Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The experimental effects of mood and stress induction on the pain intensity in migraine patients

Protocol summary

Summary

There are many researches on relationship between stress and depression with migraine; however, much experimental evidence is needed to make such a view more validated. The aim of this study was experimental investigation of mood induction and stress on pain intensity in migraine patients. Patients were included in the study if they were: aged between 18 and 65, had a formal diagnosis of migraine by a neurologist, had a complaint of migraine for six months or longer and had a high school certificate (12 years of formal education or higher). Patients excluded from the study were those with severe depression or anxiety, severe daily headache and pregnancy. The study population was all patients suffering migraine in Tehran. For this purpose, 60 migraine patients were recruited from Baqiyatallah Hospital in Tehran-Iran in 2011-2012 years, and were randomly assigned into one of three groups: negative mood induced group, positive mood induced group and control group. The following instruments and measures were used in this study: Mood induction by presenting different types of films, and a computerized cognitive task to elicit pain. The pain intensity was measured in three steps (at baseline, after computerized task, and after showing film). All eligible participants were asked to complete baseline self-report measure of pain intensity prior to receiving pain and mood induction. Following this, computerized task of cognitive exhaustion to elicit pain was used, and after this stage, the mood induction procedure by showing a film was applied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052417813N1**
Registration date: **2014-07-09, 1393/04/18**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-07-09, 1393/04/18

Registrant information

Name
Zahra Goli
Name of organization / entity
Kharazmi University
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Iran (Islamic Republic of)
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+98 21 8832 9220
Email address
golim.psych@gmail.com

Recruitment status

Recruitment complete

Funding source

individual

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-06-01, 1391/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The experimental effects of mood and stress induction on the pain intensity in migraine patients

Public title

effect of mood and stress on pain intensity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 18 and 65; formal diagnosis of migraine by a neurologist; experience of migraine for six months or longer; 12 years of formal education or higher Exclusion criteria: severe depression or anxiety; severe daily headache; pregnancy

Age

From **18 years** old to **65 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

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

-Kharazmi University

Street address

-Faculty of Psychology, Kharazmi University, Daneshgah Sq., Shahid Beheshti Str., Karaj, Iran

City

-Karaj

Postal code

-

Approval date

2010-04-21, 1389/02/01

Ethics committee reference number

-63/824

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura [classical migraine]

2

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

Pain intensity

Timepoint

At baseline, after half an hour, after one hour

Method of measurement

Pain Numerical Rating Scale

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Control group: (1) implementation of computerized cognitive exhaustion task in order to stress and pain induction, (2) break time for 7 minutes, (3) to read a neutral magazine for 12 minutes.

Category

Other

2

Description

Elated group: (1) implementation of computerized cognitive exhaustion task in order to stress and pain induction, (2) break time for 7 minutes, (3) showing a happy film clip for 12 minutes in order to elated mood induction.

Category

Other

3

Description

Depressed group: (1) implementation of computerized cognitive exhaustion task in order to stress and pain induction, (2) break time for 7 minutes, (3) showing a sad film clip for 12 minutes in order to depressed mood induction.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Baqiyatallah Hospital of Tehran
Full name of responsible person
Zahra Goli
Street address
46, Navvab Safavi Ave., Amirkabir Str., kashan
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Hosein Kachuee
Street address
Baqiyatallah Hospital, Molla Sadra Str, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Baqiyatallah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kharazmi University
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Goli Zahra
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty