

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of counseling with spirituality-oriented approach on quality of life after childbirth in women with preeclampsia

Protocol summary

Study aim

The effect of counseling with spirituality-oriented approach on quality of life after childbirth in women with preeclampsia

Design

Phase 3 is a randomized controlled clinical trial with parallel groups that will be performed on 40 patients (20 intervention patients, 20 control patients). We do not have blindness. Eligible women will be selected by the available method and will be assigned to the intervention and control groups by the 4-item random block method using a random number table.

Settings and conduct

The research environment includes the postpartum ward of Ayatollah Mousavi Hospital in Zanjan and the study population including postpartum women with preeclampsia admitted to the ward by simple sampling method and then randomly assigned to the control and intervention groups in a block of 4.

Participants/Inclusion and exclusion criteria

Preeclampsia- Hospitalization less than 5 days-No other chronic diseases (diabetes - kidney disease - cancer) Not having a known mental illness- Willingness to participate in the study-Having a delivery with a singleton pregnancy, without known neonatal abnormalities - Intrauterine death of the baby Literacy for reading and writing-Score less than 22 based on the -GHQ-28 General Health Questionnaire

Intervention groups

The individual counseling intervention group with a spirituality-based approach based on Richards and Bergin's pattern protocol, will be held in 5 sessions. Three face-to-face counseling sessions for 45-60 minutes during hospital stay and two sessions of postpartum telephone counseling weekly after discharge. . The control group will receive routine care.

Main outcome variables

Quality of life, preeclampsia

General information

Reason for update

Updating sampling start date

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N16**

Registration date: **2020-10-01, 1399/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-05, 1399/07/14**

Update count: **1**

Registration date

2020-10-01, 1399/07/10

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 24 3345 4264

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with spirituality-oriented approach on quality of life after childbirth in women with preeclampsia

Public title

The effect of spirituality counseling on the quality of life of preeclamptic women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

- Preeclampsia - Hospitalization less than 5 days - No other concomitant chronic diseases (diabetes - Kidney disease - Cancer) - No known mental illness - Willingness to participate in the study - Having a delivery with a singleton pregnancy, without abnormalities Known Infant - Intrauterine Infant Death - Literacy for reading and writing - Score less than 22 based on GHQ-28 General Health Questionnaire - Hospitalization less than 5 days - No other concomitant chronic diseases (diabetes - Kidney disease - Cancer) - No known mental illness - Willingness to participate in the study - Having a delivery with a singleton pregnancy, without abnormalities Known Infant - Intrauterine Infant Death - Literacy for reading and writing - Score less than 22 based on GHQ-28 General Health Questionnaire

Exclusion criteria:

Having postpartum complications (bleeding, infection, etc.) Infant death Reluctance to continue cooperation in the study Changing the treatment process (eg transfer to the intensive care unit) Failure to answer a phone call during the follow-up period

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples will be selected by convenience sampling method and then randomly assigned to 4 control and intervention groups of 4 blocks. For the intervention group, one-on-one counseling with a spirituality-based approach based on the Richards and Bergin's pattern protocol will be held in 5 sessions. Three face-to-face counseling sessions for 45-60 minutes during hospital stay and two sessions of postpartum telephone counseling weekly after discharge. (39, 43). The control group will receive routine care. Data collection tools include demographic characteristics questionnaire, postpartum quality of life questionnaire, general health questionnaire: GHQ and DSES questionnaire (daily spiritual experiences) which in two stages before the intervention and 6 weeks after the end of counseling sessions by research units. Complete and

will be analyzed using SPSS statistical software version 20 and statistical methods of chi-square, independent t-test and paired t-test, MANCOVA statistical methods and multivariate analysis of variance MANOVA in case of abnormal distribution of non-parametric tests The equivalent will be used.

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 Zanjan University of Medical Sciences

Street address

Zanjan Azadi Blvd. Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.ZUMS.REC.1398.376

Health conditions studied**1****Description of health condition studied**

Quality of life after childbirth in women with preeclampsia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of spirituality-oriented counseling on quality of life after childbirth in women with preeclampsia

Timepoint

Three sessions of spiritual counseling modeled on Richards and Bergin, in person for 45-60 minutes during hospital stay and two sessions of telephone counseling

weekly after discharge

Method of measurement

, Postpartum Quality of Life Questionnaire, General Health Questionnaire: GHQ, DSES Questionnaire (Daily Spiritual Experiences)

2

Description

Quality of life after childbirth in women with preeclampsia

Timepoint

Three sessions of spiritual counseling modeled on Richards and Bergin, in person for 45-60 minutes during hospital stay and two sessions of telephone counseling weekly after discharge

Method of measurement

Postpartum Quality of Life Questionnaire, General Health Questionnaire: GHQ, DSES Questionnaire (Daily Spiritual Experiences)

Secondary outcomes

1

Description

Quality of Life

Timepoint

In two stages before the intervention and 6 weeks after the end of the consultation sessions by the research units

Method of measurement

General Health Questionnaire: GHQ, DSES Questionnaire (Daily Spiritual Experiences)

2

Description

Quality of life after childbirth in women with preeclampsia

Timepoint

In two stages before the intervention and 6 weeks after the end of the consultation sessions by the research units

Method of measurement

Postpartum Quality of Life Questionnaire

Intervention groups

1

Description

Intervention group: The intervention group will receive three face-to-face counseling sessions for 45-60 minutes during hospitalization and two sessions of telephone postpartum counseling weekly after discharge. The contents of the sessions include introducing oneself and getting to know the patient, expressing the goals of the project, creating empathy, talking about the disease, assessing the mental condition and physical condition, paying attention to the patient's attitude towards the disease, physical health, negative emotions, stress and

worries and strategies to deal with them. About the concept of quality of life, dimensions of quality of life and the importance of self-awareness, belief, values in life. Talking about one's expectations of life, community, values, attitude towards spiritual issues, the role of God and religion in life Talk about Positive experiences of the patient about the use of spiritual issues in dealing with stressful situations in life Recalling the role of women in creation, spiritual aspects of pregnancy and childbirth, maternal role from the perspective of Islam, review of the previous session With breathing exercises and repeating it 10 to 15 times a day, it is recommended to listen to the music of nature, the sound of the Quran during the day, the role of charity, trust, recourse, patience, charity (kindness and forgiveness) and focusing on God's blessings in reducing stress. Pre-assessment sessions on a person's mood, attitude and beliefs The role of gratitude to God in enduring hardships, increasing hope and self-confidence in adjustment and accepting the position of the role of reading the Bible in patients' comfort, the story of religious people, encouraging patients to talk to people who make them feel positive, increasing intimacy with spouse Using their participation in life-centered counseling responsibilities in telephone follow-up sessions will include reviewing and recalling the content of face-to-face counseling sessions. Including trust, empathy and honesty between midwives and mothers to communicate properly during the sessions.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Robab Rasouli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

1

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

Zanjan University of Medical Sciences

Full name of responsible person

Robab Rasouli

Position

Master Student of Counseling In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Azam Maleki

Position

PhD in Maternal And Child Health

Latest degree

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Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Possibility of Dissatisfaction of Participants

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available