Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Comparision (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

Khouzestan

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 Garnevsky 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
Garnevsky 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
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2

Recruitment center
Name of recruitment center
Mehrawaran counselling center
Full name of responsible person
Mohamadreza Kefayat
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No. 398, between Kafi & Jahanian Street, Hafez Ave, Naderi Blvd, Ahvaz
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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
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Postal code
6134937333
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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Farima Foroughi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Farima Foroughi

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Latest degree

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Other areas of specialty/work

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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