Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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,Phase2on20patients,with a3-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 includes10sessions of60minutes.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
Seddighe 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)
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Person responsible for scientific inquiries

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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