

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of spiritual self-care model and the developed parallel process model on the burden of care, resilience and self-efficacy of spouses of people with post-war stress vetera(PTSD)

#### Protocol summary

##### Study aim

The effect of spiritual self-care model and the developed parallel process model on the burden of care, resilience and self-efficacy of spouses of post-war stress vetera (PTSD).

##### Design

This research is a semi-experimental study with two intervention groups and one control group, without blinding, randomized on 45 people. Randomization will be done using the website sealedenvelope.com.

##### Settings and conduct

The environment of this research is the counseling centers of Shahid Torbat Foundation in Heydarieh and Mashhad, and the community of this research is the spouses of veterans with post-traumatic stress disorder (PTSD). Blinding will not be done in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Spouses of people with post-traumatic stress disorder caused by the blast wave; living with their spouses at the moment; awareness of time and place.

Non-inclusion criteria: People who do not want to participate in the study.

##### Intervention groups

Intervention groups 1: individual or group training sessions will be implemented based on the structures of the spiritual self-care model and intervention group 2: based on the developed parallel process model. Control group: receiving care and routine training of the centers.

##### Main outcome variables

self efficacy, burden of care, resilience

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230608058420N1**

Registration date: **2023-07-01, 1402/04/10**

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

Last update: **2024-02-11, 1402/11/22**

Update count: **1**

##### Registration date

2023-07-01, 1402/04/10

##### Registrant information

###### Name

Akram Rezaei aghuei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 938 228 9230

###### Email address

akramrezaei1365@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-11, 1402/03/21

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of spiritual self-care model and the developed parallel process model on the burden of care, resilience and self-efficacy of spouses of people with post-war stress vetera(PTSD)

## Public title

Comparison of two patterns of caregiving and behavior change on burden of care, resilience and self-efficacy of spouses of war veterans.

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Spouses of people with post-traumatic stress disorder caused by the blast wave living with their spouses at the moment awareness of time and place

### Exclusion criteria:

People who do not want to participate in the study

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **20**

The statistical population of all spouses of post-traumatic stress disorder veterans, whose sample size will be selected with G\*POWE statistical software, similar articles with a test power of 80%, 15 people in each group

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization will be done in a simple way using the website sealedenvelope.com. Randomization is done by forming blocks of size 6 as follows: ABCCBA - BCABCA - CABACB - BCAACB - CCBABA - BCACBA - BACBAC - BACCAB - BACCBA . Based on the randomization software, the subjects will be grouped in blocks of size six and will be placed in three groups A, B, and C.

## 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 in Research, Faculty of Medicine, Islamic Azad University - Mashhad Medical Science

##### Street address

Central Organization of Islamic Azad University of Mashhad, East side, University campus, Ostad Yousefi intersection, Emamieh Blvd., Qasimabad (Gharb city), Mashhad, Khorasan Razavi, Iran

## City

mashhad

## Province

Razavi Khorasan

## Postal code

9187147578

## Approval date

2023-05-03, 1402/02/13

## Ethics committee reference number

IR.IAU.MSHD.REC.1402.018

## Health conditions studied

### 1

#### Description of health condition studied

self efficacy

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

burden of care

#### ICD-10 code

#### ICD-10 code description

### 3

#### Description of health condition studied

resilience

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Self-efficacy score in Domkai questionnaire

#### Timepoint

Self-efficacy questionnaires will be completed first before the intervention and then after 6 training sessions (6 weeks).

#### Method of measurement

Dumkai self-efficacy questionnaire

### 2

#### Description

burden of care

#### Timepoint

Burden of care questionnaires will be completed first before the start of the intervention and then again after 6 training sessions (6 weeks).

#### Method of measurement

Standard burden of care questionnaire

### 3

#### **Description**

Resilience

#### **Timepoint**

The resilience questionnaire will be completed first before the intervention and then again after 6 training sessions (6 weeks).

#### **Method of measurement**

Connor and Davidson Resilience Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group 1: Before conducting the research, the researcher will explain the purpose of the research to obtain informed consent regarding the safety and anonymity of the research units, and they will be told that they can withdraw from the research even during the study. Then, individual or group sessions will be held at the counseling center of the Shahid Foundation for 45-60 minutes based on the structures of the spiritual self-care model. The spiritual self-care session will consist of six individual training sessions. The content of the sessions will be prepared based on the educational needs of patients and the protocol of similar studies (Omidi, Kazemi and Khatiban, 2014) (Salimi, Garmarodi, Hosseini and Batabi, 2014). Then after the intervention, three questionnaires are completed.

#### **Category**

N/A

#### 2

#### **Description**

Intervention group 2: Before conducting the research, while explaining the purpose of the research, the researcher assures the safety and anonymity of the research units. Then, individual or group sessions will be held at the counseling center of Shahid Foundation for 45-60 minutes based on the structures of the developed parallel process model. The parallel process model developed based on model instruments and similar articles will be conducted in six individual or group training sessions. These sessions will be held once a week (30 to 40 minutes) at the foundation or home. Then after the intervention, three The questionnaire is completed

#### **Category**

N/A

#### 3

#### **Description**

Control group: This group will receive care and routine consultations of the centers.

#### **Category**

N/A

### **Recruitment centers**

#### 1

#### **Recruitment center**

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

Consulting centers of Shahid Foundation of Torbat Heydarieh

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

Akram Rezaei Aghavi

##### **Street address**

Consulting centers of Shahid Foundation of Torbat Heydarieh, Shahada Square, Torbat Heydarieh, Khorasan Razavi, Iran

##### **City**

Torbat Heydarieh

##### **Province**

Razavi Khorasan

##### **Postal code**

9513633118

##### **Phone**

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##### **Email**

akramrezaei1365@yahoo.com

#### 2

#### **Recruitment center**

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

Consulting centers of Shahid Foundation of Mashhad

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

Akram Rezaei Aghavi

##### **Street address**

Consulting centers of Shahid Foundation of Mashhad, 2 Islamic Corner, Koh Sangi 31 Street, District 1, Mashhad, Khorasan Razavi, Iran

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##### **Email**

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### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

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

Islamic Azad University

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

Rahim Dabiri

**Street address**

Central Organization of Islamic Azad University of  
Mashhad, East side, University campus, Ostad Yousefi  
intersection, Emamieh Blvd., Qasimabad (Gharb city),  
Mashhad, Khorasan Razavi, Iran

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**Postal code**

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**Phone**

+98 51 3891 2073

**Email**

akramrezaei1365@gmail.com

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Akram Rezaei Aghuei

**Position**

Professor of teaching

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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**Province**

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**Fax****Email**

akramrezari1365@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Akram Rezaei aghuei

**Position**

Professor of teaching

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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**Fax****Email**

akramrezari1365@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Akram Rezaei aghuei

**Position**

Professor of teaching

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No 475; Daneshmoz 28 Street

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**Fax****Email**

akramrezari1365@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Its release schedule is not yet known

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

Its release schedule is not yet known

**To whom data/document is available**

Its release schedule is not yet known

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

Its release schedule is not yet known

**From where data/document is obtainable**

Its release schedule is not yet known

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

Its release schedule is not yet known

**Comments**

6 articles will be extracted from this proposal.