

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

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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

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rahim Dabiri

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Central Organization of Islamic Azad University of
Mashhad, East side, University campus, Ostad Yousefi
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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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Fax**Email**

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

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

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Fax**Email**

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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.