Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of cognitive-behavioral therapy combined with physical exercises on anxiety symptoms, resiliency and quality of life in individual with panic symptoms

Protocol summary

Study aim
Determining the effectiveness of cognitive-behavioral therapy combined with physical exercises on anxiety symptoms,resiliency and quality of life in individual with panic symptoms

Design
The study has a control group, a randomized,double-blind experimental group,phase 2on 30patients,and the RANNOR function of SAS software was used for randomization

Settings and conduct
The study is of an applied type, it is conducted in the Psychotherapy Clinic of Permanent Peace in the form of group therapy and with sports sessions in the Mellat Park sports complex, and it is double-blind.

Participants/Inclusion and exclusion criteria
Entry criteria for subjects: Age between 12 and 25 years Diagnosing panic symptoms based on Albany Barlow and Zinbarg Panic and Panic Questionnaire (APPQ) Signing the informed consent form to participate in the research. Exclusion criteria of subjects: Taking unstable psychiatric drugs for panic symptoms while participating in the research Abuse of drugs and alcohol Participation in other psychotherapy courses Inability to participate in physical exercises Illnesses that prevent the presentation of panic symptoms as a primary diagnosis

Intervention groups
people with symptoms of panic,whose age range is between 12years and 25years.The size of the sample group is 30people,who are randomly divided into two experimental and control groups.15people in the experimental group and15people in the control group.They are randomly assigned to the control group.The control group is placed on the waiting list,and the experimental group receives cognitive and behavioral therapy combined with physical training at the same time

Main outcome variables
Combining cognitive and behavioral therapy with physical exercises(independent variable) Anxiety symptoms,flexibility and quality of life(dependent variables)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240605062020N1**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date
2024-07-25, 1403/05/04

Registrant information
Name
Fatemeh Behrouzieh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3525 8576
Email address
fbehrouzieh@icloud.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-22, 1403/06/01
Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of cognitive-behavioral therapy combined with physical exercises on anxiety symptoms, resiliency and quality of life in individual with panic symptoms

Public title
Examining the effect of exercise in people with panic symptoms
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All people with panic disorder who are between 12 and 25 years old.
Exclusion criteria:
People who do not have symptoms of panic disorder. People whose age is less than 12 years and more than 25 years.
Age
From **12 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocking is usually used in order to balance the number of samples assigned to each of the studied groups. This feature helps researchers to have the same number of samples assigned to each of the studied groups in cases where intermediate analyzes are needed during the sampling process. The randomization method here is block randomization with individual units and the use of SAS software as a randomization tool. Concealment of random assignment refers to the method used to perform a random sequence on the participants in the study, in a way that is done before assigning the individual to the group. The assignment is not specific. Without hiding the random sequence, there is a possibility of revealing the random sequence, which eventually weakens the randomization process. Here, to hide the allocation concealment of opaque sealed envelopes Waxed random sequence (SNOSE) was used.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the participants, the researcher, and the person in charge of data collection have been kept blind. In such a way that none of those who were mentioned know which persons and which group is the control and which is the experiment.
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 - Neishabur branch
Street address
Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway
City
Mashhad
Province
Razavi Khorasan
Postal code
9186333080
Approval date
2024-06-05, 1403/03/16
Ethics committee reference number
IR.IAU.NEYSHABUR.REC.1403.021

Health conditions studied

1

Description of health condition studied
Panic symptoms
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety score in Beck Anxiety Questionnaire
Timepoint
Anxiety levels are measured at the beginning of the study (before the start of the intervention) and at the end of the study (end of the intervention).
Method of measurement
Beck anxiety questionnaire

2

Description
Flexibility score in acceptance and action questionnaire

Timepoint
Measuring the degree of flexibility is done at the beginning of the study (before the start of the intervention) and at the end of the study (end of the intervention).
Method of measurement
Flexibility in the acceptance and action questionnaire

3

Description
نمره میزان کیفیت زندگی در زمینه‌یابی سلامت 36 آیتمی (فرم کوتاه)36-item quality of life score in health research (short form)
Timepoint
Quality of life is measured at the beginning of the study (before the start of the intervention) and at the end of the study (end of the intervention).
Method of measurement
36-item health background questionnaire (short form)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: It is the group that receives the intervention. The intervention includes 10 sessions of cognitive behavioral therapy two days a week and 15 sessions of aerobic exercise three days a week.
Category
Lifestyle

2

Description
Control group: It is a group that performs the pre-test and post-test together with the intervention group. The intervention of group therapy and exercise is not done for the control group.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Trauma Institute
Full name of responsible person
Dr. Hashem Qadri
Street address
Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway
City
Mashhad
Province
Razavi Khorasan
Postal code
9186333080
Phone
+98 51 3525 8576
Email
behrouzieh92@gmail.com

2

Recruitment center
Name of recruitment center
Permanent Peace Counseling Center
Full name of responsible person
Dr. Ahmed Aghaei
Street address
Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway
City
Mashhad
Province
Razavi Khorasan
Postal code
9186333080
Phone
+98 51 3525 8576
Email
behrouzieh92@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Dolatabadi
Street address
Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway
City
Mashhad
Province
Razavi Khorasan
Postal code
9186333080
Phone
+98 51 3525 8576
Email
fbehrouzieh@icloud.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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

Islamic Azad University

Full name of responsible person

Fatemeh Behrouzieh

Position

resident

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway

City

Mashhad

Province

Razavi Khorasan

Postal code

9186333080

Phone

+98 51 3525 8576

Email

fbehrouzieh@icloud.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Behrouzieh

Position

resident

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway

City

Mashhad

Province

Razavi Khorasan

Postal code

9186333080

Phone

+98 51 3525 8576

Email

fbehrouzieh@icloud.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Behrouzieh

Position

resident

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Unit 14، No. 13, 12 Qajarian Alley, 10 Hashemi Street, Hashemi Rafsanjani Highway

City

Mashhad

Province

Razavi Khorasan

Postal code

9186333080

Phone

+98 51 3525 8576

Email

fbehrouzieh@icloud.com

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

The results of all things that can be published include: participant data file, study protocol, statistical analysis map, informed consent form, clinical study report, etc. can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

To receive data and other study documents, researchers working in academic and scientific institutions or people working in the industry can apply.

Under which criteria data/document could be used

The data and documentation of the study can be used for all research and treatment works.

From where data/document is obtainable

Requesters can contact the e-mail address behrouzieh92@gmail.com to receive the desired documents or data.

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

Applicants will receive the documents within a week after referring to the e-mail address behrouzieh92@gmail.com and stating the reason for using the documents, after reading and reviewing their application.

Comments