

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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)

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+98 913 443 3926

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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

Isfahan

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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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