

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The efficacy of Mindfulness-Based Art Therapy (MBAT) on reducing anxiety, depression and symptoms of people with Tension-Type Headache (TTH)

Protocol summary

Study aim

Determining the efficacy of Mindfulness-Based Art Therapy (MBAT) on reducing anxiety, depression and symptoms of people with Tension-Type Headache (TTH)

Design

A clinical trial with a control group, Unblinded, Randomized individually by coin toss method and concealment method with sealed opaque envelopes, Phase 2 on 20 patients, with a 3-month follow-up

Settings and conduct

The statistical population includes all people with symptoms of TTH in Mashhad who eventually go to an educational center for treatment. People with symptoms of headaches are invited to inform. Diagnostic questionnaire of TTH along with informed consent is distributed. Then the BSI-53 and DASS-21 questionnaires are given to the identified people so that the people who meet the entry criteria are selected. The protocol is implemented on one person so that the researcher is ethically prepared to perform on the samples. The protocol is implemented on the intervention group. In some sessions, the subjects fill out the questionnaires again.

Participants/Inclusion and exclusion criteria

Participants/Conditions of entry: Suffering from TTH, Having symptoms of anxiety and depression, Having a minimum middle school education level
Participants/Conditions of non-entry: Suffering from Migraine, Having a chronic physical illness, Having a headache caused by traumatic injury or accidents, Presence of mental disorders, Having or history of substance abuse or dependence, The presence of women in pregnancy and breastfeeding

Intervention groups

Intervention group: People with symptoms of TTH receive the MBAT protocol individually or in a group, which includes 10 sessions of 60 minutes. A meeting is held every

week. Art therapy is done through painting and is focused on physical senses, thoughts and feelings of people. Control group: Does not receive treatment. After the last follow-up, if desired, sessions will be held.

Main outcome variables

Symptoms of TTH; Anxiety; Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059292N1**

Registration date: **2023-09-21, 1402/06/30**

Registration timing: **prospective**

Last update: **2023-09-21, 1402/06/30**

Update count: **0**

Registration date

2023-09-21, 1402/06/30

Registrant information

Name

Seyyede Yasaman Zahedi Pur

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3333 3333

Email address

ysm_z@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-10-05, 1402/07/13
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of Mindfulness-Based Art Therapy (MBAT) on reducing anxiety, depression and symptoms of people with Tension-Type Headache (TTH)

Public title
The effectiveness of Mindfulness-Based Art Therapy on Tension-Type Headache

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from Tension-Type Headache Having symptoms of anxiety and depression Having a minimum middle school education level
Exclusion criteria:
Suffering from Migraine Having a chronic physical illness Having a headache caused by traumatic injury or accidents Presence of mental disorders Having or history of substance abuse or dependence The presence of women in pregnancy and breastfeeding

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization unit: Individual Randomization method: simple randomization by coin tossing method. In this way, we consider one of the study groups to be the lion and the other group to be the line, and based on the sample size, the same number of coins are tossed. Concealment method: sealed opaque envelopes. In this way, based on the sample size, envelopes are prepared and each of the random sequences created is recorded on a card, and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box respectively. Based on the order in which eligible participants entered the study, one of the envelopes was opened in order, the assigned group of that participant was revealed, and people were randomly assigned to two intervention and control groups. Since there is a possibility of heterogeneity in some primary characteristics in the two groups, using the stratified randomization method, we classify variables such as age,

gender, and education and try to eliminate heterogeneity in the groups.
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

Ethics committee in medical research of Shahed university

Street address

Secretariat of ethics committee in biomedical research, Research and technology Vice-chancellor, 2nd floor, Central building, Shahed university complex, In front of Imam Khomeini's Holy Shrine, At the beginning of the Tehran-Qom freeway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.SHAHED.REC.1402.017

Health conditions studied

1

Description of health condition studied

Tension-Type Headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description

The number, duration and severity of headaches and the type of Tension-Type Headache

Timepoint

Before the start of the intervention, The third session, The sixth session, The tenth session, One month after the tenth session, Three months after that

Method of measurement

Tension-Type Headache diagnostic questionnaire

2

Description

Anxiety score

Timepoint

Before the start of the intervention, The third session, The sixth session, The tenth session, One month after the tenth session, Three months after that

Method of measurement

Depression Anxiety Stress Scales (DASS-21)

3

Description

Depression score

Timepoint

Before the start of the intervention, The third session, The sixth session, The tenth session, One month after the tenth session, Three months after that

Method of measurement

Depression Anxiety Stress Scales (DASS-21)

Secondary outcomes

1

Description

Mental disorders score

Timepoint

Before the start of the intervention, The Fifth session, The tenth session, One month after the tenth session, Three months after that

Method of measurement

Brief Symptom Inventory (BSI-53)

Intervention groups

1

Description

Intervention group: session 1: Members get to know each other and the group leader by drawing their names with shapes and colors, Establishing a therapeutic alliance, Explaining the rules of the group and agreeing on the rules, Introducing the program and stating the process of the meetings with emphasis on the principle of confidentiality in the group, The basics of mindfulness and comparing the functional state (Automatic) and the state of being (Conscious)/ Homework: Attention to daily tasks. Session 2: Mindfulness intervention: Eating a raisin with conscious attention (Freeing from the automatic state)/ Art therapy intervention: Face painting of the real and imaginary self/ Homework: Eating with conscious attention. Session 3: Mindfulness intervention: Body monitoring meditation/ Art therapy intervention: Drawing the feelings created in the body and paying attention to the shape and color of these feelings/ Homework: Using awareness attention in normal daily activities. Session 4: Mindfulness intervention: Comparing two ways of thinking and being aware/ Art therapy intervention: Drawing life, emotions and values in it/ Homework: Performing a normal activity with a new quality in the form of conscious attention. Session 5: Mindfulness intervention: Breathing awareness attention meditation/ Art therapy intervention: Drawing the now state of mind with special signs, shapes and colors/ Homework: Calendar of pleasant experiences and related feelings. Session 6: Mindfulness intervention: Sitting meditation (non-selective awareness and awareness attention towards breathing, body and sounds)/ Art therapy intervention: Drawing thoughts, emotions and Unpleasant bodily sensations and their opposite feelings/ Homework: Awareness of the senses are full of tension caused by physical discomfort in different parts of the body. Session 7: Mindfulness intervention: Inviting problems and difficulties and dealing with them in the body/ Art therapy intervention: Drawing feelings of difficulty, dislike of the body and life problems and overcoming them/ Homework: Daily reactive breathing exercise (Breathing consciously during the day). Session 8: Mindfulness intervention: Gateway to conscious attention activity (Pleasant activity)/ Art therapy intervention: Self-advertisement/ Homework: Doing a popular activity consciously. Session 9: Mindfulness intervention: Identifying an encouraging reason to continue awareness attention practices/ Art therapy intervention: Drawing your dreams and values/ Homework: Using mindfulness in daily life. Session 10: Reviewing the previous sessions, Answering questions, Encouraging to continue the exercises and summing up.

Category

Rehabilitation

2

Description

Control group: Does not receive treatment and remains on the waiting list. It will have pre-test, post-test and follow-up test. After the last follow-up, receives treatment sessions, if wishes.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Universities, Hospitals with neurological or pain or psychosomatic departments, Psychological clinic

Full name of responsible person

Sedighe Amirkhani

Street address

Najme technical and vocational training center of Mashhad (Specially for sisters), Ferdowsi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9184993154

Phone

+98 51 3723 7305

Email

ysm_z@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahed University

Full name of responsible person

Shahriar Bijani

Street address

Research and technology vice-chancellor, Second floor, Central organization, Shahed university, In front of Imam Khomeini's Holy Shrine, Persian Gulf highway (Tehran-Qom)

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 5106

Email

bijani@shahed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Seyyede Yasaman Zahedi Pur

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Seyyede Yasaman Zahedi Pur

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Faculty of humanities, Shahed university, In front of Imam Khomeini's Holy Shrine, Persian Gulf highway (Tehran-Qom)

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5522 8800

Fax**Email**

ysm_z@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahed University

Full name of responsible person

Hamid Yaghubi; Mohammad Reza Shairi

Position

Associate Professor; Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Faculty of humanities, Shahed university, In front of Imam Khomeini's Holy Shrine, Persian Gulf highway (Tehran-Qom)

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 2468 ext. 00982151212470

Email

shairi@shahed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Seyyede Yasaman Zahedi Pur

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Faculty of humanities, Shahed university, In front of Imam Khomeini's Holy Shrine, Persian Gulf highway (Tehran-Qom)

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5522 8800

Fax

Email

ysm_z@yahoo.com

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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Study protocol: The content of the sessions can be shared. Informed consent letter form: The content of the form can be shared, except for the contact information of the project presenter and respondent.

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

Researchers, Therapists

Under which criteria data/document could be used

Reasonable requests will be answered.

From where data/document is obtainable

Seyyede Yasaman Zahedi Pur ysm_z@yahoo.com

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

After receiving the email, the request will be reviewed and answered.

Comments