Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effectiveness of acceptance and commitment therapy on emotional resilience, cognitive avoidance, and rumination in women with migraine.

Protocol summary

Study aim
Determining the effectiveness of acceptance and commitment therapy on emotional resilience, cognitive avoidance, and rumination in women with migraine.

Design
A controlled clinical trial with parallel groups, without blinding, randomized, on 40 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
The statistical population of the present study will include all female patients with migraine who refer to neurologists at Shafa Hospital in Ahvaz during the specified time period of the study. Purposive sampling method will be used to select the sample. In this way, by referring to the neurology department of Shafa Hospital and obtaining permission from the relevant doctors, a list of patients with migraine will be received. After selecting the samples to a volume of 40 people, based on the inclusion and exclusion criteria of the study, the participants will be randomly assigned to two groups: "Acceptance and Commitment Therapy" (intervention group) and "Waiting List" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with migraine, aged 20 to 50 years, headache history for at least the past 6 months. Exclusion criteria: Participation in other psychotherapy sessions at least one month prior to the study, lack of consent to participate in the study.

Intervention groups
Intervention group: All individuals who will receive the acceptance and commitment therapy intervention. Control group: All individuals who will not receive any intervention.

Main outcome variables
Emotional resilience, Cognitive avoidance, Rumination

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260609069727N1**
Registration date: **2026-06-28, 1405/04/07**
Registration timing: **prospective**

Last update: **2026-06-28, 1405/04/07**
Update count: **0**

Registration date
2026-06-28, 1405/04/07

Registrant information

Name
Azin Bekhradi

Name of organization / entity
Islamic Azad University of Ahvaz (Science and Research Unit)

Country
Iran (Islamic Republic of)

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+98 61 3444 2015

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-16, 1405/04/25

Expected recruitment end date
2026-08-01, 1405/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effectiveness of acceptance and commitment therapy on emotional resilience, cognitive avoidance, and rumination in women with migraine.

Public title
The effect of acceptance and commitment therapy on the management of psychological symptoms in women with migraine.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women with migraine aged 20 to 50 years A history of headaches during at least the past 6 months
Exclusion criteria:
Participation in other psychotherapy sessions at least one month before the study Unwillingness to participate in research

Age
From **20 years** old to **50 years** old

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 statistical population of the present study will include all female patients with migraine who refer to neurologists at Shafa Hospital in Ahvaz during the specified time period of the study. Purposive sampling method will be used to select the sample. In this way, by referring to the neurology department of Shafa Hospital and obtaining permission from the relevant doctors, a list of patients with migraine will be received. After selecting the samples to a volume of 40 people, based on the inclusion and exclusion criteria of the study, the participants will be randomly assigned to two groups: "Acceptance and Commitment Therapy" (intervention group) and "Waiting List" (control group). Randomization will be performed using random blocks with variable sizes (4 and 6 people) by an independent statistician who is not involved in the implementation process. The random allocation list will be generated using the RAND function in Excel software and then placed in opaque, sealed, and numbered envelopes so that the researcher and participants are not aware of the allocation sequence (allocation concealment). Opening the envelope and informing the group allocation will only be done when each participant enters the study. To ensure the equality of the baseline variables (such as anxiety level, age, and headache frequency and severity), their distribution in the two groups will be examined during the statistical analysis stage.

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 of Islamic Azad University of Ahvaz Branch

Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
6134937333

Approval date
2026-04-18, 1405/01/29

Ethics committee reference number
IR.IAU.AHVAZ.REC.1405.053

Health conditions studied

1

Description of health condition studied
Neurological Migraine

ICD-10 code
G43.9

ICD-10 code description
Migraine, unspecified

Primary outcomes

1

Description
Emotional resilience

Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention

Method of measurement
Measurement will be using the Connor and Davidson Resilience Scale.

2

Description
Cognitive avoidance
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
Measurement will be done using the Cognitive Avoidance Questionnaire.

3

Description
Rumination
Timepoint
1. Pre-test (before the start of the intervention) 2. Post-test (immediately after the end of the intervention period) 3. One-month follow-up after the intervention
Method of measurement
Measurement will be using the rumination response scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Acceptance and commitment therapy. Duration of each session: 90 minutes; Total number of sessions: 8 sessions; Sequence of sessions: twice a week; Therapeutic tools used: acceptance exercises, cognitive dissociation exercises, presence-in-the-moment exercises, identification of personal values, and committed action exercises. The content of the different sessions is based on the following: Session 1: Pre-test, introduction to the concept of migraine and its relationship with excessive control, Session 2: Focus on the concept of "acceptance" instead of "coping"; teaching how to accept sensory and emotional experiences without trying to eliminate or change them in an avoidant manner. Session 3: Teaching "cognitive dissociation" techniques to reduce the power of rumination and learn how to observe thoughts instead of drowning in them. Session 4: "Presence-in-the-moment" and mindfulness exercises to reduce cognitive avoidance and focus on current experiences instead of worrying about the future or the past. Session 5: Identifying "life values"; helping participants understand what is really important to them in life. Session 6: “Committed Action” exercises; designing small, specific action plans to move toward values, even in the presence of pain or unpleasant thoughts. Session 7: Integrating concepts (self-improvement); teaching how to observe thoughts and feelings from a neutral position and maintain emotional resilience in critical moments. Session 8: Final summary, reviewing coping protocols at home, providing suggestions for maintaining psychological flexibility, administering a post-test, and scheduling a follow-up test.weekly 90-minute group sessions .
Category
Treatment - Other

2

Description
Control group: The control group will not receive any intervention during the research, but to prevent factors that threaten the internal validity of the research, such as compensatory competition by the control group or demoralization, they will receive a compassion therapy intervention after data collection.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Azin Bekhradi
Street address
Shafa Hospital, Neurology Center, Golestan
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azin.hb1378@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Egdarnezhad
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Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
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6134937333
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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
Azin Bekhradi

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable