Original article

Combined effect of Acupuncture and Hot Foot Bath on tension type headache among young adults: A randomized control trial

Ranjini Murthy P[1], Vineetha AN [2], Nitesh MK[3], Lakshmeesha[2], Balakrishna Ragavendrasamy[4], Prajwal HM[5], Shravya CN[5], Swathi S[5], Vinaya Kumar T[6]

From, [1]PG Scholar, Department of Naturopathy, [2]Associate Professor, [3]Assistant Professor, [4]Assistant Medical Officer Yoga and Naturopathy Lifestyle Clinic Government Hospital Udumalpet Tamilnadu, [5]PG Scholar, Department of Clinical Naturopathy, [6]PG Scholar, Department of Clinical Yoga, Alva's College of Naturopathy and Yogic Sciences, Moodabidri, Dakshina Kannada, Affiliated to Rajiv Gandhi University of Health Sciences, Karnataka, India.

ABSTRACT

Background & Objectives: Tension type headache (TTH) is the third most common disease worldwide causing physical and mental suffering. The main cause is the central sensitization, myofascial triggers, neuromuscular changes that lead to increased activity and muscle tension. The main objective of the study was to evaluate the efficacy of acupuncture and hot foot bath in alleviating the symptoms associated with TTH. **Materials & Methods:** A total of 90 participants (18-26 years) with headaches were screened. Out of these, 60 met the inclusion and diagnostic criteria and randomly divided into two groups using coin toss method. Pre- assessments such as Visual Analog Scale (VAS), Headache Disability Index (HDI), and Pain Disability Index (PDI) were performed before treatment. For 10 days, acupuncture was given for 30 min. in the morning, and a hot foot bath was given for 20 min. in the evening. Post- assessments were conducted at the end of the 10th day. All the details of the study were explained and informed consent was obtained from the subjects. **Results:** In the present study Paired sample t-test for within group changes showed a significant difference in all parameter (VAS, HDI, PDI) when compared within the group and control group with level of significance $p \leq 0.05$. Reduction noticed in control group in the absence of appropriate intervention may be due to consumption of analgesics on severe attacks. Between group changes performed using analysis of covariance for variables of interest adjusted for their respective baseline values indicated a significant difference in all parameter (VAS, HDI, PDI). **Conclusion:** Following the 10-days intervention, it was concluded that acupuncture and hot foot bath were found effective for treatment of TTH as demonstrated by significant differences in VAS, HDI, and PDI both before and after the treatment with $p \leq 0.05$.

Keywords: Tension-type headache, Acupuncture, Hot foot bath, Visual Analog Scale (VAS), Headache Disability Index (HDI), and Pain Disability Index (PDI)

Tension-type headache (TTH) is a type of primary headache that recurs from minutes to weeks and is accompanied by mild to moderate bilateral pressure or tension pain. Physical activity does not worsen the condition, although photophobia, rarely nausea, and vomiting can accompany TTH [1]. Certain "classic" triggers such as red wine, chocolate, and cheese can cause headaches; the common triggers for patients with TTH are weather changes (82.5%), stress (66.7%), menstruation (51.4%), and post-stress relaxation (50%). Other important factors include environmental and psychological factors, sleep disturbances, fatigue, dehydration, alcohol consumption, caffeine withdrawal, noise exposure, and eating habits [2]. Global Burden of Disease Study 2010 (GBD 2010) identified tension-type headaches (TTH) and migraine as the second and third most common diseases respectively, worldwide [3]. The average prevalence of TTH in the adult population is 42% [4].

Access this article online

Received – 29th Dec 2023

Initial Review – 17th Jan 2024

Accepted – 07th Feb 2024

Quick Response Code

Correspondence to: Ranjini Murthy P, PG Scholar, Department of Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Moodabidri, Dakshina Kannada, Mangalore, Karnataka, India. **Email:** ranjinimurthy815@gmail.com, **Tel.:** +91 9606232404.

According to the World Health Organization, about 1.7-4% of adults face headaches for at least 15 days every month [5]. Ten percent of the adult population experiences chronic tension headache (CTTH) every week and 1-3% suffer from CTTH every day [6]. Consumption of medications like non-opioid analgesics, ergot alkaloids, serotonin agonists, and combined preparations with caffeine or codeine for more than 14 days per month results in drug-induced headache (DIH) [7]. Reduction in the use of pain medication is an important first step in the treatment of TTH [8]. Recent Cochrane systematic reviews have demonstrated that the use of acupuncture is both effective and valuable in the treatment of migraine and tension headaches. In addition, acupuncture is considered a cost- effective solution for people who suffer from migraines and frequent tension headaches [9].

Six studies conducted in people with recurrent, occasional, or chronic tension headaches have shown that acupuncture can be a valuable non-pharmacological treatment [10]. Patients with episodic headaches had greater disability due to physical symptoms during the headache attack, while during chronic daily headaches, significantly more emotional disturbances were held [11]. Globally, primary headaches may appear to be the major cause of disability. When medical therapy is limited by side effects and inadequate responses, the importance of non-medical interventions is emphasized. Findings from Cochrane reviews suggest acupuncture to be a viable non-conventional treatment option for treating primary headaches [12], in which acupuncture is the process of inserting sharp needles into specific points on the body [13].

Water is used in hydrotherapy in its various forms (liquid, ice, steam) externally or internally to promote health and treat various ailments. As in a naturopathic technique, water is used at different locations of the body, at different temperatures, different pressures, and different durations, respectively [14]. A hot foot bath (HFB) helps to balance blood circulation and reduce congestion in the head, lungs, pelvis, and other internal organs. The heat helps to redistribute the blood to an important skin area and directs it away from distant internal organs, which shows its derivative effect on the body. It effectively diverts congested blood away from the brain, lungs, and pelvis. Hence, hot foot baths can improve sleep [15]. The optimal temperature for beneficial results in a HFB is 104-122°F [16].

Research shows that hydrotherapy not only reduces the frequency and intensity of headaches in migraine sufferers but also improves their vagal tone [17]. In a Lifestyle Centre combination of a HFB and foment was given to the kidney which resulted in circulatory balance and increased activity of the parasympathetic nerves. It also encouraged a drop in blood pressure [18]. A significant number of studies have been conducted on the subject of tension headaches and alternative medicine, among the primary headaches. While some studies have focused on acupuncture and hydrotherapy, there remains a dearth of research evaluating the combined effectiveness of acupuncture and hot foot baths in treating TTH. Therefore, the objective of this study is to assess the combined effectiveness of acupuncture and hot foot baths in treating TTH.

MATERIALS & METHODS

A prospective randomized control trial was conducted among college students from Alva's Engineering College, Homeopathic Medical College, and Alva's College of Naturopathy and Yogic Sciences in Mangalore, Karnataka. After obtaining a legally signed written consent. In a study, 90 participants aged 18-26yrs underwent thorough medical screening for primary headaches. After meeting inclusion and exclusion criteria, 60 were selected. Through simple randomization, participants were divided into a study group (undergoing acupuncture and hot foot baths) and a control group. Pre-assessments using VAS, HDI, PDI were recorded. The study group received acupuncture in the morning and hot foot baths in the evening for 10 days. The control group continued daily activities with standard care. Post-assessments were conducted after the 10-day treatment. Participants received detailed information, provided informed consent, and obtained ethical clearance from the Institutional Ethics Committee (ACNYS/IECHS/2021/18) **(Figure 1)**.

Inclusion Criteria

- Age: 18-26 years
- Gender: Both male and female.
- At least 8 headache attacks per month during the previous three months and during the initial period.
- Also fulfilling any four TTH-diagnostic criteria **(Table 1)** [19] and willing to participate were recruited for the present study.

Exclusion Criteria

- Additional migraine headaches
- Pain medication to use more than 10 days per month, recent prophylactic headache treatment with medication in the past four weeks, or any acupuncture in the past six months
- People on Regular use of headache medications
- People with other neurological diseases and systemic illness.

Assessments

- Visual Analog S (VAS): A pain intensity line ranges from "no pain" to "worst possible pain." Participants mark their pain level out of 100, and the distance between endpoints quantifies their pain intensity [20].
- Headache Disability Index (HDI): It comprises a 25-item inventory assessing the impact of headaches on daily life. Responses include "yes" (4 points), "sometimes" (2 points), or "no" (0 points). Scores range from 10 to 28 (mild), 30 to 48 (moderate), 50 to 68 (severe), and 72 or more (total disability) [21].
- Pain Disability Index: The disability assessment ranges from 0 (no disability) to 100 (complete disruption). Classification: mild/moderate (0-70), difficult (71-100), extreme (101-150) [22].

Intervention: Pre-assessments were performed before starting the intervention. Acupuncture was performed for 30 min in the morning before 1hr/after 2hr of taking food in a comfortable sitting position and the evening of the same day given hot foot bath with a temperature range of 40°C-45°C (104°F-113°F) for 20 min for 10 consecutive days. Follow-up was done throughout the study period and post-assessments were collected after completion of treatment on the last day for both the groups. In control group Standard care with routine activities was observed.

Study group: Acupuncture Procedure: A trained practitioner conducted 30-minute acupuncture sessions for 10 days, either one hour before or two hours after morning food intake. All participants received treatment in a comfortable sitting position at bilateral basic points. Other additional points were selected individually. The total number of sterile stainless steel disposable needles used in each session was limited to 10.

Optional Points Selection along with Main Points [24]

- Mainly frontal headache, Complaints worse with wet or cold weather, Modalities Cold, Wind: LI4 (hegu)
- In case of headache mainly in the vertex: GV20 (baihui), extra point Si Shen Cong.
- In case of mainly neck pain: ST36 (zusanli) d. Modalities Wind, Dampness, Cold: LI4 (hegu), GB34 (yanglingquan)

Hot foot bath Procedure: A hot foot bath was given for 20 minutes at a temperature of 40°C-45°C (104°F-113°F). In the Preparatory stage, the subjects were asked to relax with minimal dress, where their legs were exposed up to the calf region in hot water followed by the Operative phase. In this phase, a small tub containing hot water of temperature 40°C-45°C (104°F - 113°F) was given where the subject had to immerse the legs up to the calf muscle in water, and they were covered with a blanket to prevent the heat loss for 20 min duration of hot bath [25]. The temperature of water was monitored using a SYGA digital thermometer with a fork throughout the procedure. In the post-operative phase, the foot was dried by lightly rubbing it with a dry cloth. Additionally, the participants were advised to avoid sudden exposure to cold or stressful activity immediately after treatment.

Statistical Analysis: The data was visually inspected for manual typographic errors. The shapiro-wilk's test for Normality showed that the data was normally distributed. The study utilized a paired samples t-test to evaluate differences within groups, conducted ANCOVA to assess changes between groups while controlling for baseline values, and performed Levene's test for equality of variances. All analyses considered 95% confidence intervals, and statistical significance was defined as p-value < 0.05. Statistical analysis was carried out using IBM SPSS version 26.0 **(Table 3).**

Table 1: Shows the s diagnostic criteria of TTH [19]

Headache feature	Tension-type headache
Pain location	Bilateral
Pain quality	Pressing/Stretching(non-throbbing)
Pain intensity	Mild /moderate
Effect on activities	Not aggravated by routine activities of daily living
Other symptoms	None
Duration of headache	30 min- 7 days
Frequency of headache	<15 days per month-episodic tension-type headache (TTH)
	>15 or 15 days per month for more than 3 months-chronic TTH

Table 2: Below demonstrates the basic and optional acupuncture points [23,24]

Basic points (23)	Location
GB-20 (Fengchi)	At the apex of the posterior triangle of the neck, in the hollow directly below and between the external occipital protuberance and the mastoid process. It lies between the insertions of the trapezius and sternocleidomastoid muscles. Needling: 0.5 to 1t-sun, slanting.
GV-20 (Baihui)	On the scalp in the midline,7 t-sun above the posterior hairline,5 t-sun behind the anterior hairline, midway on a line connecting the apex of both the auricle. Needling: 0.3 to 0.5 t-sun, slanting posteriorly.
Ex-6 (sishencong)	These are groups of four points situated 1 t-sun anterior, posterior, right lateral, and

	left lateral of Baihui (GV-20) on the scalp. Needling:0.3-0.5 t-sun slanting towards Baihui (GV-20)
Optional points [24]	
LI-4 (Hegu)	On the highest point of the bulging made by 1st dorsal interosseous muscle when the thumb and index finger are held close together in addition. Needling: 0.5 to 1t- sun straight.
GB-34 (Yanglingquan)	On the Antero - lateral aspect of the leg in the depression in front and below the head of the fibula. Needling: 1 to 1.5t-sun, straight
ST-36 (zusanli)	One finger breadth lateral to the tibial tuberosity or 3 t-sun below Dubi (St-35). Needling:1 to 1.5t-sun, straight

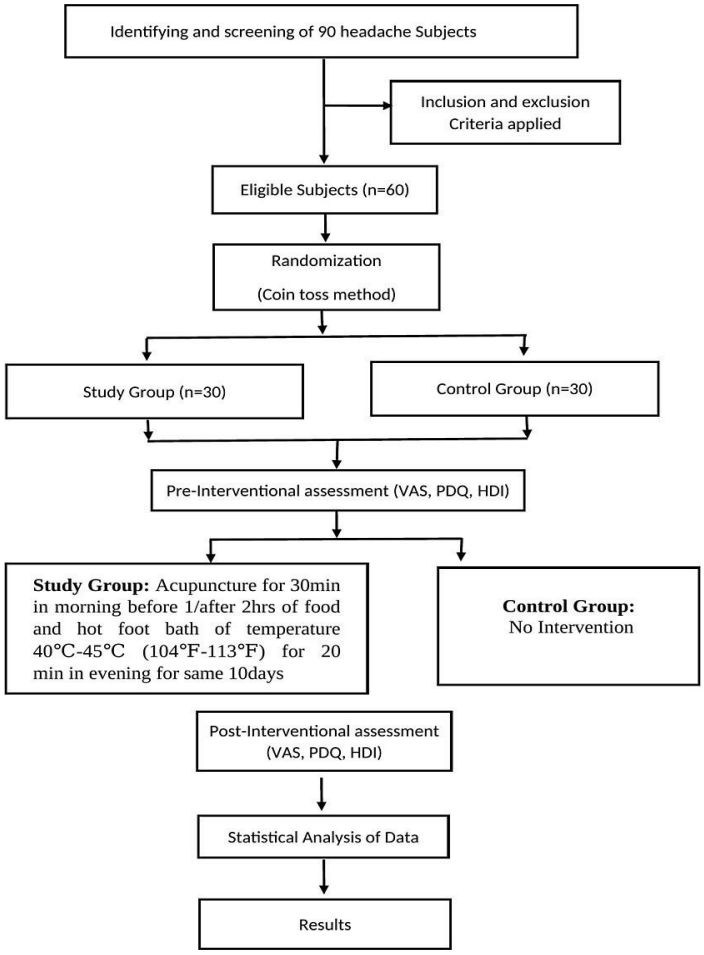

Figure 1: Illustration of study plan

RESULTS

The present study was conducted to evaluate the efficacy of acupuncture and hot foot bath in alleviating the symptoms associated with TTH. The data was analyzed by Paired samples t-test for within group changes showed significant reduction in visual analog scale for pain ($p \leq 0.05$), disability questionnaire HDI ($p \leq 0.05$) and PDQ ($p \leq 0.05$) following the intervention. Reduction noticed in control group in the absence of appropriate intervention may be due to consumption of analgesics on severe attacks.

Between group analysis using analysis of covariance for variables of interest adjusted for their respective baseline values indicated a significant difference in VAS ($F(1, 57)= 94.54$, $p \leq 0.05$, $p\eta 2 = 0.624$), HDI ($F(1, 57)= 142.37$, $p \leq 0.05$, $p\eta 2 = 0.714$) and PDQ ($F(1, 57)= 37.68$, $p \leq 0.05$, $p\eta 2 = 0.398$).

Table 3: Within and between-group comparisons through paired samples t-test and ANCOVA andthe average (Mean ± SD) values of the assessments.

	Experimental group		Control Group	
	Pre (Mean ± SD)	Post (Mean ± SD)	Pre (Mean ± SD)	Post (Mean ± SD)
1.VAS	65.6±14.99	21.57±11.39a,b	59.53±16.47	50.00±16.72a
2.HDI	49.13±10.32	18.13±10.18a,b	40.87±16.05	35.73±13.28a
3.PDQ	70.57±23.64	31.8±21.15a,b	66.7±21.78	56.37±21.88a

a. Within-group comparisons using paired t-test, level of significance $p \leq 0.05$
b. Between-group comparisons using Analysis of covariance adjusted for baseline values, level of significance $p \leq 0.05$

VAS= Visual Analog Scale; HDI=Headache Disability Index; PDI=Pain Disability Index; SD=Standard Deviation

DISCUSSION

TTH is a common type of headache with a significant socio-economic impact on society [12]. However, TTH remains one of the most neglected and difficult to treat [26]. Among complementary and alternative medicine (CAM), acupuncture is widely used as an alternative option by the European Federation of Neurological Societies in headache treatment. The UK's National Centre for Clinical Guidelines also recommends 10 sessions of acupuncture when prophylactic medication is ineffective for managing tension headaches [27]. Hence, 10 sessions of acupuncture were carried out in the present study. Acupuncture has been widely used to treat primary headaches, particularly migraine and frequent tension-type headaches (FTTH) [28].

It also has many mechanisms for targeting pain pathways among TTH individuals such as muscle nociceptors, myofascial trigger point tenderness, and muscle contraction which play a key role in TTH. Myofascial trigger points are present along the GB, GV, and EX-HNO5 meridians on the head and neck region, and stimulation of these points directly helps in relieving TTH. In particular, the combination of key points - Fengchi (GB20) and Baihui (GV20) has a beneficial effect. GB20 point is believed to regulate blood

flow, have anti-inflammatory properties and increase the activity of mast cells and macrophages, which prevents hyperalgesia. In addition, it is believed to affect the electromyographic activity of the sternocleidomastoid and trapezius muscles, which improves pain tolerance. In contrast, stimulation of GV20 is thought to relieve cerebral vasospasm, thus alleviating the symptoms of TTH. The combination of GB20 and GV20 is a popular acupuncture combination due to its rapid response and potential for symptom relief [29].

A possible mechanism behind acupuncture also can be postulated as when needles are inserted into specific acupuncture points at the special sites they are characterized by increased innervation, denser connective tissue, and a higher potency of transient receptor potential vanilloid type 1 (TRPV1) receptors which produce mechanical stimuli. These stimuli are converted into nerve signals mediated by large myelinated Aβ and Aδ fibers. These signals ascend through the dorsolateral pathways of the spinal cord and activate higher brain centers involved in pain processing. This initiates a cascade of actions including modulation of noradrenaline and serotonin (5-HT) signaling, release of endogenous neuropeptides that act on μ-opioid and N/OPQ receptors, and trigger production of neurotrophins such as somatostatin. Together, these processes increase the inhibition of nociception by spinal afferents. At the same time, local microtrauma caused by needle insertion leads to the release of inflammatory mediators that stimulate unmyelinated C fibers.

These fibers ascend through the anterolateral columns of the spinal cord and activate diffuse noxious inhibitory control (DNIC), both enhancing overall descending inhibitory control over nociception and altering anticorrelation networks in the brain. This insular-anchored process modulates higher-level pain processing. Over time, repeated sessions of acupuncture induce neuroplasticity in the dorsal horn of the spinal cord resulting from the interaction of long-term potentiation (LTP) or long-term depression (LTD) of C-fiber potentials. This results in the reduction of nociceptive signals at specific sites on a prolonged time treatment basis [30]. The pain control mechanism of acupuncture involves the activation of large fibers, especially A-beta and A- Delta fibers.

These fibers stimulate both generalized and inhibitory neurons in layers III, IV, and V of the dorsal horn. The inhibitory or antinociceptive nature of touch, pressure, and proprioceptive fibers helps to regulate pain perception by promoting the release of Gamma-aminobutyric acid (GABA) and glycine by spinal cord-level interneurons. Neurons with a wide dynamic range that receive input from joints and muscles continue through the palaeo-spinothalamic tract leading to nonspecific inhibitory thalamic nuclei. This mechanism prevents migraines by inhibiting the trigeminal nucleus by activating the thalamus [24]. Recent biomedical research has demonstrated the involvement of acupuncture in adenosine triphosphate (ATP) and transient receptor potential vanilloid channel (TRPV) stimulation at acupoints. Acupuncture modulates neurotransmissions including opioids, serotonin, norepinephrine, orexin and endocannabinoids in the central nervous system to relieve pain. It also has anti-inflammatory effects acting on the hypothalamic-pituitary-adrenal (HPA) axis by reducing levels of cyclooxygenase-2 (COX-2) and prostaglandin E2 (PGE2).

In addition, it strengthens the sympathetic nervous system, which causes the peripheral release of opioids. Acupuncture induces the release of catecholamines from the adrenal glands, which act on peripheral dopamine D1 receptors and exert systemic anti-inflammatory effects. Degranulation of mast cells plays an important role in the effectiveness of acupuncture because acupoint ST36 has a higher density of mast cells. Acupuncture increases mast cell degranulation, while inhibition of degranulation may reduce the analgesic effect of acupuncture. Transient receptor potential TRPV1, abundant in muscle and epimysium in ST36, functions as a mechanosensitive channel during manual acupuncture. TRP cation channel subfamily V, member 2 (TRPV2), a cation channel, can function as a sensor that responds to mechanical, thermal, and red laser light stimuli. Acupuncture triggers several bioactive chemicals through spinal and supraspinal mechanisms, including. (a) Opioids at both levels and (b) Serotonin and norepinephrine at a spinal level [27].

Common side effects of acupuncture are Micro-bleeding, bruising, pain, and local swelling at the needle insertion site [29]. As another modality in naturopathy, hydrotherapy also helps overcome painful stimuli by activating large myelinated fibers by sensory stimuli. This process can help to prevent the transmission of small nociceptive signals through the pain mechanism. Both hypothermia and hyperthermia have significant physiological and hemodynamic effects on the body. Earlier studies have shown that exposure to hot water reduces sympathetic activity, also improves vagal tone. The vasogenic inflammation and constriction are likely the eminent characteristics of migraine that can be modified by thermal

interventions, leading to clinical improvements [17]. It helps alleviate triggering factors of headaches like stress, anxiety, fatigue, and insomnia [31].

Another study has postulated that hot foot immersion helps to reduce congestion in the head, lungs, pelvis, and internal organs and works as a derivative therapy. This phenomenon involves the application of heat to a large area of skin, resulting in the movement of blood from distant internal organs. Hence, results reveal that a hot foot bath helps to draw congested blood from the brain, lungs, and pelvis. [23] Since a hot foot bath relieves congestion through its derivative effect, it restores vagal tone by promoting circulatory balance and increased parasympathetic activity [25,26]. Hot foot baths can be used as a simple adjuvant remedy which can be given preferably in the evening to end time of the day to avoid aggravation of symptoms in TTH which has a greater impact on quality of life. However, a hot water foot bath is generally used for healing and detoxification purposes.

It is a simple method that relieves stress, insomnia, anxiety, and fatigue by promoting the expansion of blood vessels in the legs, increasing blood flow, and delivering oxygen and nutrients to the brain to relieve fatigue. According to Perry (2011), hot water foot baths are recommended for leg and foot cramps, insomnia, nausea, and fatigue, especially among the elderly; soaking both feet and ankles in hot water for 10 to 30 minutes can be an effective way to draw blood from inflamed or congested areas of the body and can be effective in improving sleep [31]. .By adding to the current study, both acupuncture and hot foot bath can be ideally combined and used as complementary treatments in headaches because they target different aspects, where acupuncture may alleviate pain, central and peripheral nociception during headache attacks and HFB helps to prevent aggravation and severity of triggers in tension headache by restoring circulatory balance and its relaxing effect respectively.

As a result, both can potentially work together to provide relief. A combination of both treatments could offer a more comprehensive approach to headache management by addressing different aspects of TTH. Hence, further follow-up studies with larger sample sizes and reliable objective variables are warranted to build on the present findings.

CONCLUSION

The study aimed to evaluate the efficacy of acupuncture and hot foot bath in alleviating the symptoms associated with TTH. Results revealed significant reductions in pain and disability within the study group, compared to control group among all parameters (VAS, HDI and PDQ). However, between group analysis also shown significant difference among study group compare to control group. Therefore, the current study emphasizes the potential benefits of incorporating acupuncture along with a hot foot bath as a combined potential strategy for treating TTH by targeting different pathways resulting in significant reduction of pain, disability and improvement in overall quality of life, which can also be adopted as a cost-effective remedy in pain management.

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How to cite this article: Ranjini Murthy P, Vineetha AN , Nitesh MK, Lakshmeesha, Balakrishna Ragavendrasamy, Prajwal HM, Shravya CN, Swathi S, Vinaya Kumar T. Combined effect of Acupuncture and Hot Foot Bath on tension type headache among young adults: A randomized control trial. Indian J Integr Med. 2024; 4(1):18-24.

Funding: None; *Conflicts of Interest: None Stated*