

Original Article

Efficacy of Tung's Acupuncture in Managing Mild to Moderate Myopia Among the Young Adults – A Study Protocol for Randomized Control Trial

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ABSTRACT

Background: Myopia (near-sightedness) is most common eye condition in which faraway objects look blurry but not with near objects. Age between six to eight years were mostly affected by myopia which develops rapidly after 13 to 16 years of old. Acupuncture corrects the imbalance of the organs and systems by stimulating the Qi in the meridians and body's regulatory mechanisms. Tung's acupuncture method is distinguished by its significant use of distant points, straightforward needling techniques, and a distinct set of non-channel points. This study aims to investigate the effect of Tung's acupuncture in mild to moderate myopia among young adults. **Method:** This study adapts randomized controlled design. 100 Subject will be recruited using convenient sampling technique, and randomized into two group. The study group will undergo Tung's acupuncture and controlled group will not receive any intervention but standard care. Acupuncture will be given 20 minutes once a day in the alternative week for about 7 weeks. The refractive error will be assessed using TAPCON kerato-refractometer KR8900, and visual acuity by use of Snellen chart. **Results:** The outcome variables are refractory error and visual acuity which will be assessed before and after the treatment. Based on the hypothesis, this intervention may positively affect the refractive error of myopia. **Conclusion:** The positive results will confirm effectiveness of Tung's acupuncture in improving the visual acuity among mild to moderate myopia adults. Thereby, Tung acupuncture can be implemented in the regular clinical practice in managing the visual acuity among myopia patients.

Key words: Myopia, Traditional Chinese Medicine, Acupuncture, Alternative medicine, Complementary therapy, Refractive Errors.

Myopia, is also known as syndrome of inability of see distant object in traditional Chinese medicine [1]. Myopia [also known as short-sightedness or near sightedness] is a most common condition that develops primarily during childhood and early adulthood [2]. It is the most common cause of neglectable ocular disease worldwide [3, 4]. It is divided into three levels: low [≤ -3.0 D], medium [between -3.0 D and -6.0 D], and high [over -6.0 D]. Approximately one-fifth of people with myopia developed high myopia [≥ -6 D] [5]. Myopia prevalence varies in concern with age, race, ethnicity, urbanization, occupation, education level [6]. The prevalence of myopia in India is about 13.1% among school children [4], and in Chennai visual impairment [blindness + low vision] is 3.8% [7]. The incidence of myopia is approximately 80 -90% of urban adults specially those are graduating from high school [3, 4, 6, 8].

Generally, myopia allied with excessive axial eye growth and occasionally it can be occurred by disproportionate high corneal power children, adults, teens, and toddlers were

exposed to a remarkably high quantity of time spent indoors. Also, the burden of near work and digital screen time (TV, smartphones, etc) has increased due to online classes for students, raising concerns that the development and advancement of myopia among children. In addition, a large portion of the global population was confined to their homes during the COVID-19 pandemic and that led people depends on digital equipment for work and study [6]. High myopia raises the chance of irreversible vision loss [3].

Treatment of myopia in modern medicine is mainly optometric, that includes the use of spectacles like single-vision lenses and progressive addition lenses and contact lenses. Refractive surgeries include laser-assisted in situ keratectomy, photorefractive keratectomy, and posterior chamber phakic intraocular lenses [1, 8]. The pharmacological treatment has been reported to be associated with adverse effects, including pupil dilation and temporary paralysis of accommodation [3]. Alternative therapies such as acupuncture-moxibustion (auricular pressing), massage promotes blood circulation to the

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eye and relaxes the eye muscles, and medical eye drops can soften and relax the musculus ciliaris in the short-term [1]. In that acupuncture is an ancient medical health care system with history of more than thousands of years [3].

Acupuncture corrects the imbalance of the organs and systems by stimulating the Qi in the meridians and body's regulatory mechanisms [9]. Based on traditional Chinese medicine, myopia is result from combination of congenital weakness, poor postnatal development, and liver, spleen, and kidney Qi deficiency. These conditions can lead to stagnation of Qi and blood in the eye's collaterals, resulting in inadequate nourishment of the eyes. Contributing factors include emotional stress, eye strain and poor diet can cause deficiencies in the liver, kidney, spleen Qi and heart Yang [1]. Additionally, external factors such as wind, heat, excessive fire, blood loss, physical deterioration, and skin rashes are considered causes of eye problems [10].

Tung Ching Chang discovered Master Tung's acupuncture [11]. It's a distinct style of acupuncture comes under a traditional family lineage of Chinese medicine. Tung's points are distributed topographically according to anatomical zones [9]. According to the book Huang Di Nei Jing, all the meridians and collaterals interact with the internal organs, viscera, and the four extremities in the ear. As a result, auricular stimulation can regulate the Qi and Blood of the Zang-Fu organs, together with the meridians and collaterals and halt the progression of myopia. Thereby, this study aims to evaluate the effect tung acupuncture in managing mild to moderate myopia among the young adults on visual acuity. Hence, we hypothesis that selected tung's acupuncture point will have positive effect on mild to moderate myopia among young adults.

MATERIALS & METHODS

Trial design

Around 100 Participants will be recruited from Government Yoga and Naturopathy Medical College and Hospital, Chennai, Tamil Nadu, India. A detailed medical history will be taken to collect information on eligibility criteria. Subjects, age between 18 to 30 years, who are having short-sightedness, spherical lenses not less than -0.5 D and not more than -6.00 D, having normal visual functions with abnormal near visual acuity will be included in this study. Subjects with serious systemic diseases such as cerebrovascular, liver, kidney, hematopoietic system, psychiatric diseases, and who are depends on long-term use of other systemic related drugs or treatments which have not been terminated for more than a year. Diopter < -0.5 D, or combined with pathologic myopia-related fundus changes and/or significant visual function impairment, other diseases which affect the determination of acupuncture efficacy (e.g., diabetic retinopathy) and pregnant women, lactating mothers will be excluded from this study.

After which the participants will be recruited and randomized into (1:1) for study and control group. A

randomized controlled trial design will be adopted for this study. The study group will undergo needling at Fen4 Bai2, Shang4 Bai2, Zhu1 Yuan2, Eye Disorder 1 [Mu 1], Eye Disorder 2 [Mu 2], Eye Disorder 3 [Mu 3] and control group will receive standard care. Trial profile is provided in the figure 1.

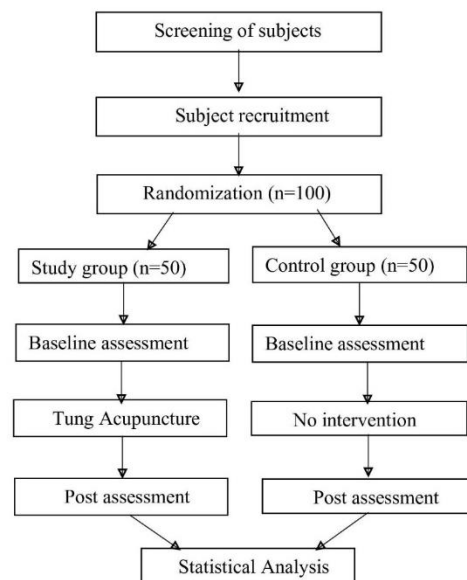


Figure 1: Trial Profile

Ethical consideration: The study has been reviewed by the Government Yoga and Naturopathy Medical College, Chennai Ethical Committee and the Scientific Review Board to guarantee participant safety and adherence to ethical standards (reference no: RES/IEC-GYNMC/2023/164 on 24.2.2023). It is registered in Clinical Trial Registry - India (CTRI/2023/08/056394). This information will be shared with the participants. In addition, participants will be given ample opportunity to think through their participation in the study and will be encouraged to speak up any concerns or ask any questions they may have about the interventions. After which they randomized into two group and receive interventions accordingly.

Withdrawal criteria: Since, participation in this study is purely voluntary and if you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time by giving it in writing without this decision affecting your medical care and health insurance provided to you during the study

Intervention

Study group: Tung's Acupuncture

All 50 patients in study group will receive acupuncture at traditional tung acupoint locations by a trained acupuncturist (primary author) for 20 minutes once a day in the alternative week for about 7 weeks between 10:00 to 17:00 (IST time). One cycle of treatment will last for seven days, followed by one week of no treatment. Four cycles of treatment will be

undertaken continuously for a total of 28 days. The patients asked to lie in a comfortable position on the yoga mat, and the acupoint locations will be cleansed by using the cotton, which soaked in 75% alcohol. Acupressure health care system, disposable sujok needles, 0.18 x 7mm in size will be used for needling. The appropriate depth of the needle is inserted using a mildly reinforcing and attenuating needling approach. The insertion angle was perpendicular for the locations on the fingers and ear. The inserted needles will be retained undisturbed without any stimulation and removed with dry cotton after 20 minutes. Subjects who were using single vision lens (SVLs) are asked to continue without any other treatment affecting visual acuity.

Location of the points

Fen4 Bai2: It is situated 1.5 cun proximal to the metacarpophalangeal joints on the dorsum of the hand, between the 2nd and 3rd metacarpal bones; needle perpendicularly 0.3 to 0.5 cun.

Shang4 Bai2: It is situated on the dorsum of the hand, 0.5 cun proximal to the metacarpophalangeal articulations. To help locate it, ask the patient to loosen up their fist; needles should be placed perpendicularly, between 0.3 and 0.5 cun.

Zhu1 Yuan2: These points are situated on the dorsum of the thumb along the interphalangeal skin crease; the needle is perpendicularly positioned 0.2 to 0.5 cun. Zhu1 Yuan2 Er4 is 0.5 cun medial [ulnar], and the other point Zhu1 Yuan2 Yi1 is 0.5 cun lateral [radial], to the posterior midsagittal plane.

Eye Disorder 1 [Mu 1]: Central side of the inter tragus notch

Eye Disorder 2 [Mu 2]: Peripheral side of the inter tragus notch

Eye: Centre of the Ear lobe, at the same location as Master Sensorial point

Eye Disorder 3 [Mu 3]: Inferior concha, below helix root [12].

Location of the points are provided in the figure 2.

Control group

The control group will not receive any intervention but standard care will be provided during the study period and they will be allowed to wear single vision lens without any other treatment affecting visual acuity.

Outcomes



Figure 2: Location of the points

The outcome variables are refractory error and visual acuity. The assessments will be made before and after the treatment.

Error refraction

Refraction test will be used to evaluate the optimal correction of refractive error in the eyes [13]. We are intended to use TAPCON kerato-refractometer KR8900 manufactured by TAPCON corporation made in Japan to assess the refractive error. An imperfection in vision where light is not properly focused on your retina. Ophthalmic physicians and other eye care professionals use autorefractors extensively throughout the world to evaluate refractive error, accommodation, prescription, and dispensing of glasses. They are a very accurate, dependable, and repeatable substitute for retinoscopy. Autorefractors can detect astigmatism with a reasonable degree of precision. In comparison to traditional retinoscopy, it is fairly accurate and beneficial for children with cycloplegic retinoscopy [15].

Visual acuity: The visual acuity test is performed to assess a patient's visual clarity or sharpness of vision. The capacity to distinguish different optotypes stylized letters or symbols at a set distance [14]. Still in clinical practice, Snellen chart is commonly used to assess visual acuity [15]. An overview of the outcomes measured at each stage shown in table1.

Participant timeline

This study planned to perform the intervention in alternative weeks for seven weeks (four weeks of Tung acupuncture and in between alternative three weeks of resting period) figure 3.

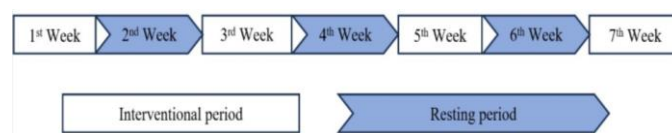


Figure 3: Participant timeline

Recruitment of subjects

Participants will be identified by the presenting complaints of eye sight or wearing spectacles or using contact lens. Individuals likely to be ineligible, or unsuitable to approach because of co-morbidity or other practical or medical obstacles to participation, will be removed. 100 eligible participants will receive an Email or call to participate in the study. Succeeding the acquisition of written informed consent, the participant will undergo additional eligibility screening.

Sample size calculation

A power analysis was conducted using G*Power version 3.1.9.7 to calculate the sample size for the study. Assuming a standard alpha of 0.05 and a power 65%, based on the mean and standard deviation of refractory error from a previous study, an initial calculation yielded 90 participants. After considering an attrition rate of 10% and rounding, the final sample size was determined to be 100 subjects.

Table.1 An overview of the outcomes measured at each stage.

S.no	Outcome tools	Pre assessment			Post assessment		
1	Error refraction		Sph [D]	Cyl [D]	Axis		Sph [D] Cyl [D] Axis
		Right eye	***	***	***	Right eye	*** *** ***
		Left eye	***	***	***	Left eye	*** *** ***
2	Visual acuity	***			***		

Sph- Spherical error, Cyl- Cylindrical error

Allocation & Sequence generation

Participants will be randomly divided (1:1 ratio) into two groups using simple random methods with the use of computerized randomization by a research consultant who will not participate in the data collection of the trial. A simple randomization procedure will be performed for 100 subjects with 1:1 ratio to get a sample size of (n=50) in each group and by using SNOSE (sequentially numbered opaque sealed envelope) technique allocation will be concealed.

Blinding

The study will be assessor-blinded. Research optician, who performs visual acuity test will be blinded to intervention assignment.

Data collection

Data collection will be performed after getting approval from Institutional ethical committee and after registration of clinical Trials registry – India. Study protocol will be explained to the subjects and a signed consent will be obtained from each subject. The outcome variable (error refraction, visual acuity) data will collect by optician at baseline and post data.

Data management

All participants will be assessed after recruitment. A well-trained assessor, who is blinded to the treatment assignment, will collect the clinical data using Snellen chart. The responsibilities of data managers will also include administration, coordination, and monitoring which includes data entry and Excel spreadsheet setup. All data will be anonymously extracted to protect patient identities, and any information that is absent, omitted, or irrelevant will be coded as such. The results of the analysis must remain confidential until the Excel spreadsheet is closed to avoid subject identification being revealed.

Statistical methods

SPSS 22.0 will be used to process the data, and a trained statistician blinded to group allocation will oversee the data analyses. The Full Analysis Set (FAS) consists of participants who will be randomized with respect to intention-to-treat (IT)

and per-protocol analysis set (PPS), and who complete the trial without experiencing major protocol violations. To evaluate the safety and therapeutic effect, the FAS and PPS will be used in parallel. Categorical data, such as gender and medical history, will be tabulated with frequencies or percentages; continuous data, such as age and the progression of a disease, will be reported as mean +, standard deviation (SD), or median.

Data monitoring and Auditing

Data monitoring in the proposed study will carry out by primary investigator, and the quality control of the entire project will be monitored by Head of the department and Lecture grade 2/ Assistant medical officer/ research guide to identify problems in the project implementation process in a timely manner and to implement the corresponding counter measures. The researchers will be handling the control bias by examining and supervising the acquired data.

Harms

Adverse reaction of acupuncture reported in the earlier studies linked with practitioners, and severe adverse reactions associated with needle are rare [16, 17]. However, some minor effects take place after the session rarely. For example, syncope [feeling sick or faint], fatigue, dizziness or blurry eyes, bruising and soreness, drowsiness, bleeding. Any unexpected symptoms or signs during the treatment will be documented regardless of their relation to the study intervention. These can be effectively managed through specific treatment in outpatient department at Government yoga and naturopathy medical college and hospital.

RESULTS

We aim to evaluate effect of Tung's acupuncture on, refractive error and standard visual acuity among mild to moderate myopia adults. We have selected the points to address the organ's pathological pattern that affect the eye condition. Those are heart, liver and kidney pattern, in addition to that eye reaction points were chosen to address the causative factors. The effect size for this study is not calculated due to lack of comparable data. With the collected data set we are planning to assess normal distribution by using Kolmogorov-Smirnov test

and the Shapiro-Wilk test will be used to assess the normality of data set. If we get significant difference in the distribution and normality, Wilcoxon Signed Ranks Test will be used to analyze data set within the group and Mann-Whitney U test for between the group analysis. Therefore, we believe that this study may bring positive result on myopia.

DISCUSSION

Currently, there have been no methodologically controlled clinical studies confirming the efficacy of tung acupuncture therapy in the treatment of myopia. This randomized controlled trial designed to investigate the possible therapeutic effect of Tung's acupuncture in order to satisfy the growing demand for high quality randomized controlled trials. In this study, we will compare the change in diopter of 2 groups and other assessments.

According to Chinese philosophy and pathophysiology, myopia is result from liver, spleen, and kidney Qi deficiency. The selected points aid in channelizing the proper flow of Qi and blood to these organs and eye's resulting in adequate nourishment of the eyes. Based on the modern concept, exact mechanisms of myopia management remain a subject of ongoing debate in the academic community. Dopamine has been identified as a key regulator of axial elongation, helping to slow the progression of myopia and it has been improved by acupuncture. However, growth factors and neurotransmitters may also be important in the ocular tissues, including nitric oxide, ZENK (Zif268, Egr-1, NGFI A, and Krox-24) and γ -aminobutyric acid (GABA). Vasoactive intestinal polypeptide (VIP), a 28-amino-acid neuropeptide found in the brain and eyes, is involved in transmitting information and regulating various physiological functions related to the eyes and vision. It has been demonstrated to be crucial for both the onset and progression of myopia as well as visual development. VIP and the dopamine pathway are tightly related.

VIP mainly uses the cAMP-dependent protein kinase pathway to produce its physiological effects after binding to its receptor [18]. Acupuncture intervenes in disease progression by mitigating inflammatory responses, enhancing tear protein secretion, increasing acetylcholine levels in the lacrimal gland, and regulating hormone levels, tear metabolism, and VIP through neurohumoral regulation. Acupuncture and auriculotherapy boost enkephalinergic activation and promote the release of dopamine and other opioid peptides, facilitated by GABA inhibition through the stimulation of mu opioid receptors from neurons [19]. Administration of acupuncture significantly lowered the levels of PI3K, PDK1, nPKC, and Rac 1 which plays a role in retinal fibrosis, a pathological process that disrupts retinal function [20, 21].

Previous clinical studies and systematic reviews show acupuncture is used in the clinical treatment of many eye diseases, including dry eye syndrome, blepharoptosis, oculomotor paralysis, blepharospasm, and other ophthalmic

diseases, and has a good effect [3, 22]. Moreover, a randomized controlled trials have reported improvement the diopter and vision by acupuncture in the children with myopia [3]. Hui Lv et al, (2015) showed 3 months of abdominal acupuncture superior to auricular acupuncture alone among myopic individuals on visual chart [23], Xiehe Kong et al, (2021) demonstrated that auricular acupuncture stimulation with atropine 0.01% for 6 months improves the spherical equivalent refraction when compared with atropine 0.01% [24], Rong Han et al, (2023) showed that the electroacupuncture once a week in addition with auricular acupressure improves the vessel density and perfusion density.

However, no statistically significant SER and axial length observed after 3 and 6 months of treatment [25]. To our knowledge, the present study will be the first clinical trial that demonstrate the tung acupuncture for treating myopia. This trial's rigorous scientific design aims to provide consolidated evidence on the effectiveness of acupuncture. Limitation of the study is small sample size so the results may not be generalizable to a larger population and follow up after the intervention is not planned, this might be a drawback in this study. Future studies could involve a larger, more diverse sample to ensure the findings are generalizable across different populations, including various age groups, ethnicities, and geographic regions and could incorporate more sophisticated control group. So, we welcome more research in future with robust randomized controlled trial that could address the limitations.

CONCLUSION

The positive results will confirm Tung's acupuncture is effective in improving the visual acuity among mild to moderate myopia adults. Even though practitioner needs expertise in the point location of tung's acupuncture, like standard acupuncture, this is also less invasive, cost-effective therapy. Thereby, tung acupuncture can be implemented in the regular clinical practice in managing the visual acuity among myopia patients.

Protocol amendments: If any changes in the eligibility criteria, outcome, data analysis that will be notified to the Head of the Department, Ethical committee members, Guide by the Principal investigator and the same will be signed in the written format.

Informed consent: Informed consent will be obtained from the all the subjects enrolled in the study after explanation of the procedure and the benefits and risks that are involved in this research.

Confidentiality: Identification and other data of the participants will be kept confidential. All the data will be collected, maintained in the Excel spreadsheet and relevant data will be shared to data analysis in coding.

Declaration of interest: The authors declare that they have no known competing financial and personal relationship that could have appeared to influence the work reported in this paper.

Access to data: The result data will be published online for the open access to the researcher, physicians and public with concealment of individual identification. There is no contractual agreement to limit the result data.

Ancillary and posttrial care: Nil

Manuscript writing: At any stage of writing in the manuscript no artificial intelligence was used.

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