Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Acceptance and Commitment Therapy on Health Anxiety, Meta-Worry, Health-Promoting Lifestyle, and Cognitive Flexibility in Psychosomatic Patients with Migraine

Protocol summary

Study aim

Determining the effectiveness of acceptance and commitment therapy on health worry, meta-worry, health-promoting lifestyle, and cognitive flexibility in psychosomatic patients with migraine

Design

The clinical trial will use a pretest-posttest design with experimental and control groups, and individuals will be randomly assigned to the experimental and control groups.

Settings and conduct

This research is a field experimental study with a pre-test-post-test design and a control group. The statistical population of the present study is psychosomatic patients with migraine referring to psychiatric clinics in Ahvaz in 1403. After preparing a list of eligible patients, 30 people were selected by simple random selection and were divided into two experimental groups (15 people) and control groups (15 people) by assigning random numbers. The experimental group will receive the acceptance and commitment therapy method from the Shirali and Dasht-e-Bozorgi package (2019) based on the Foreman and Herbert (2009) protocol in 10 60-minute sessions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Aged 31 to 50 years Diagnosis of psychosomatic symptoms and migraine in them Having consent to participate in the research Exclusion Criteria Substance addiction Use of psychiatric medications such as anti-anxiety and antidepressants Receipt of psychological services within the past three months History of receiving Acceptance and Commitment Therapy

Intervention groups

Intervention group: Receives the acceptance and commitment therapy method from the Shirali and Dasht-e-Bozorgi package (2019) based on the Forman and Herbert protocol (2009) in 10 60-minute sessions.
Control group: Receives no intervention.

Main outcome variables

Health concern; Meta-worry; Health-promoting lifestyle; Cognitive flexibility.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250915067256N1**
Registration date: **2025-09-18, 1404/06/27**
Registration timing: **prospective**

Last update: **2025-09-18, 1404/06/27**
Update count: **0**

Registration date

2025-09-18, 1404/06/27

Registrant information

Name

Hossein Namazi Furoshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 584 3408

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-07, 1404/07/15

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Acceptance and Commitment Therapy on Health Anxiety, Meta-Worry, Health-Promoting Lifestyle, and Cognitive Flexibility in Psychosomatic Patients with Migraine

Public title
Effectiveness of Acceptance and Commitment Therapy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 31 to 50 years Diagnosis of psychosomatic symptoms and migraine in them Having consent to participate in the research
Exclusion criteria:
Substance addiction Use of psychiatric medications such as anti-anxiety and antidepressants Receipt of psychological services within the past three months History of receiving Acceptance and Commitment Therapy
Age
From **31 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, to achieve complete random allocation and eliminate any researcher interference or bias, the simple randomization method will be employed. First, a complete list of women attending the counseling center who meet the inclusion criteria will be prepared. Then, each participant will be assigned an initial numerical identification code. These codes will be entered into the Random Number Generator software, which will generate a unique random number for each individual. After generating the numbers, participants will be arranged in ascending order based on their random number values. Subsequently, the first fifteen individuals on the list will be assigned to the experimental group, and participants numbered sixteen to thirty will be assigned to the control group. This process is designed in such a way that neither the order of entry nor the researcher’s prior knowledge of the participants plays any role in allocation, and it will be impossible to predict any participant’s group before the completion of the randomization process.
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 of Ahvaz
Street address
No. 44, Amir Building, Unit 9, 1st Behdari St., Behind Al-Hadi Mosque, Ariashahr
City
Ahvaz
Province
Khouzestan
Postal code
6184694880
Approval date
2025-07-23, 1404/05/01
Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.256

Health conditions studied

1

Description of health condition studied
Psychosomatic symptoms of migraine
ICD-10 code
F45.0
ICD-10 code description
Somatization disorder

Primary outcomes

1

Description
Health concern
Timepoint
before performing the intervention and two weeks after completion of the intervention
Method of measurement
Wells and Davis Anxious Thought Scale (1994)

2

Description
Metaconcern
Timepoint
before performing the intervention and two weeks after

completion of the intervention

Method of measurement

Wells and Davis Anxious Thought Scale (1994)

3

Description

Health-promoting lifestyle

Timepoint

before performing the intervention and two weeks after completion of the intervention

Method of measurement

Walker, Secrist, and Pender Health Promoting Lifestyle Questionnaire (1987)

4

Description

Cognitive flexibility

Timepoint

before performing the intervention and two weeks after completion of the intervention

Method of measurement

Dennis and Vanderwaal Cognitive Flexibility Questionnaire (2010)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acceptance and commitment therapy, as another method derived from the third wave of psychotherapy, has its roots in cognitive behavioral therapy based on contextualism and the theory of mental relations framework and has six basic principles including acceptance, fault-finding, self as context, connection to the present, recognition of values, and committed action (Garcia et al., 2023). The main goal of this therapy is to achieve a more valuable and satisfying life by increasing psychological flexibility. In this study, Forman and Herbert's (2009) model, which was also used in the study by Shirali and Dasht-e-Bozori (2019), will be used for acceptance and commitment therapy.

Category

Behavior

2

Description

Control group: They do not receive any intervention or treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ryan Psychology Clinic

Full name of responsible person

Hossein Namazi Furoshani

Street address

1st floor, Mahtab Complex, between East 4th and 5th Streets, Kianpars.

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h.namazi.f@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Parvin Ehteshamzadeh

Street address

Islamic Azad University of Ahvaz, Farhang Shahr.

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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
Hossein Namazi Furoshani

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
No. 44, Amir Building, Unit 9, 1st Behdari St., Behind Al-Hadi Mosque, Ariashahr

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participant data is completely confidential and I do not intend to publish it.

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