

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Developing a treatment protocol for pervasive anxiety disorder based on the teachings of the Holy Quran and investigating its effectiveness on the anxiety level of women with sinus tachycardia caused by anxiety

Protocol summary

Study aim

Developing a treatment protocol for generalized anxiety disorder, based on the basic model of anxiety diagnosis from the perspective of the Quran, determining and comparing the anxiety of women with sinus tachycardia caused by anxiety, in the intervention and control groups before, immediately after and one month after the intervention.

Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized, sample size of 15 people in each group

Settings and conduct

The control group is given heart rate reducing drug (propranolol) for one month, and at the same time, in the experimental group, the origin of the anxiety of the people was determined according to the diagnostic system of the Holy Quran, and their anxiety patterns were identified, and according to that, the relevant treatment strategies were given during individual counseling sessions for a period of two months. is presented. The follow-up in both the control and experimental groups was done after 1 month from the end of the respective treatments, and the final anxiety score of the experimental group It is compared with the previous score

Participants/Inclusion and exclusion criteria

The inclusion criterion is having generalized anxiety disorder and the absence of co-occurring affective disorder, the exclusion criterion is lack of companionship in the treatment process or suffering from a disease or accident affecting anxiety.

Intervention groups

In the intervention group, treatment developed according to the Holy Quran is provided during weekly and individual sessions, and anxiety levels are measured after the end of the treatment period.

Main outcome variables

physical signs of anxiety; Psychological symptoms of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230123057186N1**

Registration date: **2023-12-31, 1402/10/10**

Registration timing: **retrospective**

Last update: **2023-12-31, 1402/10/10**

Update count: **0**

Registration date

2023-12-31, 1402/10/10

Registrant information

Name

Zahra sadat Mirzahosein lashgar nevis hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7711 5304

Email address

heliahoseini96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2022-10-02, 1401/07/10

Actual recruitment start date

2022-09-01, 1401/06/10

Actual recruitment end date

2022-10-02, 1401/07/10

Trial completion date

2022-12-31, 1401/10/10

Scientific title

Developing a treatment protocol for pervasive anxiety disorder based on the teachings of the Holy Quran and investigating its effectiveness on the anxiety level of women with sinus tachycardia caused by anxiety

Public title

Investigating the effectiveness of Quranic treatment of generalized anxiety disorder on anxiety levels

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having sinus tachycardia Evidence of anxiety and certainty of anxiety diagnosis (by clinical interview and Beck anxiety questionnaire) Not suffering from uncontrolled cardiac or non-cardiac underlying disease affecting the physical symptoms of anxiety (such as tachycardia), including hyperthyroidism, fever, hypoglycemia, pheochromocytoma, bleeding, consumption of stimulants such as caffeine, congenital cardiac arrhythmias such as AVNRT or AVRT or AF, heart failure, congenital heart disease, ischemic heart disease, rheumatic heart disease Having a minimum literacy of reading and writing Having consent to participate in the research Belief and commitment to the fundamentals of Islam

Exclusion criteria:

suffering from a disease affecting the physical symptoms of anxiety during the study period Failure to follow up treatment and failure to participate in two consecutive treatment sessions The occurrence of an unexpected and extremely anxiety-provoking incident that takes a person out of the normal state (such as the experience of bereavement of loved ones, accidents, earthquakes, fires, etc.)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **30**Actual sample size reached: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, after determining the statistical population, randomization was done using the random number table method. Each member of the community was assigned a number in the table and the researcher made a random

selection by closing his eyes and placing his finger or pen tip on the table.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are aware of the type of intervention that has been done for them (drug treatment or psychotherapy). Also, clinical caregivers are aware of the treatment they have provided. The researcher who evaluated and analyzed the data is not aware of the type of intervention during the data analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Azad University of Tehran, Department of Medical Sciences

Street address

Unit 925, 2th floor, No.14, Shaghayegh 14 Building, shahrak Beheshti Ave, Bababie Free way

City

Tehran

Province

Tehran

Postal code

1651113364

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.IAU.TMU.REC.1399.278

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

Treatment of pervasive anxiety disorder according to the teachings of the Holy Quran

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

Anxiety score in Beck's questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, one month after the end of the intervention

Method of measurement
Beck's anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: women with sinus tachycardia caused by anxiety, who are treated with Quranic psychotherapy for generalized anxiety disorder for two months and in weekly and individual sessions.

Category

Treatment - Other

2

Description

Control group: women with sinus tachycardia caused by anxiety who are treated with propranolol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Hospital

Full name of responsible person

Zahra Sadat Mirzahosein Lashgar Nevis Hoseini

Street address

Imam Hossein Square, Damavand Street, Bu Ali Hospital

City

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Postal code

1651113364

Phone

+98 21 3334 8036

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heliahoseini96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Gelaleh Shahabpour

Street address

Zargandeh, Dr. Shariati Street, Imamzadeh Street, Attari Moghadam Street

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Email

Int.affairs@tms.iau.ir

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

Zahra Sadat Mirzahosein Lashgar Nevis Hoseini

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Due to privacy

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

No - There is not 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 protocol for the treatment of generalized anxiety disorder according to the Holy Quran will be published in full or in brief and practical

When the data will become available and for how long

Since 2024

To whom data/document is available

Psychologists, psychiatrists, counselors and interested people

Under which criteria data/document could be used

In order to be used to learn more about the wonderful miracles of the Holy Quran and to learn about the spiritual-religious treatment of anxiety

From where data/document is obtainable

It will be publicized in the future

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

It will be publicized in the future

Comments