

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Investigation the effect of spiritual care education on postpartum stress disorder in women with preeclampsia

#### Protocol summary

##### Summary

This study was conducted to determine the effect of spiritual care education on postpartum stress disorder in women with preeclampsia. In this randomized clinical trial, 72 women (36 in each group) were selected in a convenience way from pregnant women between the ages of 32-38 weeks and older who had severe and non-severe preeclampsia and admitted to two public hospitals in Mashhad (Imam Reza and Qa'im Hospital). The research units completed the questionnaires Spiritual Well Ellison & Paloutzian, Being Scale (SWBS), DASS21 and Duke University Religion Index in the beginning. Then they were evaluated for the symptoms by The post traumatic Disorder checklist (PCL). They will be excluded from the study, if they answer yes to any questions. Multigravida suffering from post-traumatic stress disorder fulfilled also Prenatal Posttraumatic Stress Questionnaire (PPQ). Women will be excluded from the study if they earn a score of over 6. Research units were randomly assigned to two groups of intervention and control. To do this, two bags with two envelopes in each were selected. In the first bag, the names of the Imam Reza and Qa'im Hospital were written on the envelopes. In the second bag, the intervention and control group. Then, randomly, we took a packet of the first bag and an envelope of the second bag. This will determine which hospital is the intervention group and which hospital will be the control group. In the intervention group, firstly, women were educated based on Richards and Bergin pattern, focusing on the religion of Islam, after confirmation by religious experts. Three face to face sessions, which lasted 35 to 60 min were held each day. The intervention pack was also provided on a CD for the mothers to do at home. The researcher maintained and strengthened his contact with research units through phone calls and checklists. Mothers visited the midwifery department of these hospitals and covered health centers once every two weeks to present their spiritual care checklist. And in the middle of the week,

they received phone call. The control group also received routine cares. All units were asked to visit the clinics at the 4th to 6th postpartum period in order to control the blood pressure. Both groups completed questionnaires Spiritual Well Ellison & Paloutzian, DASS21 and The post traumatic Disorder checklist (PCL). Results were analyzed in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042728911N2**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-26, 1396/06/04

##### Registrant information

##### Name

Zahra Kamali

##### Name of organization / entity

Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

kamaliz921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences.

**Expected recruitment start date**

2017-05-02, 1396/02/12

**Expected recruitment end date**

2017-09-03, 1396/06/12

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of spiritual care education on postpartum stress disorder in women with preeclampsia

**Public title**

Investigation the effect of spiritual care education on postpartum stress disorder

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Having preeclampsia; Singleton pregnancy and live fetus; gestational age between 32 to 38 week; Iranian citizenship and settle in Mashhad; Having reading and writing ability; Participation in the study; Having a contact number. Exclusion criteria: Having medical conditions; Having obstetric complications apart from preeclampsia; The use of tobacco and drugs; Suicide or thinking about suicide during the past year; Having a history of mental illness or taking psychiatric drugs; Having History of infertility; Having a history of two abortions and more; Getting a score of over 6 from post-traumatic stress disorder (PPQ) questionnaire in women multipar; Getting more and more severe scores from the DASS 21 questionnaire in the subscales of anxiety, stress, depression; Getting score above 50 from the post traumatic Disorder checklist (PCL) questionnaire.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 72

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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 Mashhad University of Medical Sciences

**Street address**

Next to the cinema Hoveizeh, University Avenue, Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences, Mashhad.

**City**

Mashhad

**Postal code**

00985138411538

**Approval date**

2017-03-11, 1395/12/21

**Ethics committee reference number**

IR.MUMS.REC.1395.618

**Health conditions studied****1****Description of health condition studied**

Preeclampsia

**ICD-10 code**

O10, O11,

**ICD-10 code description**

Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

**Primary outcomes****1****Description**

Anxiety, Stress, Depression

**Timepoint**

Before intervention and Four weeks after childbirth

**Method of measurement**

Questionnaire DASS21

**2****Description**

Spiritual Health

**Timepoint**

Before intervention and Four weeks after childbirth.

**Method of measurement**

The questionnaires Spiritual Well Ellison &amp; Paloutzian, Being Scale (SWBS)

**Secondary outcomes**

## 1

### **Description**

The Post-traumatic stress disorder after childbirth

### **Timepoint**

Four weeks after giving birth.

### **Method of measurement**

Instruments Prenatal post traumatic stress question are ( PPQ),

## **Intervention groups**

## 1

### **Description**

The training Spiritual Care intervention was applied in 3 sessions, each 45-60 min in face-to-face. Session Contents: At the first session: A) Meeting people and assessing the knowledge, attitudes and beliefs of patients and listening to patients' views on spiritual issues, religion and existential issues (separately). B) The role of the reading Qur'an and praying and in felling calm C) Positive statements based on the Quran and Hadith books. At the second session: A) Repent and seek forgiveness B) Story of religious people C) Participate in religious programs D) Addressing God and accept the current situation E) Trust, resort, patience, charity (kindness and forgiveness) and focus on the blessings of God At the third session: A) explaining the experience of spiritual care and its effects B) Use the consequences of this care and summarize the past sessions During the sessions, the following spiritual care was also provided: 1) Trust, empathy and honesty between the nurse and mothers to establish a proper communication during the sessions. 2) Listen carefully to the physical & mental problems, worries and fears of patients 3) Psychological support required by patients 4) Strengthening individuals' inner hope and powers 5) Using positive energy sentences and strengthen healthy and constructive thoughts 6) Helping the patient find the meaning of life and understanding that none of the life events is beyond the destiny. who believes in God over whole world could be saves from the feeling pessimistic, emptiness and frustrated 7) Providing the necessary facilities for religious practices 8) Encouraging the patient to read Qur'an and pray 9) touching the hands of patients in order to provide them with mental support 10) Encouraging the patient to express their religious beliefs 11) Encouraging patients to visit religious clerics 12) Encouraging patients to refer to people who feel comfortable with them 13) Encouraging patients to enjoy entertainment and do light sports activities according to their physician's opinion. 14) Assuring the patient that the nurse is always available to her clients for mental and psychological support. 15) seek forgiveness from past sins and forsaking anger against the perpetrator and guilty person 16) Encouraging the mothers to enjoy music, singing, theater, cinema, art and etc. 17) Encourage the patients to establish a friendly relationship with others 18) Encouraging the patients to laugh and do their favorite hobbies 19) Encouraging the patients to participate in religious services and social gatherings

### **Category**

N/A

## 2

### **Description**

The control group received routine care.

### **Category**

N/A

## **Recruitment centers**

## 1

### **Recruitment center**

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

Imam Reza Hospital

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

Zahra Kamali

#### **Street address**

Crossroads PhD, Ibn Sina Street, Square Imam Reza

#### **City**

Mashhad

## 2

### **Recruitment center**

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

Ghaem Hospital.

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

Zahra Kamali

#### **Street address**

Ahmadabad, square Doctor Shariati.

#### **City**

Mashhad

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Mashhad University of Medical Sciences, Vice Chancellor for Research and Technology

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

Dr Mohsen Tafaqodi (Deputy of Research and Technology)

#### **Street address**

Next to the cinema Hoveizeh, University Avenue, Vice Chancellor for Research and Technology, Mashhad University of Medical Sciences, Mashhad.

#### **City**

Mashhad

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Mashhad University of Medical Sciences, Vice Chancellor for Research and Technology

### **Proportion provided by this source**

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

School of Nursing and Midwifery, Mashhad University of Medical Sciences, Mashhad, Iran.

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Zahra Kamali

**Position**

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**Full name of responsible person**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty***Person responsible for scientific inquiries****Contact****Name of organization / entity**

Lecturer, Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sc

**Full name of responsible person**

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**Position**

Midwifery Training

**Other areas of specialty/work****Street address**

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