ISRCTN37415803 https://doi.org/10.1186/ISRCTN37415803

Vibrational tool for non-migraine headache management

Submission date
15/03/2025

Recruitment status
No longer recruiting

Registration date
26/03/2025

Overall study status
Completed

Last Edited
25/03/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
This study examines the feasibility of preventative and acute treatment of chronic cluster headaches using vibration as a potential intervention to warrant a large-scale clinical trial.

Who can participate?
Patients aged 18–50 years suffering from tension or cluster-type headaches

What does the study involve?
Participants were randomly allocated to one of two groups. The experimental group received vibratory treatment at set frequencies and the control received sham treatment. All individuals were evaluated before and immediately after the intervention and 30 and 60 days after the conclusion of treatment.

What are the possible benefits and risks of participating?
The study will determine if the use of vibration and resonance-type devices significantly reduces pain over time, pointing to their effectiveness as a maintenance or preventative type of therapy and to determine if a larger scale, multi-site randomized control trial is warranted. There are no perceived risks in participating in the study.

Where is the study run from?
The Institute for Neurology and Neurosurgery of Havana (INN) (Cuba) outpatient clinics

When is the study starting and how long is it expected to run for?
February 2023 to February 2024

Who is funding the study?
Rezzimax LLC (USA)

Who is the main contact?
Prof. Dr. Gerry Leisman, g.leisman@edu.haifa.ac.il

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
INN 2023-14

Study information

Scientific Title
Resonance massage tool effects in non-migraine headache management

Acronym
None

Study objectives
This study of standard-of-care versus traditional treatment endeavors to examine the potential of preventative and acute treatment of chronic cluster headaches using a vagal nerve stimulation device.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/02/2023, Institute for Neurology and Neurosurgery of Havana (Calle 29 No. 139 esquina D, Vedado, Plaza de la Revolución, La Habana, 10400, Cuba; +53 (0)7 834 5578; braind@infomed.sld.cu), ref: 2023-14

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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Non-migraine headache (cluster and tension)

Interventions
Randomization and blinding:
Randomization for participant allocation to two groups was provided. The groups were: Experimental (ENS) and Control A (CS) receiving sham intervention. Randomization was performed via a randomized block design with varying block sizes of two, four, and six participants. In each block, one-half of the participants were randomly assigned to Group CS and

another half to Group ENS. Using computer-generated sequence methods, randomization was achieved while maintaining participant and investigator confidentiality about both the generated allocation sequence and the randomization approach.

Since each computer-generated randomization sequence was distinct, replication was impossible. Randomization was applied to “Group ENS” or to “Group CS”. Only the designated individual at the study site knew which assignment corresponded to which experimental treatment or control group with this information not to be revealed until study unblinding occurred, after all data had been entered into the database and the database sealed before statistical analyses.

The initial study was conducted using the Rezzimax® Tuner Pro II (Rezzimax, Richmond, UT, USA) device with a tuning fork attachment. It is a battery-operated resonant massage tool containing a Precision Microdrive Model No. 320-102 vibration motor with a rated operating voltage of 3 V and rated vibrational speed of 790 rpm (+/−1600) and a normative amplitude of 17 G. The device has a range between 20 and 120 Hz with 10 preset levels. It also has four proprietary algorithms or patterns to assist in decreasing pain. For this study, the patterns were not utilized. Participants selected a comfortable level between 1 and 10 for each technique.

Each of the participants received the following instructions. Each participant placed their tongue between their teeth. They then were instructed to hum with the resonance of the Rezzimax® Tuner Pro II, illustrated in Fig. 1. The procedure is described more fully at the following link (https://www.youtube.com/watch?v=iyFZ79aw4Lk). The tuner and the tong were used and a variable level of between 5 and 10. Tongs were placed on both sides of the neck with the tuner device resting against the spine. The tuner was held in place by the back of the neck keeping it in place. The participant was requested to rotate their head from side to side maintaining pressure against the tuner. The device was kept in place for two minutes with a pillow behind the neck pressing against the tuner. An intensity level of 6 or lower was applied and the tongs were applied over the central portion of each eyebrow. After two minutes the tongs were then placed on the top of the nose towards the forehead. The tuner was then kept in place for an additional two minutes. The intensity was increased up to level 10 or lower if uncomfortable to the individual. Afterwards, the tongs were placed under the jaw with the tuner held in place with both hands by the participant. After this stage, the tongs were covered in plastic and placed inside the mouth between the cheeks and teeth. The tuner was then turned from side to side for one minute and then the participant was required to open and close the moth with the tuner in place for an additional one minute.

Statistical analysis:
This study examined a sample of 60 individuals (30 in Group ENS and 30 in CS), who were recruited at the Institute for Neurology and Neurosurgery, headache, and chronic pain programs, as well as poster advertisements in hospital clinics. Descriptive statistics and frequency distributions were used to evaluate the baseline sample characteristics.

Results were considered statistically significant with a value of <0.05. In cases where a significant group-by-time interaction was found, simple effects testing with a Bonferroni correction was performed. The blinding’s integrity was evaluated using a chi-square test. Biostatisticians provided advice during the analyses, which were carried out using SPSS software (v. 25; SPSS, Inc., IBM, Chicago, IL, USA). Requests for individual participant deidentified data are available at doi: 10.13140/RG.2.2.18953.45920.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rezzimax® Tuner Pro II device

Primary outcome measure
1. Pain is measured using:
1.1. The Headache Impact Test-6 (HIT-6)
1.2. Rivermead PPCS Questionnaire (RPSQ)
1.3. Montreal Cognitive Assessment (MoCA)
1.4. Participant Health Questionnaire-9 (PHQ-9)
2. Anxiety is measured using:
2.1. Generalised Anxiety Disorder Scale-7 (GAD-7) and/or
2.2. Post Traumatic Stress Disorder Checklist for DSM-5 (PCL-5)

Measured at baseline and after 60 and 90 days

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
23/02/2023

Completion date
11/02/2024

Eligibility

Key inclusion criteria
1. 18–50 years of age
2. Diagnosis of persistent headache criteria for at least three times/week for three months to a maximum of 5 years prior to the study (the history of chronic headache is defined as ±15 days /month for >3 months)
3. Medication, including non-steroidal anti-inflammatories, acetaminophen, ibuprofen or aspirin excluded the participant from the experimental group
4. Participants suffer from either tension-type headache (presented as dull with constant pain on both sides of the head).
5. Additional symptoms include sensitivity to light and sound, pressure-like sensation behind the eyes, and soreness in the face, head, neck, and shoulders, with episodes lasting for more than 30 minutes or cluster headaches (cluster headaches are defined as severe and recurrent headaches, including other symptoms such as wet eyes, swollen eyelids, a clogged or runny nose, sensitivity to light and sound, restlessness or agitation, along with scorching or piercing pain behind or around one eye)
8. Headaches range anywhere from 15 minutes to 3 hours and occur unexpectedly and without notice. The attacks need to happen regularly, usually a few hours after the commencement of sleep.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Transcranial Magnetic Stimulation therapy (TMS)
2. Contraindications (e.g., pacemaker, metallic implant)
3. Migraine (International Classification of Headache Disorders-3 [ICHD-3])
4. Other medical conditions (such as a history of seizures in the past or present, structural brain disease or disorders, psychotic disorders (e.g., schizophrenia, bipolar disorder), liver or kidney disease, cancer, uncontrolled hypertension, diabetes, or pregnancy)
5. History of any neurological disease or disorder
6. History of allergies, sinusitis, psychiatric disorder including PTSD, anxiety, depression, or fever
7. More than four cups of coffee per day, any form of medication, withdrawal from cigarettes, smoking, drugs or menstrual headache
8. Use of recreational drugs
9. Use of chronically employed drugs (e.g. non-steroidal anti-inflammatory drugs)
10. Headaches other than cluster or tension-type headaches including migraine (defined clinically as individuals who at the outset of a headache manifested symptoms that included partial loss of vision, numbness, tingling, and muscle weakness; sensitivity to light, sound and smell; nausea and/or vomiting; auras present before the headache appears, with or without the presence of zigzag lines, flashing lights or spots; or trouble speaking or finding words (dysnomia)
11. Hypnic headaches
12. Waking in the night from a headache
13. Medication-overuse headache
14. Sinus headache (occurring with sinusitis) accompanied by a throbbing, dull pain radiating over the forehead, cheeks and eyes; face pain or pressure; nasal discharge and plugged nose
15. Caffeine-related headaches with a high caffeine intake of greater than 400 mg, or around 4 cups of coffee per day
16. Head Injury or post-Head Injury headaches, menstrual headache and hangover headache

Date of first enrolment
25/02/2023

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
Cuba

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Rezzimax LLC

Results and Publications

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

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://www.researchgate.net/publication/381690956_Resonance_Effects_in_Non-Migraine_Headache_Management). The data is currently available and will remain in that data repository. Patient consent for aggregating the blinded anonymized data was obtained from each participant as is available on request for up to 5 years from the date of conclusion of the study according to the rules of the IRB of the Institute for Neurology and Neurosurgery of Havana.

IPD sharing plan summary
Stored in publicly available repository