Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Street address
Navab Safavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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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

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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