Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of an educational intervention on post-traumatic stress disorder and social cognitive theory constructs in women with sexual assault experience

Protocol summary

Study aim
manage PTSD, change health behavior and encourage them to pursue health care as a result of improving the quality of life in women who experienced sexual assault.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, on 40 patients. A table of random numbers was used for randomization.

Settings and conduct
The training will be provided in the place of welfare and forensic medicine. In parallel with the intervention group, double-blinding, the control group, a 1-hour session of routine training will be provided without focusing on specific theoretical structures, and during the study, they will benefit from services and care without deprivation. The questioner will not know about the groups.

Participants/Inclusion and exclusion criteria
18 to 45 years Women who have experienced at least one sexual assault with a gap of at least one month from the incident People who according to the score obtained (score 35 to 70 for low PTSD severity and score 70 to 105 for moderate PTSD severity) in the Mississippi questionnaire and confirmed by the team's clinical psychologist/psychiatrist have PTSD. No drug use and no severe neurological and brain diseases at present, no mental retardation Not suffering from major psychiatric disorders and being treated or having a history and psychiatric record No pregnancy at the time of entering the study Being literate in reading and writing (otherwise, reading and helping to complete questionnaires)

Intervention groups
Educational intervention for 6 sessions of 60 minutes one day a week for 6 weeks and the content of the program is based on social cognitive theory (SCT) for the intervention group and a parallel 1 hour session for the control group. will be

Main outcome variables
Behavior change and health follow-up by the individual; Improving and reducing the burden of post-traumatic stress disorder

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230926059526N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date
2023-10-18, 1402/07/26

Registrant information
Name
Nasrin Vafaeinezhad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 913 443 3926
Email address
www.nasrinvafa@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-23, 1402/08/01
Expected recruitment end date
2024-02-04, 1402/11/15
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational intervention on post-traumatic stress disorder and social cognitive theory constructs in women with sexual assault experience

Public title

The effect of an educational intervention on post-traumatic stress disorder and social cognitive theory constructs in women with sexual assault experience

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women who have experienced at least one sexual assault with an interval of at least one month from the incident (if there are symptoms of disorder, no maximum) People who according to the score obtained (score 35 to 70 for low PTSD severity and score 70 to 105 for moderate PTSD severity) in the Mississippi Questionnaire with the ability to diagnose based on the DSM-5 diagnostic system and confirmed by the clinical psychologist/psychiatrist of the PTSD team are. No drug use at the moment Absence of severe neurological and brain diseases at present absence of mental retardation Not suffering from major psychiatric disorders and being treated or having a history and psychiatric record (psychotic disorders: psychosis, bipolar, schizophrenia) No pregnancy at the time of entering the study Being literate in reading and writing (otherwise, reading and helping to complete questionnaires)

Exclusion criteria:

Age

From **18 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use the table of random numbers to allocate the sample in two intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind the control group, a 1-hour session for the control group will be provided with the routine training of the mentioned centers without focusing on specific theoretical structures, and during the study they will use the services and routine care provided in the mentioned centers and will not be deprived and the questioner will not know about the groups.

Placebo

Not used

Assignment

Other

Other design features

. The people assigned to the intervention group will be invited to participate in 4 groups of 5 people according to their age and education, or according to the desire of not having a group member to participate in individual meetings.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences,Isfahan

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2023-09-17, 1402/06/26

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.103

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder caused by sexual assault

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description

Reducing and managing post-traumatic stress disorder, changing health behaviors and encouraging health care follow-up

Timepoint

Before and two months after the intervention

Method of measurement

Mississippi questionnaire/GSE-10 self-efficacy/awareness,

attitude and performance of health-related behavior/background characteristics/perceived social support/

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Intervention group: Women who have experienced sexual assault, referred to the social emergency center of Isfahan Welfare and Forensic Medicine Organization, who have the conditions to enter the study, will form the sample of this research. An educational intervention has been designed and compiled by considering the structures of social cognitive theory and focusing on health-related behavior.

Category
Rehabilitation

2

Description
Control group: In order to double-blind the control group, a 1-hour session for the control group will be provided with the routine training of the mentioned centers without focusing on specific theoretical constructs, and during the study they will use the services and routine care provided in the mentioned centers and will not be deprived. and the questioner will not know about the groups.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Social Emergency Center and Forensic Medicine formed the environment of this research

Full name of responsible person
Dr. Mansour Firouzbakht

Street address
Isfahan

City
Isfahan

Province
Isfehan

Postal code
8165875735

Phone
+98 31 3661 3426

Fax
+98 31 3661 6310

Email
es@lmo.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Research Vice President of Isfahan Midwifery and Nursing Faculty of Medical Sciences

Street address
Isfahan University of Medical Sciences,Isfahan,Iran

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Fax
+98 31 3669 9398

Email
boroumandfar@nm.mui.ac.ir

Web page address
http://www.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Zahra boroumandfar

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Iran. Esfahan. University of Medical Sciences

City
Isfahan

Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7536
Email
boroumandfar@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Boroumandfar
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Iran. Esfahan. University of Medical Sciences
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7536
Email
boroumandfar@nm.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra boroumandfar
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Iran. Esfahan. University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7536
Email
boroumandfar@nm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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