

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effectiveness of cognitive-behavioral therapy and motivational interviewing on the symptoms of anxiety sensitivity, depression and self-esteem in divorced women covered by comprehensive health service centers in Khomein city.

Protocol summary

Study aim

Comparison of the effectiveness of cognitive-behavioral therapy and motivational interviewing on the symptoms of anxiety sensitivity, depression and self-esteem in divorced women covered by comprehensive health service centers in Khomein city.

Design

This study includes an experimental group (cognitive-behavioral therapy) and a comparison group (motivational interview) of the control and follow-up group. And random assignment of 20 participants to each group and implementation of interventions (two experimental groups and one control group).

Settings and conduct

Divorced women in the age group of 20-50 years with health records in all comprehensive urban and rural service centers in the form of group sessions of experimental groups undergo cognitive-behavioral therapy interventions and motivational interviews and the control group does not receive any intervention. The results are analyzed using multivariate analysis of covariance.

Participants/Inclusion and exclusion criteria

Divorced women with depression, low self-esteem and anxiety sensitivity

Intervention groups

This research is a quasi-experimental design with pre-test-post-test in experimental group (cognitive behavioral therapy), comparison group (motivational interview) and control and follow-up group (without intervention). Beck, (1986), Reese & Peterson (1985) Anxiety Sensitivity Questionnaire

Main outcome variables

The self-esteem variable is assessed by the Rosenberg Self-Esteem Questionnaire (1965), the Depression variable is assessed by the Aaron Beck Depression

Inventory (1986), and the Anxiety Sensitivity variable is assessed by the Reese and Peterson Anxiety Sensitivity Questionnaire (1985).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220328054360N1**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Abbas Bayatasghari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 4622 3613

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of cognitive-behavioral therapy and motivational interviewing on the symptoms of anxiety sensitivity, depression and self-esteem in divorced women covered by comprehensive health service centers in Khomein city.

Public title

Comparison of the effectiveness of cognitive-behavioral therapy and motivational interviewing on the symptoms of anxiety sensitivity, depression and self-esteem in divorced women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The borderline score in the Rosenberg Self-Esteem Questionnaire is 10 questions, 30 and below The borderline score in the Anxiety Sensitivity Questionnaire is 25 and higher The borderline score in the Anxiety Sensitivity Questionnaire is 25 Absence of psychotic and paranoid disorders in the subjects Receiving voluntary and informed consent At least 6 months have passed since their divorce Age gap between 20 to 50 years Have at least a diploma

Exclusion criteria:

Absence for more than two sessions Lack of interest of people to continue education

AgeFrom **20 years** old to **50 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The research sample includes 60 divorced women (20 to 50 years old) who have the criteria to enter the intervention and are selected by systematic random sampling and Then there is a random assignment of 20 participants to each group and the implementation of interventions. Randomly (table of random numbers) are divided into three experimental groups (two experimental groups) and a control group (20 people in each group).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Islamic Azad University
- Kerman Branch

Street address

Kerman, Valiasr Blvd., Islamic Azad University,
Kerman Branch

City

Kerman

Province

Kerman

Postal code

7635168111

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.IAU.KERMAN.REC.1400.027

Health conditions studied**1****Description of health condition studied**

Depressive disorder

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

2**Description of health condition studied**

anxiety sensitivity

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

The primary outcome is the "Depression Score in the Beck Questionnaire".For this purpose, achieving the differential rate of depression between the two depressed and healthy groups, number 17, is determined, which is the appropriate number of differentiation between this group.

Timepoint

Experimental groups undergo motivational interview therapy for 5 sessions of 75 minutes and cognitive-behavioral therapy for 12 sessions of 75 minutes from May 1401, one session per week until the end of July.

Method of measurement

The research instrument is Aaron Beck, Beckward, Mendelson, Mark and Arbaf (1986) Depression Scale Questionnaire

2

Description

The primary outcome is the anxiety sensitivity score obtained in the Anxiety Sensitivity Questionnaire. In this questionnaire, the highest score that a person can get is 80 and the lowest score is 16. A high score close to 80 will mean that the person has a high anxiety sensitivity, and a low score on this test will mean that the person is experiencing a low anxiety sensitivity. The borderline score is 25 or higher.

Timepoint

Experimental groups undergo motivational interview therapy for 5 sessions of 75 minutes and cognitive-behavioral therapy for 12 sessions of 75 minutes from May 1401, one session per week until the end of July.

Method of measurement

Research tool Anxiety Sensitivity Questionnaire: is a self-report questionnaire that has 16 items. This questionnaire was developed by Reese and Patterson (1985)

3

Description

The primary outcome is the self-esteem score obtained on the Rosenberg Self-Esteem Questionnaire. This scale contains 10 general terms that measure life satisfaction and feeling good about oneself.

Timepoint

Experimental groups undergo motivational interview therapy for 5 sessions of 75 minutes and cognitive-behavioral therapy for 12 sessions of 75 minutes from May 1401, one session per week until the end of July.

Method of measurement

The research tool is the Rosenberg Self-Esteem Scale Questionnaire, which consists of 10 items that are answered based on the Likert scale of four degrees from strongly agree to strongly disagree.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive-behavioral therapy: A type of psychotherapy that helps patients understand the thoughts and feelings that affect behaviors. Cognitive-behavioral therapy is based on the book of applied cognitive-behavioral group therapy written by Najmeh

Hamid and consists of 12 sessions of 75 minutes. The experimental group undergoes cognitive-behavioral therapy interventions. , Mendelssohn, Mark and Arbaf (1986), and the results are analyzed using multivariate analysis of covariance.

Category

Treatment - Other

2

Description

Intervention group: Motivational interviewing is a patient-centered method that uses to examine and resolve ambiguities in order to increase people's inner motivation to change behavior. Motivational interviewing is based on the practical guide of group motivational interviewing written by Dr. Ali Navidian and Dr. Hamid Poursharifi in 5 sessions of 75 minutes The research tool is the Rosenberg Self-Esteem Questionnaire (1965) and the results are analyzed using multivariate analysis of covariance.

Category

Treatment - Other

3

Description

Control group: In this study, except for CBT therapeutic interventions for the experimental group and motivational interview therapeutic intervention for the comparison group, no other intervention is performed. In addition, for the control group (control) only the mentioned questionnaires (depression, self-esteem, anxiety sensitivity) are distributed and collected as pre-test and post-test. In the control group, no intervention is performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban and rural health service centers affiliated to Khomein School of Medicine

Full name of responsible person

Abbas Bayatasghari

Street address

Health Deputy, Quds Boulevard, Khomein

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein School of Medical Sciences

Full name of responsible person

Hamid momeni

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Markazi Province - Khomein County - Quds Boulevard
-Deputy of Education and Research

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

khomein Medical Sciences and Health Services

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**

Khomein School of Medical ScieKhomein School of
Medical Sciencesnces

Full name of responsible person

Abbas Bayatasghari

Position

Disease control expert of the health deputy

Latest degree

Master

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Disease control expert of Khomeini Health
Department

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Email

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data such as the original outcome information

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

For researchers working in academic and scientific institutions as well as applications in other industries

Under which criteria data/document could be used

Use of documents and other data analysis only by observing the principles formulated in scientific and ethical laws

From where data/document is obtainable

Email address or website

What processes are involved for a request to access data/document

Request and request documents or files through this site and email address

Comments