

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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2

Recruitment center

Name of recruitment center

Zainab Hospital

Full name of responsible person

Fatemeh Ahmadi nezhad

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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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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

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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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

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