

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of virtual and telephone self-care training methods based on health belief model on quality of life of primigravid women with preeclampsia in the postpartum period

Protocol summary

Study aim

Comparative study of the effect of virtual and telephone self-care training methods based on health belief model on quality of life of primigravid women with preeclampsia in the postpartum period

Design

This randomized clinical trial design is a parallel, non-blind design with a control group. This randomized study, phase 2-3 study will be performed on 75 nulliparous women. Random number table is used for randomization and participants are assigned to three groups (two intervention groups and one control group).

Settings and conduct

This study will be performed in Motazedi Hospital of Kermanshah. It is a non-blinded one. Before performing the interventions in the target groups, the needs assessment will be performed based on the health belief model, then the intervention design and the content of the educational program will be based on the health belief model.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who have preeclampsia of different severity during pregnancy and childbirth (except eclampsia) based on preeclampsia criteria and clinical and paraclinical evidence approved by a gynecologist; Primiparous women with preeclampsia whose labor has resulted in the birth of a live baby. Exclusion criteria: Different types of severe mental disorders that are under medical treatment or need hospitalization

Intervention groups

The first intervention group for 7 sessions of 30 to 60 minutes, one session per week using WhatsApp virtual messenger network will be under a training program based on the pattern of health belief. The second intervention group will undergo a training program based on the health belief model for 7 weeks (one phone call

per week, the duration of phone calls is at least 30 and at most 60 minutes, and the time is between 9 am and 9 pm). The control group does not receive any intervention

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N176**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-07-06, 1401/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of virtual and telephone self-care training methods based on health belief model on quality of life of primigravid women with preeclampsia in the postpartum period

Public title
A comparative study of the effect of virtual and telephone self-care training methods on the quality of life of nulliparous women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having a mobile phone and internet access Women who have preeclampsia of different severity during pregnancy and childbirth (except eclampsia) based on preeclampsia criteria and clinical and paraclinical evidence approved by a gynecologist Primiparous women with preeclampsia whose labor has resulted in the birth of a live baby.
Exclusion criteria:
Different types of severe mental disorders (psychosis, schizophrenia, etc.) that are under medical treatment or need hospitalization

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
The random assignment method is based on a table of random numbers and numbers between zero and 0.333 are in group one, from 0.334 to 0.666 in the second group and from 0.667 to 0.999 in the third group. Random assignment is done by someone who has no role in measuring the variables

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-08-09, 1400/05/18

Ethics committee reference number

IR.KUMS.REC.1400.407

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

O14.9

ICD-10 code description

Unspecified pre-eclampsia

Primary outcomes

1

Description

Quality of Life

Timepoint

Before the intervention, 1 and 3 months after the intervention

Method of measurement

Based on Quality of Life Questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group 1, for 7 sessions of 30 to 60 minutes, one session per week using WhatsApp virtual messenger network will be under a training program

based on the pattern of health belief (text, video, poster, discussion, question and answer)

Category

Treatment - Other

2

Description

The intervention group 2, will undergo a training program based on the health belief model for 7 weeks (one phone call per week, the duration of phone calls is at least 30 and at most 60 minutes and the time is between 9 am and 9 pm).

Category

Treatment - Other

3

Description

The control group will receive routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Motazedi Hospital

Full name of responsible person

Zahra Hosseini Shoar

Street address

Motazedi Hospital, Ferdowsi Square

City

Kermanshah

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Kermanshah

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67188 14474

Phone

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zahrahoseini7620@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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rkhodarahmi@kums.ac.ir

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

Zahra Hosseini Shoar

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Dolatabad Blvd, Isar Square

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zahrahoseini7620@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mastaneh KamervaManesh

Position

Faculty member of Kermanshah University of Medical

Sciences

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

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Full name of responsible person

Zahra Hosseini Shoar

Position

Master student of counseling in midwifery

Latest degree

Bachelor

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

There is no more information

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