

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

investigation the effect of neck and head massage on the intensity of pain, frequency of attacks and analgesic usage in patients with migraine

Protocol summary

Study aim

Determining the effect of massage therapy on pain intensity, number of attacks and frequency of analgesic use in patients with migraine referred to the office of internal neurologists in Bandar Abbas in 2021

Design

This study consists of three groups of touch massage and control of 20 people.

Settings and conduct

The massage will be performed by a trained family member at the patient's home. The patient lies on a mattress that feels comfortable. Massage the trapezius and neck muscles and the occipitofrontal, vasculature and frontal muscles with moderate pressure in the massage group and without pressure in the touch group. The control group is monitored without any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of the diagnosis of migraine by a neurologist using the International Index to diagnose headache for at least one year Headaches occur at least four times a month (once a week) Age over 18 years Written consent to participate in the study
Exclusion criteria: neurological disorders and other severe physical diseases and chronic systemic diseases addiction to drugs and alcohol Absence of wounds, thrombosis, hematoma, malignancy and skin changes and abnormalities in the head and neck areas that prevent massage take anticoagulants cardiovascular disease pregnancy and lactation

Intervention groups

In the massage therapy group, the method of massage will be taught by one of the researchers who has received the certification of the training course on massage therapy protocol, to a member of the patient's family who is introduced by the patient and the person volunteers to receive training and massage. For the touch group, only touch without pressure will be performed with the same duration and location as the massage therapy group

Main outcome variables

Pain intensity - number of attacks and frequency of painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201116049403N1**

Registration date: **2021-03-12, 1399/12/22**

Registration timing: **retrospective**

Last update: **2021-03-12, 1399/12/22**

Update count: **0**

Registration date

2021-03-12, 1399/12/22

Registrant information

Name

zakieh faghihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 1010

Email address

faghihi_2020@ yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
investigation the effect of neck and head massage on the intensity of pain, frequency of attacks and analgesic usage in patients with migraine

Public title
investigation the effect of neck and head massage on the intensity of pain, frequency of attacks and analgesic usage in patients with migraine

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of the diagnosis of migraine by a neurologist using the International Index to diagnose headache for at least one year Headaches occur at least four times a month (once a week) Age over 18 years Written consent to participate in the study
Exclusion criteria:
neurological disorders and other severe physical diseases and chronic systemic diseases addiction to drugs and alcohol Absence of wounds, thrombosis, hematoma, malignancy and skin changes and abnormalities in the head and neck areas that prevent massage take anticoagulants cardiovascular disease pregnancy and lactation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be assigned to the three groups of massage therapy, control and touch by randomization method based on sex classes (male and female) and duration of infection (5 years and less - more than 5 years). The entry of the first sample in the table is based on a lottery. For example, a man with a history of more than 5 years will be placed in the massage group by drawing lots between the three groups, the next people like him will be assigned to the touch and control group, respectively, and the rest will be a man with a history of less than 5 years. A woman with a history of more than 5 years and a woman with a history of less than five years will be performed in the same way to reach the quorum.

Blinding (investigator's opinion)
Double blinded

Blinding description

n this study, participants in the non-pressure touch group are unaware of the placebo of this method. Also, the clinical caregiver of the touch group is unaware of the placebo of this study during the study. Data analyzer of which Reforms are not known to which group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of rafsangan University of Medical Sciences

Street address

West daneshvar

City

Bandar Abbas

Province

Hormozgan

Postal code

7919748306

Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.RUMS.REC.1399.176

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain score in Visual Analogue Scale and Headache Impact Test-6 (HIT-6)

Timepoint

Measurement of headache severity one month before the intervention, one month during the intervention and one month after the intervention

Method of measurement

Visual Analogue Scale, Headache Impact Test-6 (HIT-6)

2

Description

number of attacks

Timepoint

Number of migraine attacks in one month before the intervention and one month during the intervention and one month after the intervention

Method of measurement

frequency of analgesic use

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: massage group; In the massage therapy group, the method of massage will be taught by one of the researchers who has received the certification of the training course on massage therapy protocol, to a member of the patient's family who is introduced by the patient and the person volunteers to receive training and massage. After the training, the massage protocol will be repeated on the patient by the family member in the presence of the researcher to ensure accurate and complete learning. The massage will be performed by a trained family member of the patient. The intervention will be performed in a quiet, private, clean and hygienic room, safe, without noise and without disturbing the movement of others, with proper air conditioning and with the protection of the patient's privacy. The patient will wear disposable comfortable clothing so that his shoulders and neck are available for massage. The patient lies on a mattress that feels comfortable and the therapist is placed on top of the patient. The therapist also needs to wear comfortable and soft clothes to be able to perform massage movements gently and gently. Before starting the massage, the hands should be warm, and if the hands are cold, they should be gently warmed by rubbing the palms on top of each other. Baby oil is turquoise, it will be used for massage. Trapezius muscle massage: The massager is placed on top of the patient and the patient in the prone position and we use the skin roll technique (3 minutes), muscle roll (3 minutes) and needling (3 minutes). In the skin roll method, we use lifting the skin with the thumb by starting from the midline of the spine and continuing to the lateral end of the rotation of the scapula under the armpits on both sides, and from the shoulders from near the scapula to the base of the neck. We continue. Muscle roll technique, which is done by applying pressure with the length of sixty fingers from the midline of the spine to the periphery at the site of the trapezius muscle, and the technique of needling, which is performed by direct pressure of the thumb on the sacrospinalis on both sides of the patient. Neck massage: To massage the neck, we use the prone position (2 minutes) and the needling technique, and with the fingers of both hands, we continue the massage from the back of the occiput to the area where the neck extends and below the scapular area. . In the lateral part of the neck (2 minutes) we use

all the fingers and continue the protrusion of the trapezius. The palm while the fingers are in front of the upper fiber of the trapezius, we start kneading with pressure, then the patient in the lateral position (2 minutes) and then supine (2 minutes) and massage with your fingertips the muscles of the upper trapezius that is attached to the neck in the same way. Massage of the occipital frontal muscle: To massage the occipital frontal muscle of the patient in the supine position, we use the muscle stitching technique (2 minutes) by placing the palm of one hand on the forehead and the palm of the other hand under the sub-occipital muscle. We place the forehead and move it downwards or towards the eyebrows and the hand under the head upwards at the same time so that it feels like the scalp is moving forward and backward. Scalp massage: To perform this massage, three techniques of floristry (2 minutes), needling (2 minutes) and vibration (2 minutes) are used. In the flossing technique, the therapist places the fingers of both hands on both sides of the temporal area and the patient's scalp. Gently massage in a circular motion. In the needle massage technique, massage is performed on the whole skull, in the occipital frontal area and above the afferent massage area by the movements of all fingers. The vibration technique is common with the location of the needle method, so that the palms of both hands are on the area. Massage is performed and gentle reciprocating movements are performed in the form of vibration. Frontal area massage: Needling technique (2 minutes) and afferage (2 minutes) are used. In needling method, it is done using two, three or four fingers by massaging the midline of the forehead in the frontal and temporal directions. All fingers are used and the midline is drawn around and down in a curve (21). And 1 minute is spent rotating the patient. It should be noted that massage maneuvers will be performed with moderate pressure. The therapist made sure that his nails were not long and that he did not have a ring or ring in his hand so as not to damage the patient's skin. , Be comfortable and warm. All stages of massage in one step are taught in person with the patient and in the presence of the patient. Also a copy of the massage training video, to prevent possible forgetfulness. It is provided to the patient. The duration of the intervention will be 4 weeks, twice a week with a minimum interval of 48 hours between each session and each session will be performed for 30 minutes.

Category

Rehabilitation

2

Description

second intervention group: Touching the neck and neck exactly according to the massage method without applying pressure

Category

N/A

3

Description

Control: No intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of the Holy Prophet Research and Therapeutic Center

Full name of responsible person

Zakia Faqihi

Street address

Islamic Republic of Iran Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3334 7000

Fax**Email**

shmh@hums.ac.ir

Web page address<https://shmh.hums.ac.ir/>**2****Recruitment center****Name of recruitment center**

Private office of Dr. Elham Ospid, neurologist

Full name of responsible person

Zakia Faqihi

Street address

no 12 ,Sharif Building ., Seyed Jamaluddin Asadabadi Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7914715152

Phone

+98 76 3221 3099

Email

elyouspid@gmail.com

Web page address<http://trtv.hums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Shamsizadeh

Street address

Central Organization, Imam Ali Boulevard, Rafsanjan,

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Fax

+98 34 3428 0071

Email

info@rums.ac.ir

Web page address<http://www.rums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Zakieh Faghihi

Position

Medical surgical nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.501. khaligefars building.west daneshvar. shahid tabdar blvd .

City

Bandar abbas

Province

Hormozgan

Postal code

7919748306

Phone

+98 76 3334 1010

Fax**Email**

faghihi_2020@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Mrs. Dr. Tayebah, the guard of Bonabi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No.501. khaligefars building.west daneshvar. shahid tabdar blvd .

City

Rafsanjan

Province

Kerman

Postal code

7718967755

Phone

+98 34 3425 5900

Fax**Email**

negahbant@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Zakieh Faghihi

Position

Master student of internal surgery nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.501. khaligefars building.west daneshvar. shahid tabdar blvd .

City

Bandar abbas

Province

Hormozgan

Postal code

7919748306

Phone

+98 76 3334 1010

Fax**Email**

faghihi_2020@ yahoo.com

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