

# 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 Kamravamesh

##### Street address

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

**City**

Isfahan

**Province**

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**Postal code**

8174675731

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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

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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

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## Person responsible for scientific inquiries

**Contact**

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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**

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## Person responsible for updating data

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**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