

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Impact of Spiritual Care Skills on quality of life in spouses of veterans with Post Traumatic Stress Disorder

#### Protocol summary

##### Study aim

determine the effect of Spiritual care education in quality of life in Wives of Veterans with Post Traumatic Stress Disorder

##### Design

Clinical trial with control group on spouses of veterans with post-traumatic stress disorder and quality of life before, immediately and two months after intervention

##### Settings and conduct

60 eligible spouses are selected by simple random sampling. The research samples receive 9 training sessions for two consecutive weeks. Participants are evaluated before, immediately and two months after the intervention.

##### Participants/Inclusion and exclusion criteria

ability to answer questions, informed consent to participate in the study and exclude criteria of the study including: absenteeism in more than two sessions in educational interventions and the willingness to leave the study.

##### Intervention groups

Interventions (spiritual care education) were performed in group and in 9 sessions for the intervention group and in the control group, routine training is given

##### Main outcome variables

Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130618013710N1**

Registration date: **2022-07-11, 1401/04/20**

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

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

##### Registration date

2022-07-11, 1401/04/20

##### Registrant information

###### Name

ali meshkinyazd

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1711 0266

###### Email address

meshkina1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-20, 1401/03/30

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Impact of Spiritual Care Skills on quality of life in spouses of veterans with Post Traumatic Stress Disorder

##### Public title

Effect of Spiritual Care Skills on quality of life

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

ability to answer questions informed consent to participate in the study

**Exclusion criteria:**

receiving psychiatric treatments  
absenteeism in more than two sessions in educational interventions  
willingness to leave the study

**Age**

From **18 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The number of samples was 60. According to the previous studies, 95% confidence interval and using the sample size formula, considering the probability of dropping the research units of 34 in each group (68 in total) Were selected and Were randomly assigned to two groups of 34 person. The odd numbers of the intervention group and the even numbers of the control group. Finally, with the loss of 8 units (4 people due to lack of participation in the workshop, and 4 people due to lack of response to the questionnaire at follow up), 60 (30 in the experimental group and 30 in the control group) in the study Participated.

**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**

Mashhad University of Medical Sciences

**Street address**

School of Nursing, PhD Crossroads

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9196776749

**Approval date**

2020-11-25, 1399/09/05

**Ethics committee reference number**

IR. MUMS. REC. 1399. 504

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

PTSD

**ICD-10 code**

F43.1

**ICD-10 code description**

Post-traumatic stress disorder (PTSD)

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

Quality of Life

**Timepoint**

Before and after training, two months after the intervention

**Method of measurement**

Quality of Life Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: spiritual care training during 9 sessions

**Category**

Behavior

**2****Description**

Control group: Routine training during discharge

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ibn Sina Psychiatric Hospital

**Full name of responsible person**

Ali Meshkinyazd

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Boulevard Bouali

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Abbas Heidary

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ramresearch@mums.ac.ir

**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

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ali Meshkinyazd

**Position**

Nurse

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

Ali Meshkinyadz

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All variables collected

### When the data will become available and for how long

Since 1401

### To whom data/document is available

Available only to members of scientific institutes.

### Under which criteria data/document could be used

No condition

### From where data/document is obtainable

Via email: meshkina1@mums.ac.ir and Ali Meshkin Yazd will be responsible

### What processes are involved for a request to access data/document

by Email

### Comments