The Effect of Prolonged Exposure Therapy on Social Support, Negative Posttraumatic Cognitions, Aggression and the Severity of Symptoms in Patients with Post-Traumatic Stress Disorder

Protocol summary

Study aim
The Effect of Prolonged Exposure Therapy on Social Support, Negative Posttraumatic Cognitions, Aggression and the Severity of Symptoms in Patients with Post-Traumatic Stress Disorder

Design
The sampling method will be as follows: from all PTSD patients who refer to the psychiatric clinic of Farabi Hospital in Kermanshah, With respect to entry and exit measures among the parties involved, the number of 30 people will be selected and allocated in two groups of experiment and control (15 people in each group), and pre-test and post-test and follow-up will be done for them.

Settings and conduct
In the same situation and at the same time, pre-test will be done based on asocial support questionnaire, post-traumatic negative cognitions questionnaire, tendency to aggression questionnaire and the fifth edition of the list of post-traumatic stress disorder for both experimental and control groups. Then, the intervention will be done in ten 90-minute group sessions.

Participants/Inclusion and exclusion criteria
Admission Requirements: Have at least diploma, receive a diagnosis of PTSD based on a structured diagnostic interview for psychiatric disorders (SCID-I), no use of psychotherapy in the past 6 months. Non-entry conditions: Receive a diagnosis of borderline, antisocial, and schizotypal personality disorder based on structured interviews for SCID-II, symptoms of psychosis, substance abuse, and brain injury or other physical illnesses.

Intervention groups

Main outcome variables
Social support; Negative posttraumatic cognitions; Aggression; Severity of symptom.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20210202050216N1
Registration date: 2021-02-26, 1399/12/08
Registration timing: prospective

Last update: 2021-02-26, 1399/12/08
Update count: 0

Registration date
2021-02-26, 1399/12/08

Registrant information
Name
Zahra Forooghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 83 3837 0832
Email address
foroughi.za@fh.lu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-03, 1400/01/14
Expected recruitment end date
2021-04-17, 1400/01/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Scientific title
The Effect of Prolonged Exposure Therapy on Social Support, Negative Posttraumatic Cognitions, Aggression and the Severity of Symptoms in Patients with Post-Traumatic Stress Disorder

Public title
The Effect of Prolonged Exposure Therapy on Social Support, Negative Posttraumatic Cognitions, Aggression and the Severity of Symptoms in Patients with Post-Traumatic Stress Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Have at least diploma
Receive a PTSD Diagnosis Based on a Structured Diagnostic Interview for Axis One Mental Disorders (SCID-I)
Not using psychotherapy in the last 6 months

Exclusion criteria:
Receive a diagnosis of borderline personality disorder, antisocial vasctotypal based on structured interview for Axis Two (SCID-II)
Existence of symptoms of psychosis and substance abuse
Existence of brain injury or other physical illnesses

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Not 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 Kermanshah University of Medical Sciences

Street address
No. 7, 11th Alley, Atlas Street, Elahieh Town

City
Kermanshah

Province
Kermanshah

Postal code
6719949589

Approval date
2020-11-10, 1399/08/20

Ethics committee reference number
IR.KUMS.REC.1399.778

Health conditions studied

1
Description of health condition studied
Post-Traumatic Stress Disorder

ICD-10 code
F43.10

ICD-10 code description
Post-traumatic stress disorder, unspecified

Primary outcomes

1
Description
Sherborn & Stewart Social Support Scale (1991)

Timepoint
Pre-test, post-test, two-month follow-up period

Method of measurement
Sherborn and Stewart Social Support Scale (1991)

2
Description
Score of Cognitive Questionnaire after Foa et al. (1999)

Timepoint
Pre-test, post-test, two-month follow-up period

Method of measurement
Questionnaire of post-traumatic cognition of Foa et al (1999)

3
Description
Vistal and Albert Aggression Tendency Scale Score (2011)

Timepoint
Pre-test, post-test, two-month follow-up period

Method of measurement
Vistal and Albert Aggression Tendency Scale (2011)

4
Description
Score of the fifth edition of the Post-Traumatic Stress Disorder Questionnaire

Timepoint
Pre-test, post-test, two-month follow-up period
Method of measurement
Questionnaire of the fifth edition of the list of post-traumatic stress disorder Waters et al. (2013)

Secondary outcomes
empty

Intervention groups

1
Description
Category
Treatment - Other

2
Description
Control group: They will not receive any intervention.
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
Farabi hospital, Kermanshah
Full name of responsible person
Zahra Forooghi Aghmioni
Street address
No. 7, 11th Alley, Atlas Street, Elahieh Town
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Sponsors / Funding sources

1
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Name of organization / entity
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Person responsible for general inquiries
Contact
Name of organization / entity
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Full name of responsible person
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Position
University student
Latest degree
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Zahra Forooghi Aghmioni
Position
University student
Person responsible for updating data

Contact
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Full name of responsible person
Zahra Forooghi Aghmioni
Position
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Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After the study, the data related to the participants (without mentioning) and the results of their analysis and the statistical methods used in the study will be provided to other people along with the protocol.

When the data will become available and for how long
Access starts 1 month after the article is published

To whom data/document is available
Everyone can access the data.

Under which criteria data/document could be used
Individuals can use data for therapeutic and research use.

From where data/document is obtainable
Zahra Forooghi Aghmioni. Contact number: 09923048270 z.forooghi1992@gmail.com

What processes are involved for a request to access data/document
The researcher contacts the mentioned communication methods and receives the information via email after a maximum of 1 month.

Comments