

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The combined effect of transcutaneous electrical nerve stimulation and massage therapy on disease-related disability in people with migraine headaches

Protocol summary

Study aim

Determining the combined effect of Transcutaneous Electrical Nerve Stimulation (TENS) and massage therapy on disease-related disability in patients with migraine headache

Design

Randomized Clinical trial study with a control group, on 200 patients and randomized by List Randomization site

Settings and conduct

The study was done in clinic of Dr. Bidaki, a neurologist in Shiraz. Tennis is performed by a Memos-T-VNS machine and massage in 6 steps according to the protocol

Participants/Inclusion and exclusion criteria

Inclusion Criteria: aged 18-55 years, having chronic migraine criteria according to the International Classification of Headache Disease (ICHD III, 2010), confirmation of the diagnosis of migraine headache by a neurologist, score of 50 and above headache impact test (HIT) and get a score of 11 and more from the Migraine Disability Assessment Questionnaire (MIDAZ), literacy. Exclusion criteria are: any history of tennis, and other complementary or psychological treatment, patients with persistent migraine headaches, and tension, cluster and secondary headache, cancer, pregnancy, lactation, addiction, other chronic disease, and any anatomical and pathological disorders in the ear.

Intervention groups

Patients are divided into 4 groups. In group 1, auricular TENS is performed for two days a week at intervals of 2 to 3 days and for 4 weeks on each ear for 5 minutes and a total of 10 minutes in both ears. In group 2, massage intervention is performed for 4 weeks a week, 2 sessions at intervals of 2 to 3 days, 30 minutes. In group 3 for 4 weeks, twice a week for 2 to 3 days, first TENS and then massage according to standard protocols. Control group, will received routine treatment.

Main outcome variables

Migraine- related disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020401N8**

Registration date: **2022-04-16, 1401/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-16, 1401/01/27**

Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combined effect of transcutaneous electrical nerve stimulation and massage therapy on disease-related disability in people with migraine headaches

Public title

The combined effect of transcutaneous electrical nerve stimulation and massage therapy on disease-related disability in people with migraine headaches

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

migraine with out urea and more than three month At least 2 to 3 signs of unilateral headache and pulsating headache, moderate to severe pain with routine physical activity such as walking or climbing stairs or avoiding these activities. At least one of the symptoms of nausea or vomiting and photophobia or phenophobia.

Confirmation of migraine headache by a neurologist Get a score of 50 or higher on headache impact test (HIT)

Earn a score of 11 or more on Migraine disability assessment (MIDAS) Literacy for reading and writing

Exclusion criteria:

The use of tennis and other complementary medicine or psychological drugs in the past Patients with persistent migraine headaches or migraines with aura , Patient with tension and cluster or secondary headache Psychological and neurological diseases Cancer, pregnancy, lactation, addiction. patients with other chronic disease Anatomical and pathological disorders in the ear

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

More than 1 sample in each individual

Number of samples in each individual: **1**

The study sample included 200 eligible patients with migraine headache who referred to the private office of neurologist Dr. Bidaki. Participants were randomly assigned to 3 intervention groups (50 participants in each group) and 1 control group including 50 controls.

Randomization (investigator's opinion)

Randomized

Randomization description

block randomize: Eligible people using the List

Randomization site at

(<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) and creating a number of different blocks, In three groups, intervention 1 (auricular tense), intervention 2 (massage), intervention 3 (combination)

and control will be allocated. Blocking method will be used to assign individuals to the studied groups. Random allocation by blocking method is to make sure that exactly the same number of patients enter the intervention and control groups at consecutive but equal intervals. The groups will be A, B, C, D. Before assigning people to one of the groups, a list of these letters (A, B, C, D) are formed as blocks. Each of the eligible applicants will be assigned to one of the groups. The advantage of blocked randomization is that the balance of the number of patients in each group is guaranteed. To avoid the predictable risk of assigning people to different groups, blocks of different sizes will be created.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The study is a randomized clinical trial with a control group.

Secondary Ids

empty

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

Research Ethics Committees of Yasuj University of Medical Sciences

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Kohgiluyeh and Boyer-Ahmad Provinces, Yasuj, Motahhari Blvd., University of Medical Sciences, Vice Chancellor for Education, Research and Technology, First Floor.

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Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.YUMS.REC.1400.194

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

Migraine

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Disability related to Migraine

Timepoint

Before, after and 4 weeks following intervention

Method of measurement

The Migraine Disability Assessment Test and Headache Impact Test

Secondary outcomes

1

Description

Pain score

Timepoint

during 4 weeks Before intervention, 4 weeks intervention and 4 weeks following intervention

Method of measurement

pain score

Intervention groups

1

Description

Electrical stimulation of the auricular nerve

Category

Treatment - Devices

2

Description

Intervention group 2: massage therapy

Category

Treatment - Other

3

Description

Electrical stimulation of the auricular nerve and massage therapy

Category

Treatment - Devices

4

Description

Control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic of Dr Bidaki

Full name of responsible person

Zivar Amani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Yasuj 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

Yasouj University of Medical Sciences

Full name of responsible person

Nazafarin Hosseini

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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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