

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of spiritual therapy and therapy based on acceptance and commitment on the psychological well-being of spouses of veterans with post-traumatic stress disorder.

Protocol summary

Study aim

-Implementation of a program designed for the psychological well-being of spouses of veterans with post-traumatic stress disorder -Evaluation of a program designed for the psychological well-being of spouses of veterans with post-traumatic stress disorder

Design

A clinical trial with a control and intervention group, a blind strain, randomized using block randomization, the intervention will be conducted on 20spouses of veterans with post-traumatic stress disorder.

Settings and conduct

The place of conducting the research is the Foundation of Martyrs and Veteran Affairs of Saveh city. Before starting the intervention, the researcher will take a pre-test from both the intervention and control groups using a psychological well-being tool, and this tool will be completed 1 and 3 months after the intervention.

Participants/Inclusion and exclusion criteria

Spouses of veterans with post-traumatic stress disorder whose diagnosis of veterans' post-traumatic stress disorder has been confirmed by a neurologist

Intervention groups

The test group will receive the intervention made by the researcher, which includes increasing the quality of life and mental well-being based on the spiritual therapy of Richards and Briggs and the third wave therapies, especially the therapy based on acceptance and commitment, and the control group will receive the usual interventions at Shahid Saveh Foundation. they do.

Main outcome variables

Improving mental health and psychological well-being of spouses of veterans with post-traumatic stress disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231028059879N1**

Registration date: **2023-12-16, 1402/09/25**

Registration timing: **retrospective**

Last update: **2023-12-16, 1402/09/25**

Update count: **0**

Registration date

2023-12-16, 1402/09/25

Registrant information

Name

zahra maddah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

maddah_z550@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-04, 1402/08/13

Expected recruitment end date

2023-12-09, 1402/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of spiritual therapy and therapy

based on acceptance and commitment on the psychological well-being of spouses of veterans with post-traumatic stress disorder.		Due to The Nature of The Intervention, Blinding Is Not Possible For The Participant And The Researcher, Only The Data Analyst Is Unaware Of The Research Conditions.	
Public title	"Intervention Based on Commitment and Acceptance on Psychological Well-Being"	Placebo	Not used
Purpose	Education/Guidance	Assignment	Other
Inclusion/Exclusion criteria	Inclusion criteria: Women whose husbands have suffered from post-traumatic stress disorder as diagnosed by a psychiatrist Live together at the time of research Be able to speak Persian and have no hearing problems At least have reading and writing literacy Exclusion criteria: Spouses of veterans suffering from severe mental disorders and receiving psychiatric treatment Marked physical disorder Attending similar training sessions or programs at the same time Desire to withdraw from the study	Other design features	
Age	No age limit	Secondary Ids	empty
Gender	Female	Ethics committees	
Phase	N/A	1	
Groups that have been masked	Data analyser	Ethics committee	
Sample size	Target sample size: 60	Name of ethics committee	Joint Organizational Ethics Committee of Nursing, Midwifery and Rehabilitation Faculties of Tehran U
Randomization (investigator's opinion)	Randomized	Street address	Tawheed Square, Dr. Mirkhani St. (East Nusrat)
Randomization description	The Samples Were Selected Based on The Inclusion Criteria and Available Sampling Method, and After Obtaining Written Consent, They Were Divided into Two Control and Intervention Groups Using Random Block Allocation Method. According to The Sample Size, 30 Blocks of 4 Are Needed For Random Block Allocation. The Intervention Group Was Represented By A And The Control Group By B. According to The Number of Study Groups, The Size of The Blocks Is Considered to be 4, And Thus, The 6 Modes of Placement of The Samples in The Two Test And Control Groups Were as Follows. Then, Each Mode Is Assigned a Number From 1 to 6. 1AABB 2ABAB 3BBAA 4BABA 5ABBA 6BAAB In Order to Hide The Random Allocation, 120 Dark Envelopes Were Prepared And Each of The Random Sequences Created Was Recorded On a Card And Placed Inside The Envelope, And Finally The Lids of The Envelopes Were Glued. The Samples Were Randomly Assigned to Two Test and Control Groups By The Supervisor. At The Time of Starting The Registration of People, Based On The Order of The Samples, An Envelope Whose Number Is The Same As The Order Of The Samples Was Opened And The Group of That Sample Was Determined.	City	Tehran
Blinding (investigator's opinion)	Single blinded	Province	Tehran
Blinding description		Postal code	1419733171
		Approval date	2022-03-13, 1400/12/22
		Ethics committee reference number	IR.TUMS.FNM.REC.1400.225
		Health conditions studied	
		1	
		Description of health condition studied	Psychological well-being of spouses of veterans with post-traumatic stress disorder
		ICD-10 code	-
		ICD-10 code description	-
		Primary outcomes	
		1	
		Description	Increasing the psychological well-being score to a score above 18, according to the RIF psychological well-being questionnaire
		Timepoint	1 month and 3 months after the intervention
		Method of measurement	RYFF psychological well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The intervention will be held in 11 sessions, 2 sessions per week, each session will last 60 minutes at the Martyr and Martyr Affairs Foundation of Saveh city.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Saveh Martyrs and Martyrs' Affairs Foundation

Full name of responsible person

Shahzad Pashaeypoor

Street address

Tawheed Square, Dr. Mirkhani St. (East Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

maddah_z550@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Pashaeypoor

Street address

Tawheed Square, Dr. Mirkhani St. (East Nusrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

sh-pashaeipour@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahzad Pashaeypoor

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Postal code

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra maddah

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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maddah_z550@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
zahra maddah
Position
PhD Candidate
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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

Start access after printing the results

To whom data/document is available

Participants, if they wish, the officials of the Shahid Foundation and Martyrs Affairs, researchers working in academic institutions

Under which criteria data/document could be used

It is possible to use documents by mentioning the source

From where data/document is obtainable

Zahra Maddah Mobile: 09124557287

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

To receive the data, send a message to the email below and mention the method and reason for using the documents maddah_z550@yahoo.com

Comments