

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the effectiveness of compassion-based emotion-focused combination therapy package with compassion-based therapy on quality of life in patients with primary headache symptoms

#### Protocol summary

##### Study aim

The main purpose of this study was to compare the effectiveness of compassion-based emotion therapy package with compassion-based therapy on the quality of life of patients with primary headache symptoms.

##### Design

This research is a three-group quasi-experimental method with pre-test-post-test design and follow-up with a control group. The statistical population was all patients with symptoms of primary headache referred to the clinic of Khatam Al-Anbia Hospital in Tehran in the winter of 1399 in the ages of 18 to 45 years, from which 45 patients were purposefully selected. After purposeful selection of sample members, randomly selected individuals were divided into three groups of 15 people (in quasi-experimental research, at least 15 people are recommended for each group). After sampling, the subjects were divided into two experimental groups and one control group

##### Settings and conduct

The statistical population was all patients with symptoms of primary headache referred to the clinic of Khatam Al-Anbia Hospital in Tehran in the winter of 1399 in the ages of 18 to 45 years, from which 45 patients were purposefully selected. After purposeful selection of sample members, randomly selected individuals were divided into three groups of 15 people (in quasi-experimental research, at least 15 people are recommended for each group).

##### Participants/inclusion and exclusion criteria

Inclusion criteria: informed consent for treatment, being in the age group of 18 to 45 years, high score in the quality of life scale, diagnosis of primary headache by a specialist and having a file, are not under parallel psychiatric and psychological treatments

##### Intervention groups

The first experimental group was the compassion-based

emotion therapy group The second experimental group was the compassion-based treatment group The third control group

##### Main outcome variables

Quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210901052355N1**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

##### Registration date

2021-10-13, 1400/07/21

##### Registrant information

##### Name

neda behvandi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3500 2612

##### Email address

nedabehvandy@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-19, 1400/06/28

##### Expected recruitment end date

2021-12-06, 1400/09/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of compassion-based emotion-focused combination therapy package with compassion-based therapy on quality of life in patients with primary headache symptoms

**Public title**

Comparison of the effectiveness of compassion-based emotion-focused combination therapy package with compassion-based therapy on quality of life in patients with primary headache symptoms

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Conscious satisfaction of the subjects and willingness to participate and continue to participate in treatment  
Being in the age group of 18 to 45 years according to the disability assessment questionnaire caused by headache  
Diagnosis of primary headache by a specialist and having a record Do not undergo parallel psychiatric and psychological treatments

**Exclusion criteria:**

Dissatisfaction and unwillingness to participate and continue to participate in treatment Do have secondary headaches Absence of three consecutive or non-consecutive sessions Undergo other psychiatric and psychological treatments.

**Age**From **18 years** old to **45 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**Target sample size: **45****Randomization (investigator's opinion)**

Randomized

**Randomization description**

45 patients from the community of patients with primary headache symptoms of Khatam Al-Anbia Hospital will be purposefully selected based on sample adequacy (Sarmad, Hejazi and Bazargan, (1997) in experimental and quasi-experimental research recommend at least 15 to 20 people for each group). The assignment of both experimental groups, including compassion-based emotion therapy and compassion-based therapy, and the control group will be a simple random lottery. In this

way, each sample person is given a special code and then the codes are poured into a bag or container and mixed. It then pulls out the codes one by one, writes down their number, and so on until the groups are completed. Then, for random and unpredictable allocation of 15 people in the first, second and third groups for two experimental groups and one control group, coin toss will be used.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This study is a three-way blind. In this study, three sample groups, treatment administrators and an evaluation group that analyzed the obtained data, were kept blind. In this study, the facilitator, participants, treatment executives, and the assessment team did not already have any knowledge or physical, telephone, or online contact with each other. In this study, three groups of samples are kept blind to each other and to the treatment. Also, the executors of the treatments and the information evaluation team are outside the treatment plan team

**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

**Street address**

University Blvd, Arqavanieh, Jey Street, Isfahan Azad University

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Isfahan

**Province**

Isfahan

**Postal code**

۳۹۹۹۸-۸۱۵۵۱

**Approval date**

2020-06-10, 1399/03/21

**Ethics committee reference number**

IR.IAU.KHUISF.REC.1399.063

**Health conditions studied****1****Description of health condition studied**

Primary headache

**ICD-10 code**

G43: G44.2

**ICD-10 code description**

Migraine: Tension type headache: Cluster headache syndrome

## Primary outcomes

### 1

#### Description

In the present study, the outcome variable is a quality of life score below 40 in the Quality of Ware & Sherbourne Questionnaire, which indicates a low quality of life.

#### Timepoint

Before the intervention and 80 days later (completion of the intervention) and then 60 days later (follow-up)

#### Method of measurement

The tool for measuring the outcome variable is the quality of Life Ware & Sherbourne Questionnaire. The quality of life variable is measured in three stages before the intervention, after the intervention (80 days after the start of the intervention) and in the follow-up stage (60 days after the end of the intervention). In the instrument of measuring the quality of life Ware & Sherbourne , the maximum scores are 100 and the minimum scores are zero. High scores mean high quality of life and low scores mean low quality of life.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: Emotion-based therapy group is based on compassion. The experimental group or the first intervention received compassion-based emotion therapy for 10 sessions one day a week for 60 minutes. The first group intervention based on the protocol developed by Behvandi, Khayatan and Golparvar (1399) based on the need-based inductive thematic analysis (theme) (based on the needs of patients with primary headache symptoms) and interviews with patients with symptoms Initial headache, then adaptation of needs to emotion-based and compassionate treatment texts, and finally obtaining specialized agreement and approval of initial executive preparation were prepared. The content of emotion-based therapy includes: 1. Creating awareness, regulation and emotional transformation as three principles of emotional change 2. Intervening in disturbances to deal with emotions and 3. Cultivating compassion and soothing system in patients with early headache symptoms Help

#### Category

Behavior

### 2

#### Description

Intervention group2: The treatment group is based on

compassion. The experimental group or the second intervention received compassion-based treatment for 8 sessions one day a week for 60 minutes. Compassion therapy sessions were prepared based on the validated and tested protocol of Gilbert (2010). The content of compassion-based sessions includes: introduction to emotional regulation systems, familiarity with the conscious brain, familiarity with the characteristics of compassion and cognition of the compassionate person, compassionate reasoning and compassionate attention, compassionate visualization and compassionate sensory experience, compassionate feeling and compassionate behavior

#### Category

Behavior

### 3

#### Description

Control group: without receiving any treatment

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam Al Anbia Hospital

##### Full name of responsible person

Felor Khayatan

##### Street address

University Blvd, Arqavanieh., Jey Street., Isfahan Azad University

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr.Hadi Farhadi

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FarhadiHadi@yahoo.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**

Isfahan Azad University

**Full name of responsible person**

Dr.Felor Khayatan

**Position**

Assistant Professor, Faculty

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Latest degree**

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Dissemination of information at the individual or private

level: For each of the participants in the present study, the files related to that person and also the main outcome of the study in which the person participated are prepared as a personal file and if requested as a CD file or email Will be provided to them. Dissemination of information at the public level: The results of the present study will be published in the form of articles, lectures and other forms of public media in the form of identifiable information and maintaining the confidentiality and privacy of study participants

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

Access to the data will start 4 months after the results are published and in 1400

**To whom data/document is available**

Anyone interested in psychological studies in the field of headache and its symptoms can benefit from the information published in this study. Researchers and students with studies related to the present study, if they need more information about the research process and more information about the results obtained, can be informed through the email address and phone number of the responsible author

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

1.Researchers and researchers can refer to the present

study by citing the source 2. Researchers and researchers can compare the treatments used in the present study with other studies by mentioning the reference or by referring to the reference as a new protocol

**From where data/document is obtainable**

Applicants can refer to the following e-mail address and contact numbers to receive the required documents or data. F.khayatan@yahoo.com; Nedabehvandy@gmail.com 09131289531 09902175301 09388481122 031- 35002612

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

1. Sending an official e-mail or telephone call requesting a respectful and formal request on the subject of the research requesting the documents and the reason for the need for the documents 2. Receive valid details from the applicant for documents, including complete and valid personal details, valid email address, valid contact number to verify the validity of the request of the document applicant 3.Check emails and calls within 48 hours and if the request of the applicant is confirmed, send the documents while maintaining the privacy and confidentiality in the form of email, fax and post for the applicant

**Comments**