

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effectiveness of cognitive-behavioral stress management (CBSM) on reducing headaches, endurance distress, emotional collapse and cognitive avoidance in patients with tension headaches And compare it to drug therapy

Protocol summary

Study aim

The effect of cognitive behavioral stress management method on reduction of headache, cognitive avoidance and alexithymia in patients with tension headaches and comparison of this method with Pharmacotherapy.

Design

In this study, clinical trial, Forty people with tension headaches in Sari Will be divided. into four groups Selected by random sampling method and randomly. Three experimental groups and one control group

Settings and conduct

Groups that should be present in the management class, in 8 sessions, in the mental Health and Psychiatry Clinic of Sari, will be treated by the researcher under stress management training and are familiar with research goals before attending the class. (Not all research goals). The two and four groups that do not need to know the goals of the project are only given general information.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complaint of headache for at least three months, having tension headaches according to the International Association of Headache, the ability to read and write, Exclusion criteria: Having a known malignant disease or cognitive impairment caused by psychosis.

Intervention groups

Samples Will be divided into 4 groups. 3 experimental groups and one control group. The first group of experiments receive only cognitive-behavioral management therapy for stress The second group of experiments was purely pharmacotherapeutic and The third group received the third test for both cognitive-behavioral management and drug therapy and No control group received any treatment.

Main outcome variables

Independent variables include drug therapy, stress

management cognitive-behavioral therapy. Dependent variables include tension headaches, cognitive avoidance, and emotional distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200413047057N1**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Seyed abdollah Amiri argmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 1386

Email address

seyedamiri93@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-08, 1399/02/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of cognitive-behavioral stress management (CBSM) on reducing headaches, endurance distress, emotional collapse and cognitive avoidance in patients with tension headaches And compare it to drug therapy

Public title

Comparison of the effectiveness of two methods of drug therapy and cognitive-behavioral stress management (CBSM) To reduce tension headaches, cognitive avoidance and emotional distress of patients with tension headaches

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A history of at least three months complaining of headaches Having complete specifications of tension headaches according to the criteria of the International Headache Association Satisfaction with attending all training sessions Has a minimum literacy degree Having enough time to attend meetings

Exclusion criteria:

The presence of a known malignancy or disease Cognitive disorders caused by psychosis such as schizophrenia, deep depression, alcoholism, drugs or other psychotropic substances

Age

From 17 years old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethics committee of Islamic Azad University, Sari Branch

Street address

Unit 9, Mahsai building 4, Alley of Victory 12, Piroozi street

City

sari

Province

Mazandaran

Postal code

4818774341

Approval date

2019-11-09, 1398/08/18

Ethics committee reference number

IR.IAU.SARI.REC.1398.127

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

Tension headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

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

Tension headache score in the questionnaire designed based on the diagnostic standards of the International Headache Association

Timepoint

At the beginning of the study and at the end of the study (after the treatment process, which takes about two months).

Method of measurement

Designed form of tension headache based on the diagnostic standards of the International Headache Association.

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

The Sexton and Dadgas Cognitive Avoidance Questionnaire scores 25 questions.

Timepoint

Before treatment and after treatment, the interval between them is two months

Method of measurement

Using a questionnaire of 25 cognitive avoidance questions of Sexton and Dagas

2

Description

Simmons and Gauger's Anxiety Tolerance Score

Timepoint

Before treatment and after treatment, the interval between them is two months

Method of measurement

Using Simmons and Gauger's Anxiety Tolerance Questionnaire, which is 15 questions.

3

Description

Toronto's Emotional Questionnaire Score

Timepoint

Before treatment and after treatment, the interval between them is two months

Method of measurement

Using Toronto's Emotional Questionnaire, which has 20 questions.

Intervention groups

1

Description

First Intervention Group: The group will merely receive stress management training in cognitive-behavioral manner. This treatment is in the form of a stress management class in 8 sessions of one hour, which is presented to subjects according to Anthony's book.

Category

Treatment - Other

2

Description

Intervention group:

Category

Treatment - Other

3

Description

Intervention group: This group receives medicine and stress management together.

Category

Treatment - Other

4

Description

Control group: This group does not receive any treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Baghbanian Neurology Clinic

Full name of responsible person

Dr. Seyed mohammad Baghbanian

Street address

Sougal Building, Qaani Alley, Farhang Street

City

sari

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Postal code

4818774251

Phone

+98 11 3311 3527

Email

smbaghbanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rahman Ghaffari

Street address

Farahabad Street

City

Sari

Province

Mazandaran

Postal code

4818774197

Phone

+98 11 3444 5111

Email

Rghaffari@ut.ac.ir

Web page address

Http://www.iausari.ac.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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyed abdollah Amiri argmand

Position

Psychological counselor

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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