Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Survey the effect of app-based acupressure therapy in patients with migraine pain in

Protocol summary

Study aim
Investigating the effectiveness of two different groups of acupressure points through dedicated mobile phone applications in migraine control

Design
Acupressure training is done in the video attached to the application. The randomization of 2 groups is done by the http://random.org system located in the system. The pressure of each of the 4 points is 3 minutes with 1 minute of rest between the points. The intervention is once a day and the duration of the intervention is 1 month. The patient's symptoms will be registered daily in the system. Forms are completed 3 times before the intervention, immediately after the intervention and 3 months after the intervention. Resolving ambiguities by contacting the student's cell phone, which is stated in the informed consent form.

Settings and conduct
Self-care at the patient's home.

Participants/Inclusion and exclusion criteria
Migraine patients with compliance with entry and exit criteria

Intervention groups
Intervention group points: GV-20, BL-2, EX-HN5, LI-4
Points of the control group: LU-7, GB-21, ST-36, , TW-17

Main outcome variables
Pain severity, pain frequency in every month, pain duration

General information

Reason for update

Acronym
Acupreesure for migraine

IRCT registration information
IRCT registration number: **IRCT20121228011912N6**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **registered_while_recruiting**
Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date
2023-05-15, 1402/02/25

Registrant information

Name
Hamidreza Bahrami Taghanaki

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2024-04-03, 1403/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey the effect of app-based acupressure therapy in patients with migraine pain in

Public title
Survey the effect of app-based acupressure therapy in patients with migraine pain in Mashhad population

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Previous and definitive diagnosis of migraine (without aura) by a neurologist based on the criteria of the international association of Headache (IHS) at least 6 months ago (upload the latest prescription for migraine treatment by a neurologist) Experiencing acute migraine at a frequency of 2-8 times per month for the previous 3 months Being in the age range of 18-45 years Absence of pregnancy and breastfeeding Absence of other neurological diseases Absence of cancer and skin malignancy or wound in the acupressure area All eligible participants must be able to understand the research instructions and be willing to give informed consent. All participants should answer and complete the entire designed questionnaires All participants should provide a daily report of the severity, duration, and number of migraine attacks

Exclusion criteria:
A headache that has an organic cause (Subarachnoid hemorrhage, cerebral hemorrhage, cerebral embolism, cerebral thrombosis), vascular malformations, temporal artery arthritis, high blood pressure, or having another neurological disease for headache are excluded from the study. Participants who had received headache prophylaxis treatment during the previous 3 months Participants who (women) intend to get pregnant during the study Non-cooperation of the patient (failure to perform intervention more than 8 times) Changing the type and dosage of drugs used during the intervention Has used acupuncture or acupressure in the last 6 months

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **152**

Randomization (investigator's opinion)
Randomized

Randomization description
The website https://www.random.org/ will be used to generate random numbers. The randomization ratio will be one to one. Random numbers will be transferred to the specially created software and will be assigned to study groups completely randomly when users log in.

Blinding (investigator's opinion)
Double blinded

Blinding description
After the participants entered the desired application and registered and answered the questionnaires, and if they met the criteria for entering the study, using the application software, they were randomly assigned in an equal ratio of 1:1 (n1 = 76 and n2 = 76) between the groups. This study will be conducted in a randomized double-blind manner (participants and analysts are blind in this study). Patients in the two acupressure groups will be blinded to the type of treatment received, and patients will be blinded to whether they are in a group receiving different acupressure points. Also, the study analyst was also blind and without information regarding the type of treatment group, which disease received which type of treatment.

Placebo
Not used

Assignment
Parallel

Other design features
In order not to be deprived of the standard treatment of classical medicine, patients should be treated by one of the standard methods of migraine by a neurologist.Then, after random grouping and compliance with medical ethics standards, both groups will have real acupuncture points leading to more and less effect. that the treatment will be carried out as self-care acupressing and after making sure to learn the taught items through the mobile phone application by the patient himself.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Mashhad University of Medical Science

Street address
3rd floor - Abuzar qafari Bulv - Abuzar qafari 38- Ahmad Abad Ave.

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Mashhad

Province
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Postal code
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Approval date
2022-11-19, 1401/08/28

Ethics committee reference number
IR.MUMS.REC.1401.286

Health conditions studied

1

Description of health condition studied
Migraine Headache

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura

Primary outcomes

1

Description
pain severity
Timepoint
Before the intervention and 1 and 3 months after the intervention
Method of measurement
Using visual analogous scale (VAS)

Secondary outcomes

1

Description
Quality of life
Timepoint
Before the intervention and 1 and 3 months after the intervention
Method of measurement
WHO quality of life-BREF 26 questionnaire

Intervention groups

1

Description
The intervention is acupressure, which is one of the therapeutic branches of Chinese medicine. Acupressure is pressure on specific points of the body, which are acupuncture points, by thumb pulp and with vertical pressure on the surface of the patient's body. The amount of pressure is such that the patient gets as close as possible to the bone below that point and feels pain. The treatment protocol consists of pressing each point for 3 minutes, and since we use 4 points, a total of 12 minutes in each patient's self-treatment session. One treatment session per day and the duration of the treatment is 1 month. In this study, 4 mentioned acupuncture points are used for the intervention group. GV-20, BL-2, EX-HN 5, LI-4
Category
Treatment - Other

2

Description
The same explanation given regarding intervention group 1 is also applicable in this group. But the points that are used in the control group are different and they are: LU-7, GB-21, ST-36, TW-17
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک طب سوزنی بیمارستان امام رضا (ع) مشهد
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person

Dr. Hamidreza Bahrami-Taghanaki
Position
Faculty member
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The statistical details of the data will be mentioned in the published article.
When the data will become available and for how long
After finishing research
To whom data/document is available
All those who have access to the published article or with the supervisory permission of the Vice Research of Mashhad University of Medical Sciences
Under which criteria data/document could be used
With the request of the responsible researcher and the consent of the University Research Council and only for survey purposes without any possibility of exploiting the content of the data.
From where data/document is obtainable
After printing the article to the responsible author and before printing, if required by relevant authorities, to the responsible researcher
What processes are involved for a request to access data/document
By means if Vice research of Mashhad University of Medical Science
Comments