Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 و 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
Street address
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

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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
Yasouj 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
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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