

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Educational Intervention to Apply Pain Coping Strategies Among Female Patients with Migraine

Protocol summary

Study aim

Determining the Effect of Educational Intervention Based on the Pattern of Changes in the Applying of Overcoming Pain Mechanisms in Patients with Migraine

Design

This quasi-experimental case-control study was randomized. The statistical population of this study will be all migraine patients whose disease has been determined by a specialist physician. Approximately estimated patients are about 650 volunteers. The sample size is estimated at 60, randomly divided into two groups of 30 test and control groups. Considering the small number of patients and the limited number of clinics available in the city, in order to prevent possible overlap between the samples and the probability of bias in the information, the two health centers that have the greatest distance from each other were selected and randomly assigned to Experimental and control groups were assigned.

Settings and conduct

This study will be conducted in Anzali. The statistical population of this study will be all migraine patients whose disease has been determined by a specialist physician and will be referred to Anzali Health Centers in co-ordination with specialized psychiatric and neurological clinics in Anzali.

Participants/Inclusion and exclusion criteria

Entry requirements: 1) Inactive stages of fitness for change including pre-thinking, thinking, and intention. 2) Diagnosis of chronic migraine headache by a psychiatrist and neurologist based on the International Society for Headache criteria; Conditions of non-arrival: 1) Stay in active stages, including the implementation and maintenance of 2) Severe physical illness, severe neurological dysfunctions

Intervention groups

A group of migraine patients undergoing educational intervention to learn a number of pain relief methods. The control group is also a migraine patient who does

not receive any training during this period.

Main outcome variables

It reduces the frequency and frequency of migraine attacks and, as a result, increases the quality of life of migraine patients and prevents them from imposing additional costs on the community.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180120038452N1**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Tahereh Seifpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4450 2946

Email address

t.seifpoor@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Educational Intervention to Apply Pain Coping Strategies Among Female Patients with Migraine

Public title

Effects of Educational Intervention on Migraine

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of chronic migraine headache by a specialist
Have 4 Migraine attacks or more during a month
No history of psychotic disorders
Not participating in educational and interventional programs
Being a woman
Contingency in the passive stages of readiness for change involves pre-thinking, thinking, and intent
Being volunteering
No working shift shifts
Have at least reading and reading
The age range is between 18 and 42 years
Accommodation in Anzali Headache intensity 5 or higher based on numerical scale of pain assessment

Exclusion criteria:

Unwillingness to work together at any time
Severe physical illnesses, severe neurological impairments
The incidence of suicidal ideation and suicide that requires emergency intervention
Having diseases that make it impossible for a person to continue to work together.
Staying in active stages involves running and keeping
Unwillingness to continue treatment

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to two groups of 30 test and control groups. Considering the small number of patients and the limited number of clinics available in the city, in order to prevent possible overlap between the samples and the probability of bias in the information, the two health centers that have the greatest distance from each other were selected and randomly assigned to Experimental and control groups were assigned. Then, from the patients referring to these centers, sampling will be done using a sample-based sampling method to reach the sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2018-01-04, 1396/10/14

Ethics committee reference number

IR.QUMS.REC.1396.353

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

pain coping

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Applying pain reliever strategies

Timepoint

At the beginning of the study and one month after the end of the intervention

Method of measurement

Mouse and Billings Coping Strategies Questionnaire

2**Description**

People who are in the process of passive pain change.

Timepoint

At the beginning of the study and one month after the end of the intervention

Method of measurement

Pain Stages of Change Questionnaire

Secondary outcomes

1

Description

Self-efficacy in dealing with pain

Timepoint

Start the study and one month after the end of the intervention

Method of measurement

Self-efficacy questionnaire on Nicholas pain

Intervention groups

1

Description

Intervention group: Educational intervention in relation to migraine headaches and ways to cope with it will be emphasized on the various stages of de-stressing. In this study, the training provided to the target group under the educational intervention will consist of 5 sessions of 60 minutes in five consecutive weeks, which will be conducted in a group.

Category

Behavior

2

Description

Control group: During the study, they will not receive any special intervention. But after the completion of the study, they will be provided with intensive training.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Anzali Health centers

Full name of responsible person

Tahereh Seifpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Qazvin University of Medical Sciences

Full name of responsible person

Tahereh Seifpoor

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

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