Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Sceinces

Street address
Birjand University of Medical Sceinces, Ghaffari St.,

City
Birjand,

Postal code

Approval date
2016-04-27, 1395/02/08

Ethics committee reference number
Ir.bums.1395.5

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder

ICD-10 code
F43.1

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.,
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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

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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