

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparison of the effectiveness of acceptance and commitment therapy (ACT) with compassion-focused therapy on emotion regulation, anxiety tolerance and flexibility in women with migraine

#### Protocol summary

##### Study aim

Comparing the effectiveness of acceptance and commitment therapy with compassion-focused therapy on Emotion Regulation, Distress Tolerance, and Resilience in Women with Migraine

##### Design

A randomized clinical trial with the control group, parallel groups, without blinding. The number of 108 qualified samples will be included in the study using the convenience sampling method and will be randomly assigned to the study groups using cards/envelope shuffling method.

##### Settings and conduct

Group therapy is held for 8 sessions of one and a half hours for each approach, once a week in a selected counseling center in Ahvaz city. After the end of the research, 4 treatment sessions will be performed for the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Migraine disease with the diagnosis of a specialist doctor, having a minimum education of a diploma to do homework, and age range of 20-50 years. Exclusion criteria: Having a head injury or injury, participating in educational workshops related to acceptance and commitment therapy and compassion-based therapy outside of therapy sessions, not cooperating with the therapist, suffering from severe medical mental disorders as diagnosed by a psychological specialist through a diagnostic interview, having dependence or substance abuse, the absence of evidence based on the existence of a serious and chronic physical illness that requires treatment.

##### Intervention groups

In the acceptance and commitment therapy group, the concepts of therapy based on acceptance and commitment will be taught in group sessions (8 sessions of one and a half hours). In the compassion-focused

therapy group, the concepts of compassion-based therapy will be taught in group sessions (8 one-and-a-half-hour sessions). No intervention will be done in the control group.

##### Main outcome variables

Emotion regulation, anxiety tolerance, and flexibility in women

#### General information

##### Reason for update

##### Acronym

(ACT) (CFT)

##### IRCT registration information

IRCT registration number: **IRCT20220517054892N1**

Registration date: **2023-06-08, 1402/03/18**

Registration timing: **retrospective**

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

##### Registration date

2023-06-08, 1402/03/18

##### Registrant information

##### Name

Farima Foroughi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3338 7064

##### Email address

fv.foroughi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-25, 1402/01/05  
**Expected recruitment end date**  
2023-04-04, 1402/01/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### **Scientific title**

Comparison of the effectiveness of acceptance and commitment therapy (ACT) with compassion-focused therapy on emotion regulation, anxiety tolerance and flexibility in women with migraine

#### **Public title**

Comparison ( ACT) & (CFT) on psychological values in migraine

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Migraine disease with the diagnosis of a specialist doctor. Having a minimum education of a diploma to do homework, and age range of 20-50 years.

##### **Exclusion criteria:**

The main conditions of not entering the study before randomization: Having a head injury or injury, participating in educational workshops related to acceptance and commitment therapy and compassion-based therapy outside of therapy sessions, not cooperating with the therapist, suffering from severe medical mental disorders as diagnosed by a psychological specialist through a diagnostic interview, Having dependence or substance abuse, and the absence of evidence based on the existence of a serious and chronic physical illness that requires treatment

#### **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: **108**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Randomization will be such that 108 cards are prepared and in 36 of the cards the letter A (for the treatment group focused on acceptance and commitment), in 36 cases the letter B (for the treatment group focused on compassion) and in 36 cases the letter C (for the control group) will be recorded. Subjects will appear at a certain time in a place prepared for this purpose in advance, and each person will be randomly assigned to the group registered inside the card by picking a card that will be placed inside a sealed envelope.

#### **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, Ahvaz branch

##### **Street address**

Azad University, Farhangshahr Blvd

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6155954394

#### **Approval date**

2022-12-08, 1401/09/17

#### **Ethics committee reference number**

IR.IAU.AHVAZ.REC.1401.185

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Migraine

#### **ICD-10 code**

G43.909

#### **ICD-10 code description**

Migraine, unspecified, not intractable, without status migrainosus

## **Primary outcomes**

### 1

#### **Description**

Psychological flexibility: The score obtained from the 20-question questionnaire of Dennis and Vanderwaal (2011).

#### **Timepoint**

At the beginning of the study (before the start of the intervention), immediately after the intervention and one month after the intervention

#### **Method of measurement**

Dennis and Vanderwal psychological flexibility questionnaire

## 2

### **Description**

Distress tolerance: The score obtained from the 15-question questionnaire of Simon and Gaher's Distress Tolerance Questionnaire.

### **Timepoint**

At the beginning of the study (before the start of the intervention), immediately after the intervention and one month after the intervention

### **Method of measurement**

Simon and Gaher Distress Tolerance Scale

## 3

### **Description**

Emotional regulation: The score obtained from the 36-question emotional regulation questionnaire of Garnevsy et al. (2002).

### **Timepoint**

At the beginning of the study (before the start of the intervention), immediately after the intervention and one month after the intervention

### **Method of measurement**

Garnevsy cognitive emotion regulation questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: does not receive any training or intervention.

#### **Category**

N/A

### 2

#### **Description**

Compassion-focused therapy: In group sessions (8 sessions, each session for an hour and a half) will teach about the concepts of compassion-focused therapy. These concepts will be taught and discussed in the context of structured group therapy sessions.

#### **Category**

Rehabilitation

### 3

#### **Description**

Acceptance and Commitment Therapy: In group sessions (8 sessions, each session for one and a half hours), the concepts of therapy based on acceptance and commitment will be taught. These concepts will be taught and discussed in the context of structured group therapy sessions.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Office of Dr Hossein Safari

##### **Full name of responsible person**

Dr Hossein Safari

##### **Street address**

Medical complex of East of kianpars, East 14 Street, Kianpars Blvd, Ahvaz

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

۶۱۵۵۸۶۴۸۹۵

##### **Phone**

+98 61 3337 6416

##### **Email**

Hoseinsafari1382@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Mehrawaran counselling center

##### **Full name of responsible person**

Mohamadreza Kefayat

##### **Street address**

No. 398, between Kafi & Jahanian Street, Hafez Ave, Naderi Blvd, Ahvaz

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6195665917

##### **Phone**

+98 61 3223 7722

##### **Email**

Mehrawaran32221313@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Maryam gholamzade jefre

##### **Street address**

Azad University, Farhanshahr Blvd

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6134937333

##### **Phone**

+98 61 3334 8420

**Email**

Gholamzadeh.m723@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**

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**

Maryam gholamzade jefre

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Azad University, Farhangshahr Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6134937333

**Phone**

0098 33 348420

**Email**

Gholamzadeh.m723@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farima Foroughi

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No 19, East 9 Street, Kianpars Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6155954394

**Phone**

+98 61 3338 7064

**Email**

fv.foroughi@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farima Foroughi

**Position**

Student of consultant, phd

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No.19, 9 East Street, Kianpars Blvd

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6155954394

**Phone**

+98 61 3338 7064

**Fax**

**Email**

Fv.foroughi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The information about the pre-test and post-test of the participants will be published after the end of the study.

**When the data will become available and for how long**

The data access period will start six months after the end

of the study

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Researchers who need data to conduct research under common scientific and humanitarian ethical standards can submit their request by email.

**From where data/document is obtainable**

You should send your request to these two emails.

fv.foroughi@gmail.com and

Gholamzadeh.m723@gmail.com

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

The researcher sends her request in writing to the mentioned two emails and within ten days, her request will be reviewed and if approved, the data will be sent to her.(feminine)

**Comments**