

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Determining the effects of acupressure on sleep quality and fatigue of patients with migraine

Protocol summary

Summary

A total of 80 potential participants will be selected from the available list of patients with migraine will be selected by convenience sampling and according to inclusion criteria: Age from 18 to 60 years; non-pregnant, non-continuous use of drugs affecting sleep; report of any accident that has affected mood and mind of the patient by him/herself; a history of migraine attacks at least twice in recent months; non-use of preventive medicine; not having psychological disorders; lack of diseases such as cancer, lupus, skin diseases and severe congestive heart failure; lack of ulcers or amputations in the concerned parts; lack of drug addiction; lack of dysarthria and hearing problem; score 5 or higher on Pittsburgh Sleep Quality Index (a score greater than 5 indicates severe sleep disorder); attainment of qualifications needed to do acupressure techniques; literacy to read and write. They will first complete demographic characteristics form and Fatigue Severity Scale (FSS). The participants will be assigned into intervention (n=40) and placebo (n=40) by blocking technique. The intervention group will receive acupressure in each of the Nei Guan and Yin Tang points three times a week for four weeks. The placebo group will have acupressure with 2.5 centimeter distance from Nei Guan point and 3 cm above Yin Tang. This technique will be performed by the patients themselves after patient education and qualification. At the end of four weeks of massage, the questionnaires will be completed by both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061117756N3**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-06-25, 1395/04/05

Expected recruitment end date

2016-07-26, 1395/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effects of acupressure on sleep quality and fatigue of patients with migraine

Public title

Effects of acupressure on sleep quality and fatigue

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age from 18 to 60 years; non-pregnant, non-continuous use of drugs affecting sleep; report of any accident that has affected mood and mind of the patient by him/herself; a history of migraine attacks at least twice in recent months; non-use of preventive medicine; not having psychological disorders; lack of diseases such as cancer, lupus, skin diseases and severe congestive heart failure; lack of ulcers or amputations in the concerned parts; lack of drug addiction; lack of dysarthria and hearing problem; score 5 or higher on Pittsburgh Sleep Quality Index (a score greater than 5 indicates severe sleep disorder); attainment of qualifications needed to do acupuncture techniques; literacy to read and write. Exclusion criteria: Disinterest to continue participation; occurrence of any problem during treatment against inclusion criteria.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari Street

City

Birjand

Postal code**Approval date**

2016-05-23, 1395/03/03

Ethics committee reference number

lr.bums.1395.11

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

sleep quality

ICD-10 code

g47.8

ICD-10 code description

Sleep disorder, unspecified

2**Description of health condition studied**

fatigue

ICD-10 code

f48.0

ICD-10 code description

Neurasthenia

Primary outcomes**1****Description**

fatigue

Timepoint

four weeks

Method of measurement

Fatigue Severity Scale

2**Description**

sleep quality

Timepoint

4 weeks

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: They will first complete demographic characteristics form and Fatigue Severity Scale (FSS). The group will receive acupuncture in each of the Nei Guan and Yin Tang points three times a week for four weeks. This technique will be performed by the patients themselves after patient education and qualification. At the end of four weeks of massage, the questionnaires will be completed by group members.

Category

Rehabilitation

2

Description

The placebo group: The members will first complete demographic characteristics form and Fatigue Severity Scale (FSS). The members will have acupressure with 2.5 centimeter distance from Nei Guan point and 3 cm above Yin Tang. This technique will be performed by the patients themselves after patient education and qualification. At the end of four weeks of massage, the questionnaires will be completed by both groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital

Full name of responsible person

Street address

Vali Asr Hospital, Ghaffari St.

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Birjand University of Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Deputy of Reserach, Birjand University of Medical Sciences, Ghaffari St.

City

Birjand

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology, Birjand 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

Faculty of Nursing and Midwifery, Birjand University of Medical Sciences

Full name of responsible person

Mohadeseh Salmabadi

Position

Master Student of Medical-Surgical Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

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Web page address

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