

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of peer-group support on subjective well-being and family adaptation of spouses of men diagnosed with post-traumatic stress disorder

Protocol summary

Summary

This study aims to investigate the effect of peer-group support on subjective well-being and family adaptation of spouses of men diagnosed with post-traumatic stress disorder. The sample includes a total of 80 spouses of men diagnosed with post-traumatic stress disorder referring to a special psychiatric clinic affiliated to Birjand University of Medical Sciences. In this one site study, there will be no blinding, and the participants will be selected using convenience sampling and regarding inclusion criteria. At first, demographic characteristics form, Subjective Well-being Questionnaire, and Family Adaptation Scale will be completed by all selected subjects. In the next step, the participants will be randomly assigned into control (n=40) and intervention groups (n=40) using blocking. For the intervention group, weekly peer-group support sessions will be held for 6 weeks. The control group will not receive any intervention. At the end as well as one month after intervention, both groups will complete the Subjective Well-being Questionnaire and Family Adaptation Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083117756N5**

Registration date: **2016-09-30, 1395/07/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-30, 1395/07/09

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of peer-group support on subjective well-being and family adaptation of spouses of men diagnosed with post-traumatic stress disorder

Public title

Effect of peer-group support on subjective well-being and family adaptation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Confirmed diagnosis of post-traumatic stress disorder in spouses of potential participants by a psychiatrist, based on Diagnostic and

Statistical Manual of Mental Disorders 4th edition (DSM-IV) criteria; 2. Lack of history of psychiatric illness or drug abuse among potential participants; 3. Informed consent for participation in the study; 4. Residence in Birjand or the possibility of attending in the sessions designed in the study; 5. Having at least reading and writing ability; and 6. At least two years history of PTSD in spouses of potential participants. Exclusion criteria: Failure to attend in more than two sessions of the designed sessions in the study.

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Postal code

Approval date

2016-04-27, 1395/02/08

Ethics committee reference number

lr.bums.1395.5

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder

ICD-10 code

43.1

ICD-10 code description

Post-traumatic stress disorder

Primary outcomes

1

Description

Family adaptation

Timepoint

Before, immediately after, and 30 days after intervention

Method of measurement

Family Adaptation Questionnaire

2

Description

Subjective Well-being

Timepoint

Before, immediately after, and 30 days after intervention

Method of measurement

Subjective Well-being Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Weekly peer-group support sessions will be held for them for 6 weeks.

Category

Other

2

Description

Control Group: This group will not have any interventions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized psychiatric clinic affiliated to Birjand University of Medical Science

Full name of responsible person

Seyyed Abolfazl Vagharseyyedin

Street address

Birjand University of Medical Sciences, Ghaffari St.

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research of Birjand University of Medical Sciences

Proportion provided by this source

100

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

Birjand University of Medical Sciences

Full name of responsible person

Dr Seyyed Abolfazl Vagharseyyedin

Position

Assistant Professor

Other areas of specialty/work

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PhD Candidate of Translation

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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