

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

The effectiveness of cognitive-behavioral therapy on stress, cognitive flexibility and quality of life in patients with migraine

Protocol summary

Study aim

The effectiveness of cognitive-behavioral therapy on stress, cognitive flexibility and quality of life in migraine patients

Design

In terms of the research method, the current research is a semi-experimental study with a pre-test and post-test design with a control group. Simple randomization was used on 40 patients with migraine.

Settings and conduct

The statistical population of this research includes patients with migraines who refer to medical centers in Rasht city. All participants complete the questionnaires of perceived stress by Cohen et al., the World Health Organization's short quality of life scale, and the cognitive flexibility questionnaire, and only the intervention group is subjected to cognitive-behavioral therapy, and at the end, a post-test will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria; A person's migraine disease must be confirmed by a doctor and a neurologist exit criteria; Not having migraine, Participant suffering from other physical diseases

Intervention groups

After completing the questionnaires, the patients participating in the research are divided into two groups, and then the intervention group is subjected to cognitive-behavioral therapy, and in the intervention group, the consent form to participate in the research is provided to them. The tasks and the way of conducting the sessions are explained, and the questions and doubts of the participants in the research are answered, so the participants are mentally prepared to attend the treatment sessions. The control group does not receive the treatment and Then at the end of the post-test in both groups.

Main outcome variables

Stress, cognitive flexibility, quality of life, cognitive behavioral therapy.

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20220723055535N1**

Registration date: **2022-07-30, 1401/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-30, 1401/05/08**

Update count: **0**

Registration date

2022-07-30, 1401/05/08

Registrant information

Name

Sahereh Asan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3188 4999

Email address

asansahereh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-29, 1401/05/07

Expected recruitment end date

2022-08-27, 1401/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral therapy on stress, cognitive flexibility and quality of life in patients with migraine

Public title

The effect of cognitive behavioral therapy on stress, cognitive flexibility and quality of life

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A person's migraine must be confirmed by a doctor and a neurologist

Exclusion criteria:

The person does not suffer from migraine Participants suffering from other physical diseases

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple randomization in which 40 patients with migraine are randomly selected in the centers. The randomization tool is a random table of numbers that the researcher moves the numbers down on one of the numbers in the random table and moves to the right and down, and finally records the numbers and divides them into two experimental groups (20 people), assigns the control group (20 people) whose number has already been determined.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics Committee of Lahijan Islamic Azad University

Street address

Kashif Sharfi Street, Lahijan, Gilan Province.

City

Lahijan

Province

Guilan

Postal code

۳۹۵۱۵-۴۴۱۶۹

Approval date

2022-06-12, 1401/03/22

Ethics committee reference number

IR.IAU.LIAU.REC.1401.019

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

Migraine disease

ICD-10 code

G43

ICD-10 code description

Migraine

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

Stress variable in the perceived stress scale of Cohen et al

Timepoint

Before and after treatment

Method of measurement

The perceived stress scale of Cohen et al

2**Description**

Cognitive flexibility in cognitive flexibility questionnaire

Timepoint

Before and after treatment

Method of measurement

Cognitive flexibility questionnaire of Dennis and Vanderwaal

3**Description**

Quality of life in the World Health Organization quality of life questionnaire

Timepoint

Before and after treatment

Method of measurement

World Health Organization Quality of Life Short Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The number of 40 patients will be randomly selected and will be allocated in two intervention groups (20 people) and control group (20 people). At the beginning and at the end of the treatment, both groups complete the questionnaires of perceived stress by Cohen and colleagues and the World Health Organization's short scale of quality of life and cognitive flexibility as a pre-test and post-test, and only the intervention group will undergo cognitive-behavioral therapy. took The informed consent form is provided to the participants, and necessary explanations are provided regarding the purpose and structure of the treatment, how to conduct the treatment sessions, and the questions are answered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht city medical centers

Full name of responsible person

Sahereh Asan

Street address

Hasti Building, Koche Nevut 4, Sergol Square, Rasht, Gilan

City

Rasht

Province

Guilan

Postal code

41586-18485

Phone

+98 990 933 0388

Email

asansahereh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hossein Khara

Street address

Kashif Sharfi Street, Lahijan, Gilan Province

City

Lahijan

Province

Guilan

Postal code

۳۹۵۱۵-۴۴۱۶۹

Phone

+98 13 4222 9081

Email

asansahereh@gmail.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

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

Islamic Azad University

Full name of responsible person

Sahereh Asan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Hasti Building, Koche Nevut 4, Sergol Square, Rasht, Gilan

City

Rasht

Province

Guilan

Postal code

41586-18485

Phone

+98 13 3188 4999

Email

asansahereh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Sahereh Asan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Hasti Building, Koche Nevut 4, Sergol Square, Rasht, Gilan

City
Rasht
Province
Guilan
Postal code
41586-18485
Phone
+98 13 3188 4999
Email
asansahereh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Sahereh Asan
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Hasti Building, Koche Nevut 4, Sergol Square, Rasht,
Gilan
City
Rasht
Province
Guilan
Postal code
41586-18485
Phone
+98 13 3188 4999
Email
asansahereh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

All the data obtained from the questionnaire and test results will be published

When the data will become available and for how long

The access period starts 5 months after the results are published

To whom data/document is available

Data and documentation will be accessible to all researchers in the field of research under study.

Under which criteria data/document could be used

If people want data and documents, send a message to a personal email.

From where data/document is obtainable

Applicants should contact Sahereh Asan with mobile number 09909330388 or personal email asansahereh@gmail.com to request the desired documents or data.

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

Applicants should call 09909330388 or email asansahereh@gmail.com to receive data or documents, documents will be provided to them within 72 hours or one week.

Comments