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Can acupuncture, exercise training or a combination of the two reduce tension-type headaches compared with standard drug treatment?

Submission date
19/11/2018

Recruitment status
No longer recruiting

Registration date
08/01/2019

Overall study status
Completed

Last Edited
08/01/2019

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Headache is a common condition affecting many people and has a major impact on a person's professional and personal life. Headaches cause discomfort which may lead a person to miss out on important activities, work or school. The most common type of headache is called tension-type headache. Some causes include stress, depression and improper posture. There are medicines that can help with this kind of headache, but these medicines often have unwanted side-effects. The researchers are interested in investigating non-medicinal treatments for tension-type headache. Acupuncture is a type of non-medicinal treatment that can help for many conditions, including headache, and is becoming more popular. Western medical exercise training is another non-medicinal method of treatment that can help. This study aims to find out whether acupuncture, Western medical exercise training, or a combination of these two options will lead to a better result than treatment with pain-relieving medicine alone.

Who can participate?
Adults aged 18 to 65 years who have at least 5 tension-type headaches per month that are at least moderately severe.

What does the study involve?
The participants will be randomly allocated to one of four groups. One group will receive acupuncture at acupuncture points thought to help relieve headaches, with some of the points selected to target individual patterns of headache. One group will do exercises including strength training, cardiovascular training and posture training. One group will have both the acupuncture and the exercise and the last group will receive ibuprofen tablets to take when they have a headache. The treatment will be for 6 weeks for all groups. Participants will keep a headache diary to record the number and severity of headaches and the amount of medication taken. The participants will also fill in questionnaires at four timepoints during the trial to assess their

What are the possible benefits and risks of participating?
The main potential risk of acupuncture is slight discomfort or bruising. The main potential benefit would be improvement of the headache either in reduction of pain intensity (as measured by the NRS scale) or frequency (occurrence per week or month).

Where is the study run from?
Xiyuan Hospital (China)

When is the study starting and how long is it expected to run for?
August 2018 to December 2019

Who is funding the study?
China Academy of Traditional Chinese Medicine

Who is the main contact?
Philip Lee, philiplee7@hotmail.com

Contact information

Type(s)
Public

Contact name
Mr Philip Lee

ORCID ID
http://orcid.org/0000-0002-5911-3144

Contact details
Xiyuan Playground No. 1, Haidian District
Beijing
China
100091

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Comparison of acupuncture, exercise training and a combination of acupuncture and exercise training with stand-of-care pharmacological treatment in reducing frequency and severity of headache in adults with chronic tension-type headache

Study objectives
Acupuncture, Western medical training or a combination of acupuncture and Western medical fitness training will have a greater positive impact on patients with tension-type headache than standard of care using Western medications

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xiyuan Hospital Ethics Committee, 24/10/2018, ref: 2017XLA029-3

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Tension-type headache

Interventions
Interventional multicenter study, 3 centers. The grouping of patients in accordance with the chronological order of 1:1: 1:1 proportion of random group assigned to the treatment group 1, Treatment Group 2, treatment Group 3, control group.
The reviewers were blind: The random grouping sequence was kept by the principal, and was uncovered after the test, and the data analyst did not know the patient group information.

Total study duration is 30 weeks, treatment will be six weeks.

Participants were randomized 1:1:1:1 into one of the four treatment groups. The treatment period is 6 weeks, with treatment administered three times per week in Weeks 1 and 2, twice a week in Weeks 3 and 4 and once weekly in Weeks 5 and 6. All patients receive a written exercise program and receive tailored training instructions.

Treatment group 1 (acupuncture protocol): For the acupuncture group, each patient is treated with about 10-19 acupoints of acupuncture each time. According to STRICTA standards, the points are identified by the meridian of the headache. Yangming Meridian headaches can select Yintang, ST 44. Shaoyang Meridian headaches can select SJ 5 and GB 41. For Taiyang Meridian headaches can select SI 3 and BL 60. Finally Jueyin Meridian headaches can select “Four Spirit Alert” and LR 3 and PC 6. Additionally, the following four acupoints may be selected from according to the location of the headache: DU 20, Taiyang, GB 20, LI 4. All acupuncture points require de qi (needling sensation), needle time of 30 minutes. Needle with the use of sterile disposable acupuncture needles (stainless steel Osmondit OCr18Ni9) length of 25-40mm and diameter 0.25-0, 3mm (Brand: Hua Cheng acupuncture needles, Beijing Keyuan Tatsu Medical Supplies Factory).

Treatment Group 2 (Western medical exercise training): In a 45-minute training session, participants in the study participate in the following programs:
15 minutes of aerobic cardiovascular endurance training, up to 75% heart rate, using the following training equipment: dynamometer, treadmill, alternating training, rowing machine
10 minutes of strength endurance training, including rows, reverse butterfly and drop down repeated 21-30 times, with weight at 40% limit
10 minute posture-body feeling training involving (in phase one) use of sensomotoric therapeutic apparatus with unstable pendulum surfaces (Posturomed®, Haider Bioswing) for 3-5 minutes of training and (in phase two) use of flexible oscillating rod systems (Propriomed®, Haider Bioswing) for 5-7 minutes of exercise.
10 minutes of additional posture training including:
1. Muscular segmental spinal stability training (flexion/extension) of the arms level at the height of the chest
2. Single arm vertical 90° shoulder outward to stabilize the segmental scoliosis of muscle
3. Muscular stability of the spine rotation
4. Decompression by activating the muscles on both sides of the neck and upper shoulder
5. Spine activity according to instructions, approximately 10 minutes of flexible training
6. Stretching and tension release techniques for shoulder and neck muscle tissue:
6.1. Stand on tiptoe and lengthen the spine by breathing in, then bending forward to stretch
6.2. One leg knee extension and flank extension
6.3. Four-footed animal posture for spine activation
6.4. Supine position-stretching and abdominal breathing, shoulder bridge and "candle type"
6.5. Spinal rotation with respiration
6.6. Seat stretching the trapezius muscle, stretching the pectoralis major on the wall

Treatment Group 3 (combination of acupuncture and Western medical exercise training): Participants undergo both acupuncture and medical exercise training as above.

Treatment control group 4 (Western medicine analgesia): Ibuprofen 400 to 800 mg can be taken as needed, up to 10 tablets a month.

Intervention Type
Mixed

Primary outcome measure
1. Number of headaches assessed using patient-reported headache diary. The patient recorded a daily headache diary during the clinical trial, starting from recruitment date to the end of trial. The diary asks the patient to fill in information only if a headache occurs, otherwise it is left blank. The degree of severity of headache was subjectively rated by the patient using the NRS

scale. The patient also recorded a qualitative description of the headache using qualifiers such as aching, throbbing, sharp, dull or pounding. Also the patient recorded how long the headache lasted and if ibuprofen was taken, including mg amount and number of tablets.
2. Degree of headache assessed using a numerical rating scale (NRS) scale at baseline (week 0 after randomization), first week of treatment (week 5 after randomization), after the end of treatment period (week 10 after randomization), first follow-up (week 16 after randomization) and second follow-up (week 24 after randomization)

Secondary outcome measures
1. Headache disability was evaluated by MIDAS questionnaire at baseline (week 0 after randomization), first week of treatment (week 5 after randomization), after the end of treatment period (week 10 after randomization), first follow-up (week 16 after randomization) and second follow-up (week 24 after randomization)
2. Depressive mood assessed using the PHQ-9 scale at baseline (week 0 after randomization), first week of treatment (week 5 after randomization), first follow-up (week 16 after randomization) and second follow-up (week 24 after randomization)
3. Anxiety assessed using GAD-7 Generalized Anxiety scale at baseline (week 0 after randomization), first week of treatment (week 5 after randomization), after the end of treatment period (week 10 after randomization), first follow-up (week 16 after randomization) and second follow-up (week 24 after randomization)
4. Quality of life assessed using the the SF-12 questionnaire at baseline (week 0 after randomization), first week of treatment (week 5 after randomization), first follow-up (week 16 after randomization) and second follow-up (week 24 after randomization)

Overall study start date
14/08/2018

Completion date
14/12/2019

Eligibility

Key inclusion criteria
1. Frequent or chronic tension headache, in which the number of days of tension-type headaches is at least 5 per month and the severity of the headache is more than 4 out of 10 on a visual analog scale (VAS)
2. Aged 18-65 years
3. Has signed the informed consent letter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
96 patients

Key exclusion criteria
1. Other subtypes of tension-type headache, migraine, cluster headache and other causes of headache
2. Headache caused by systemic diseases, such as cardiovascular disease, acute infectious diseases, blood diseases, endocrine metabolic diseases, allergies, poisoning, etc
3. Headache caused by facial problems, such as glaucoma, otitis media, sinusitis, wisdom teeth, and other diseases
4. Headache caused by intracranial organic lesions, such as intracranial infection, brain tumor, subarachnoid hemorrhage, etc
5. Blood pressure control not ideal
6. Severe anxiety or severe depression
7. Serious hypertension or serious heart, liver or kidney disease

Date of first enrolment
14/12/2018

Date of final enrolment
14/03/2019

Locations

Countries of recruitment
China

Study participating centre
China Academy of Chinese Medical Sciences Xiyuan Hospital
Xiyuan Hospital Playground No.1, Haidian District, Beijing, China
Beijing
China
100091

Sponsor information

Organisation
Xiyuan Hospital

Sponsor details
Xiyuan Playground No.1, Haidian District
Beijing

China
100091
18611142837
zhanglu7810@sina.com

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02y0vze35

Funder(s)

Funder type
Government

Funder Name
China Academy of Traditional Chinese Medicine

Alternative Name(s)
CATCM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
14/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date