

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

A study of a post partum cares educational interventional program for women with preeclampsia

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the Effect of Educational Intervention Program on Postpartum Care on Lifestyle in Preeclamptic Women

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Design

randomized trial with two groups

Registrant information

Name

Fatemah Zaremobini

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 7500

Email address

m_kamravamanesh@kums.ac.ir

Settings and conduct

Researcher will refer to Alzahra Hospital affiliated to Isfahan University of Medical Sciences. Participants randomly will allocate into two groups. In the intervention group, an designed education program will performed for women with pre eclampsia , and the usual care will taken for the control group

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria are women aged between 15-49 years, Iranian nationality, consent to participate in the study, ability to understand questions or ability to read and write, not participating in any other clinical trials at the same time, no severe mental disorders that requires to be under medical treatment or hospitalization, the nulliparous women with preeclampsia whose delivery resulted in live births.

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Educational intervention consists of 4 sessions of 50 to 60 minutes that will be conducted during the 2 weeks in the form of 3 combined training, lecture, question and answer, group discussion in hospitals and health centers to improve lifestyle in the experimental group. In the control group, routine care is provided.

Scientific title

A study of a post partum cares educational interventional program for women with preeclampsia

Main outcome variables

life style

Public title

post partum cares educational program for women with preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170927036445N2**

Registration date: **2018-03-10, 1396/12/19**

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria are women aged between 15-49 years, Iranian nationality, consent to participate in the study, ability to understand questions or ability to read and write, not participating in any other clinical trials at the same time, no severe mental disorders that requires to be under medical treatment or hospitalization, the nulliparous women with preeclampsia whose delivery resulted in live births.

Exclusion criteria:

The exclusion criterion is not completing the intervention for any reason and being under treatment due to sever complication of preeclampsia, severe life stress , the death of the spouse or immigration and so on .

Age

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

Simple randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random assignment is provided to intervention and control groups with the help of random numbers and one day.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اصفهان

Street address

Hezar jarib Ave, Isfahan, Isfahan University of Medical Sciences,

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.MUI.REC.1395.3.390

Health conditions studied

1

Description of health condition studied

preeclampsia

ICD-10 code

Pre-eclamp

ICD-10 code description

014

Primary outcomes

1

Description

life style

Timepoint

Before intervention, 1 month later, 3 months after intervention

Method of measurement

life style questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, an interventional educational program designed for women with preeclampsia history.

Category

Lifestyle

2

Description

Control group: the usual care was taken for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital in Isfahan

Full name of responsible person

Mastaneh Kamravamanesh

Street address

Esfahan - Shahid Keshari Highway - Scaff Blvd - Al-Zahra Educational Center

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

m_kamravamanesh@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Isfahan- Thousand Jerib Ave.- Isfahan University of Medical Sciences- Faculty of Medicine- Social Medicine Center-2nd floor- Dr. Ziba Farajzadegan

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3668 0042

Email

farajzadegan@mui.med.ac.ir

Grant name

Grant code / Reference number

395390

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mastaneh Kamravamanesh

Position

Ph.D. in Reproductive Health, School of Nursing and Midwifery, Isfahan University of Medical Science

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Isfahan University of Medical Sciences, Faculty of Nursing Midwifery, Department of Ph.D. Students, Mastaneh Kamravamanesh

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7153

Email

m_kamravamanesh@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

Isfahan University of Medical Sciences - preventive Medicine Group

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3668 0042

Email

farajzadegan@mui.med.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mastaneh Kamravamanesh

Position

Ph.D. in Reproductive Health, School of Nursing and Midwifery, Isfahan University of Medical Science

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Isfahan University of Medical Sciences- Faculty of
Nursing Midwifery- Department of Ph.D. Students -
Mastaneh Kamravamanesh

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7153

Email

m_kamravamanesh@kums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable