

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of self-care education in pregnancy with perceived stress and perceived social support in patients with Preeclampsia

#### Protocol summary

##### Study aim

Determining the Effect of self-care education in pregnancy with perceived stress and social support  
Preeclampsia

##### Design

population of the study is women with Preeclampsia who are referred to the research environment at the time of study. According to the population covered by each clinic, the number of samples will be calculated for each clinic. The sample size is 96 people (each case and control group, 48 people). Samples are included in the study by available sampling method and after obtaining written consent.

##### Settings and conduct

The research environment of the selected hospitals in Shiraz. The reason for choosing this environment is easy access to the sample. According to the population covered by each clinic, the number of samples will be calculated for each clinic. Samples are included in the study by available sampling method and after obtaining written consent. Data is obtained through self-care questionnaire, stress and perceived social support. The researcher completes the questionnaires by conducting the interview.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Iranian nationality; Women with Preeclampsia ; 18-45 years old; Pregnant age 20 to 42 weeks; Singleton pregnancy; No history of neonatal death in previous pregnancies; The number of deliveries is less than 4; Lack of chronic diseases; Residence in Shiraz for attending educational classes. Exclusion criteria: History of blood pressure; Dissatisfaction of people.

##### Intervention groups

A self-care education group will be provided and then self-care questionnaire, stress and socially perceived social support will be completed. The control group completes questionnaires without any training.

##### Main outcome variables

perceived stress and social support

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180127038526N1**

Registration date: **2018-05-01, 1397/02/11**

Registration timing: **prospective**

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

##### Registration date

2018-05-01, 1397/02/11

##### Registrant information

##### Name

Fatemeh Ahmadinezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3229 5884

##### Email address

ahmadi\_776@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-05, 1397/02/15

##### Expected recruitment end date

2018-07-06, 1397/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of self-care education in pregnancy with perceived stress and perceived social support in patients with Preeclampsia

### Public title

The effect of self-care education in pregnancy with perceived stress and social support in patients with Preeclampsia

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Iranian nationality pregnant women with preeclampsia  
18-45 years old pregnant age 20 to 42 weeks  
No history of neonatal death in previous pregnancies  
The number of deliveries is less than 4  
Lack of chronic diseases such as: diabetes, severe obesity, kidney disease, cardiovascular disease, anemia  
Lack of mental illness  
residence in Shiraz for attending educational classes

#### Exclusion criteria:

History of Prepregnancy blood pressure  
Dissatisfaction of people

### Age

From **18 years** old to **45 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **96**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The research environment of this study was clustered in three hospitals (mother and child clinics of Shooshtari and Hafez and Zainabiyeh Hospitals). Hospitals were selected randomly in a draw. Then, the proportion of the population covered by each clinic was calculated for each clinic. Samples are included in the sampling method. The samples are women with pre-eclampsia who at the time of study are randomly referred to the research environment and have criteria for entering the study.

### 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 Shiraz University of Medical Sciences

##### Street address

Zand Ave., Al-Crescent, Central Branch of the University of Medical Sciences, Dept. of Research Shiraz, Fars, Iran 1978 -71345

##### City

Shiraz

##### Province

Fars

##### Postal code

71345-1978

#### Approval date

2017-12-10, 1396/09/19

#### Ethics committee reference number

IR.SUMS.REC.1396,144

## 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

Perceived stress: The phenomenon of stress in the very general sense is the psychological responses to the psychological and physical needs and threats (stressors). According to Cohen's definition of stress, when the needs of the environment, whether internal or external, true or imagined, or greater than individual capacity, cause psychological and biological changes that pose a person at risk of disease.

#### Timepoint

Complete the questionnaire for the control group without any training and completion of the questionnaire for the case group after five sessions of Self-care education.

#### Method of measurement

Dass perceived stress questionnaire

### 2

#### Description

Perceived Social Support: Perceived support is equivalent to satisfying and having social support with positive emotions, and receiving social support is as much as the individual's enjoyment of obvious emotional support, such as the help and assistance provided by the family

and friends, which can be measured in size The number of supporters and the level of access and enjoyment of the types of social support were determined.

#### **Timepoint**

After five self-care training sessions

#### **Method of measurement**

Perceived Social Support Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Self-care education: Intervention is self-care education, which will be provided to the intervention group in five sessions and each session for half an hour. Group meetings and training will be held in the form of a conference and question and answer session. Self-care education is based on self-care guidelines in health centers and contains information on the principles of nutrition and healthy lifestyle, the impact of physical activity and the manner of control and principles of prevention and treatment of hypertension. Finally, after completing the training sessions, the researcher completes self-care self-care questionnaire, stress and social support.

##### **Category**

Prevention

#### **2**

##### **Description**

Control group: This group of women with Preeclampsia without any training will complete self-care questionnaires, stress, and perceived social support through interviews.

##### **Category**

Prevention

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Shooshtari Hospital

###### **Full name of responsible person**

Fatemeh Ahmadi nezhad

###### **Street address**

Bascule Nader Ave.

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Shiraz

###### **Province**

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###### **Postal code**

7173775617

###### **Phone**

+98 71 3232 4805

##### **Email**

Ahmadi\_776@yahoo.com

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Zainab Hospital

###### **Full name of responsible person**

Fatemeh Ahmadi nezhad

###### **Street address**

Sacred Defense Square

###### **City**

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#### **3**

##### **Recruitment center**

###### **Name of recruitment center**

Hafez Hospital

###### **Full name of responsible person**

Fatemeh Ahmadi nezhad

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Chamran Blvd.

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Shiraz University of Medical Sciences

###### **Full name of responsible person**

Dr. Ramin Niknam

###### **Street address**

Zand Street - Ahead of the Red Crescent - Central Station of the University of Medical Sciences - Class 7 - Research Deputy

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president@sums.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Marzieh Akbarzadeh

**Position**  
Faculty member

**Latest degree**  
Master

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Midwifery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Islamic Azad University

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**Latest degree**  
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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

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