session, in subsequent sessions will be in the same group. Considered for a quiet and private environment and counseling will be done in the form of GATHER counseling steps (Greet, Ask, Tell, Help, Explain, Return). In group counseling sessions, you will first introduce your counselor to the group and share information about their expertise and experiences with clients. He then asks each member to introduce themselves. The consultant will then explain the purpose of forming the group and their duties and those of the group members. The goals of counseling will include identifying mothers 'problems with self-care, prioritizing them, reviewing existing solutions to their problems, their advantages and disadvantages, and deciding on mothers' free choice of self-care behaviors. The role of the guidance counselor will be to encourage group participation and facilitation. The group rules process will be introduced by the counselor and the counselor will seek to establish a therapeutic relationship that will be accomplished with the skills of listening, empathy, understanding emotions, empathy, companionship, attention, and other techniques. Description: Session 1: Greetings, greeting pregnant mothers and asking open-ended questions, group Q&A with mothers about their own problems and needs, identifying misconceptions and beliefs about physical, mental and behavioral health Self-care and encouraging them to think about ways to reduce the risk to the mother and fetus. (G and A) In this session, the counselor asks mothers to take turns presenting their problems in a problem-oriented manner, and members comment on it. And comment on problems with the help of brainstorming. The list of mothers' problems is compiled by the counselor. Session 2: Providing self-care

counseling based on the needs and problems of mothers, and providing information to pregnant mothers about the proper diet of these mothers (low-salt and low-fat diet, fruit consumption and Green leafy vegetables contain potassium fiber, magnesium, etc.), proper physical activity in them, stress management and improving relationships between these mothers in interaction with family and relatives, strengthening self-care awareness and effective ways to reduce maternal and fetal risks. . (T). Session 3: Helping to freely choose the best self-care behaviors. In this session, the counselor will use group problem-solving techniques to explore possible solutions to the remaining problems of mothers and prioritize them, and the best solution for correct self-care behaviors will be freely selected by mothers. (H) Session 4: The counselor will strengthen awareness and review the content, explain to the mother about how to use the correct self-care behaviors according to the individual needs of mothers. Also in the fourth session, follow-up times and weekly contacts with mothers will be explained (E and R) two weeks later. At the end of the counseling sessions, a 36-item quality of life questionnaire and a self-care questionnaire in patients with hypertension (HTN-SCP) as a post-test with the aim of assessing the researcher's success in conducting self-care counseling and answering potential problems and questions by units

Category

Lifestyle

2

Description

Control group: The control group will also receive routine pregnancy care.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad health centers

Full name of responsible person

Golnaz sadat Ahmadinezhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

991424

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

Golnaz Sadat Ahmadinezhad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Other areas of specialty/work
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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 response via email or phone: golnazahmadi56@gmail.com Tel: 44665881 51 0098
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