

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Attention rehabilitation for anxious patients

Protocol summary

Study aim

The effectiveness of attention rehabilitation in anxious patients

Design

The present study is a randomized clinical trial with a semi-experimental design with pre-test and post-test with control group with a one month follow-up plan.

Settings and conduct

The intervention was carried out at Arash Mani psychotherapy clinic, The intervention was performed in the daily hospital. Meetings were held twice a week. Participants were randomly assigned to groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) having received diagnosis of a anxiety disorder by a psychologist or psychiatrist, 2) average score of 16-25 on Beck Anxiety Test, 3) having at least a diploma qualification or above, 4) over 18 years of age, 5) If one has received psychiatric intervention, at least 4 months must have passed, meaning that the medication has exerted its therapeutic effect and we have controlled its effectiveness. In the pre-test, we are in the maintenance stage of drug treatment. Exclusion criteria : 1) Suffering from an acute psychiatric disorder or other disorders such as schizophrenia spectrum, 2) suffering from severe physical illnesses requiring hospitalization, 3) dependence and addiction to drugs, medicine or alcohol, 4) suffering from mental retardation.

Intervention groups

Intervention group: Receives group therapy sessions (if receiving medication treatment, 4 months have passed since the treatment). The interventions lasted for 3 weeks. The sessions were held twice a week and each session was two hours. Control group: Does not receive individual or group psychotherapy. If receiving medication treatment, 4 months have passed since the medication treatment.

Main outcome variables

The score of anxiety in Beck Anxiety Inventory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230617058502N1**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **retrospective**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Leila Khabir

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-10, 1402/05/19

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Attention rehabilitation for anxious patients

Public title

Attention rehabilitation for anxious patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having received diagnosis of anxiety disorders by a psychologist or psychiatrist average score of 16-25 on Beck Anxiety Inventory minimum educational qualification is a diploma over 18 years of age If one has received psychiatric intervention, at least 4 months must have passed, meaning that the medication has exerted its therapeutic effect and we have controlled its effectiveness. In the pre-test, we are in the maintenance stage of drug treatment.

Exclusion criteria:

Suffering from an acute psychiatric disorder or other disorders such as schizophrenia spectrum Suffering from severe physical illnesses requiring hospitalization Dependence and addiction to drugs, medicine or alcohol Suffering from mental retardation.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

For the random allocation of the participants to the intervention and control groups, which were named A and B respectively, 30 numbers from the random number table were selected by computer. First, numbers 1 to 30 were given to each participant and then using the simple random sampling method, 15 people were randomly selected and placed in the intervention group. The remaining 15 people also entered the control group.

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**

Research Ethics Committees of Islamic Azad

University- Shiraz Branch

Street address

South Qa'ani street, 14th Alley, Faculty of Dentistry

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Postal code

00000000

Approval date

2023-06-19, 1402/03/29

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1402.067

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

Anxiety Disorders

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

Anxiety score in Beck Anxiety Inventory

Timepoint

Assessing the anxiety level of the participants before, immediately and one month after the intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes**1****Description**

Executive functions score in Wisconsin Card Sorting Test

Timepoint

before, immediately and one month after the intervention

Method of measurement

Wisconsin Card Sorting Test (WCST)

2**Description**

Memory score in Digit Span

Timepoint

before, immediately and one month after the intervention

Method of measurement

Digit Span (DGS) measure in WISC

3**Description**

Attention score in The Stroop Color and Word Test

Timepoint
before, immediately and one month after the intervention

Method of measurement
The Stroop Color and Word Test

Intervention groups

1

Description

Intervention group: Cognitive attention rehabilitation for the intervention group was conducted in six sessions. The first session included pre-test and introduction of attention and levels of attention as input in the information processing model and explained the impairment and involvement of attention in anxious patients. In the second session, intervention training at the first level of attention and selective attention was explained to the patients and exercises were performed in this area. The third session included intervention training at the level of attention maintenance and exercises in this area. The fourth session included intervention training in divided attention and exercises in this area. The fifth session included re-explaining the levels of attention and integrating the techniques and performing the exercise. In the sixth session, exercises were performed in the field of attention and also included completing the post-test. Between sessions, exercises were also given to be done at home, which were checked at the beginning of the next session. At the beginning of all sessions, a form was given to the patient and asked to rate their anxious thoughts and anxiety level from 0 to 100, and at the end of the sessions, patients were asked to rate their anxiety level again from 0 to 100.

Category

Rehabilitation

2

Description

Control group: no psychological intervention: Subjects in this group did not receive psychological interventions individually or in groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez hospital

Full name of responsible person
Yalda Nasihatkon

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Recruitment center

Name of recruitment center
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3

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University of Shiraz

Full name of responsible person
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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
Islamic Azad University of Shiraz

Proportion provided by this source
100

Public or private sector
Private

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
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Full name of responsible person
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student

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable