

Guided Meditation For Vision Acuity Training On Adolescent Myopia: Study Protocol For A Prospective, Multicenter, Randomized Controlled Trial

Yibo Li

Beijing University of Chinese Medicine

Lili Zhu

Beijing University of Chinese Medicine

Raoying Wang

Beijing University of Chinese Medicine

Xinqi Jiang

Beijing University of Chinese Medicine

Tao Lu (✉ taolu@bucm.edu.cn)

Beijing University of Chinese Medicine <https://orcid.org/0000-0002-8247-8387>

Study protocol

Keywords: Simple myopia, Meditation, Vision acuity training, Randomized controlled trial

Posted Date: April 28th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-450181/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background: Currently, the population with myopia climbs steadily, and developing toward younger age, posing a great concern to the health of adolescents. Myopia in severe cases can cause irreversible consequences such as glaucoma, blindness and other complications. At present, the solutions for myopia are glasses, medication and surgery. This study aims to investigate the role of a physiotherapy category based on guided meditation for vision acuity training on adolescent myopia.

Methods: This is a prospective, randomized, multicenter clinical trial. 1140 primary and secondary school students aged 8-18 years old from 27 schools will be recruited and randomly divided into an experimental group and a control group at a ratio of 2:1 in two phases, with a training period of 30 days in each phase and a follow-up period of 3 months. No interventions will be conducted during the follow-up period, nor will other interventions employed. Inclusion criteria will meet the diagnostic criteria for simple myopia and $-6.00D \leq \text{spherical lenses} \leq -0.50D$, cylindrical lenses $\leq 1.50D$. The primary observation index will be to compare the statistical differences in distant visual acuity between the two groups; the secondary observation indexes will be ocular symptoms (mainly including eye fatigue, dryness, pain, double vision, neck pain, thought disorders, and lags in response), diopter and astigmatism.

Discussion: The purpose of this two-phase trial is to compare the clinical effectiveness of focused vision-guided meditation with Chinese eye exercises that are also non-pharmacological, non-invasive interventions for myopia, and to maximize the benefit to the subjects. The results will indicate whether the training based on focused vision-guided meditation has the ability to improve distant visual acuity, relieve ocular symptoms and ameliorate diopter. In addition, this trial will provide clinical efficacy of the training, which is expected to provide meaningful data for vision rehabilitation. At the same time, the vision acuity training method, which is permeated with the concept of Traditional Chinese Medicine (TCM) rehabilitation and health maintenance, will be applied to achieve the goal of preventing or alleviating myopic development and reducing myopia rate.

Trial registration: Chinese Clinical Trial Registry (identifier: ChiCTR2000038642; Registered 26 September 2020, <http://www.chictr.org.cn/showproj.aspx?proj=61729>).

Background

The prevalence of myopia is increasing yearly and has become one of the most serious public health problems worldwide [1]. It is expected that by 2050, 50% of the world's population will be affected by myopia [2]. The increase in the myopic population is accompanied by an earlier age of onset, usually occurring between 6 and 8 years old, growing rapidly between 13 and 16 years of age, and stabilizing after 16 years old [3]. In countries of East and Southeast Asia, approximately 80% to 90% of urban adolescents have myopia by the time they graduate from high school [1], and China has the second highest number of adolescents with myopia in the world with more than 450 million [4].

Myopia can be divided into simple myopia and pathological myopia. The most common one in adolescents is the simple myopia, which is induced by a combination of genetic and environmental factors, and is related to the weakening of visual regulation caused by spasm of the extraocular and ciliary muscles, which will gradually lead to the growth of the eye axis if it is not restored in time. Therefore, the functions of the extraocular and ciliary muscles are crucial for maintaining good vision [5]. If not corrected in time, myopia will lead to serious and irreversible complications such as retinal detachment, macular degeneration, glaucoma, and blindness [6]. Strengthening vision protection for adolescents has become an urgent issue that needs to be addressed.

Currently, optical correction by glasses is the main intervention method for simple myopia, but it cannot improve visual acuity of the naked eye. Drugs such as atropine can improve visual acuity, but once the drug is discontinued, vision problem will rebound or causing even worsen myopia, along with some side effects such as photophobia, blurred vision and allergic conjunctivitis [7]. Laser surgery may be complicated by other eye diseases such as near vision impairment and dry eye, and has age restrictions [8, 9].

Vision acuity training refers to the use of optical, psychological, physical and other methods to produce a certain cognitive load on the visual system of the eyes (including regulation, convergence, eye movements and the associated movements between them), in a bid to improve the visual function and visual comfort of the visual system and achieve the goal of improving and repairing visual abnormalities in both eyes. It is considered as a purely physical, non-invasive, non-drug therapy with no side effects to relieve eye fatigue and improve vision, with a long history. The earliest and most widely known is the Bates Vision Acuity Training Method, including eye sunbathing, palm massage, rope games, ruler games, pencil games, etc. But due to the complexity of its training, long cycles, etc., it has not been widely promoted. At present, the common vision training mainly relieves the ciliary muscle tension by repeatedly focusing on the distant visual target, looking at the distance and movement of the image to adjust the function of the extraocular muscles, and through the different light color changes to stimulate the visual cortex, as ways to improve vision and restore to a good visual system.

Defined as a form of training to improve concentration and mood, meditation involves a range of practices such as mindfulness meditation, yoga, tai chi and qigong [10]. Meditation is however not limited to sitting still; one can be in a meditative state while walking, standing, sitting, lying, or even working [11]. A recent article in the New England Journal of Medicine highly valued the contemporary value of meditation as "embarking on a new era in psychosomatic medicine" [12]. In recent years, meditation has attracted widespread attention and in-depth research across the world, mainly focusing on psychological diseases [13, 14], pain [15], sleep disorders [16], chronic disease rehabilitation [17, 18] and other fields. However, due to long intervention period, complex indicators, and difficulty in objective quantification, it is difficult to fully reflect the effects of meditation.

The training based on Guided meditation for vision acuity belongs to a kind of regulation training method in the scope of physiotherapy, which mainly uses audio and video guidance to instruct myopia patients to

focus on breathing, associate images, enter a meditation-like state and specialize the current practice. Meanwhile, the patients could exercise the extraocular and ciliary muscles by incorporating simple actions such as hand-eye coordination with the stimulation of meridian points. In doing so, visual function and comfort can be improved. As this training method is simple and has a short period, it is welcomed by youngsters, and the indicators for evaluating vision acuity are simple, so it is easy to quantify the effect objectively.

Therefore, we will conduct a multicenter, randomized controlled study based on guided meditation for vision training. It is hoped that this study, from the perspective of psychosomatic medicine, can stimulate the self-healing ability in adolescent students under the guidance of external physical operations.

Methods

Ethics

This trial is designed in accordance with "Ethical Review of Biomedical Research Involving Human Subjects" issued by the Ministry of Health of the People's Republic of China. The implementation of this project has been reviewed and approved by the Ethical Review Committee of Beijing University of Chinese Medicine(4 June 2020, Approval Number: 2020 BZYLL0306). Written informed consent will be obtained from each subject and his/her guardian.

Study design

This study will be a prospective, multicenter, randomized controlled clinical trial. The included subjects (n=1140) will be randomly assigned to the experimental (n=760) and control (n=380) groups in a 2:1 ratio. The aim of this study is to objectively evaluate the clinical efficacy of the guided meditation of vision training for adolescent myopia. This report will be compiled according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Statement 'Defining Standard Protocol Items for Clinical Trials' (Fig. 1).

Recruitment

In this trial, 1140 primary and secondary school students with simple myopia will be recruited from 27 schools in Sichuan and Hunan provinces or other cities with relatively uniform schooling conditions. The main points for the diagnosis of simple myopia in China's "Myopia Prevention and Treatment Guidelines" [19] will be used as a reference standard for recruitment: near visual acuity is normal, distance visual acuity is less than 1.0 (5.0 by the Mucosal method), there are no pathological changes in the fundus, the progression is slow, vision can be corrected to normal with appropriate lenses, while other visual function indicators are mostly normal; and the subject recruited meet the quantitative criteria for myopia according to the "White Paper on Myopia Prevention and Control" of the International Myopia Institute (IMI) [20]: myopia diopter $\leq -0.50D$.

Inclusion Criteria

- (1) ≥ 8 years old and ≤ 18 years old;
- (2) Meeting the diagnostic criteria for simple myopia, with $-6.00 \text{ D} \leq \text{refractive state} \leq -0.50 \text{ D}$, astigmatism $\leq 1.50 \text{ D}$, and having a normal vision after optically corrected.
- (3) Able to cooperate to complete the study.
- (4) The subjects and their guardians must both voluntarily sign an informed consent form.

Exclusion criteria

- (1) Those who have comorbidities or complications of other eye diseases, such as glaucoma, amblyopia, eye infections, etc.
- (2) Those who have comorbidities of very severe heart, brain, liver, kidneys, hematopoietic system diseases and neuropsychiatric diseases, or systemic diseases that may affect the progression of myopia.
- (3) Those who have had eye surgery or a history of eye trauma;
- (4) Those who have comorbidities of hearing abnormalities;
- (5) Those who are unable to cooperate with the study for personal or family reasons;
- (6) Those who refuse to sign an informed consent form by himself/herself or any of his/her guardians.

Withdrawal Criteria

Subjects have the right to withdraw from the study, as defined in the informed consent document, or to "drop out" if they do not explicitly withdraw from the study but are no longer undergoing training and testing. The reason for withdrawal should be understood as far as possible, and recorded. For example, (1) perceiving lack of efficacy; (2) intolerance of certain adverse effects; (3) inability to continue the clinical study; (4) or lost to follow-up without explanation. Case record forms for withdrawn subjects will be kept and the results of the last trial will be considered final. The data on the clinical efficacy and adverse effects of the focused vision-guided meditation training will be fully analyzed.

Suspension Criteria

The investigator will decide to terminate the study of a subject who has been enrolled in the study that the subject is unfit to proceed the study. For example, (1) the subject develops certain comorbidities and complications under study; (2) the subject is unfit to continue the study due to unexpected events or specific physio-pathological changes during the study. (3) The subject meets the criteria for cure in less than 30 days, the study may be discontinued early if the subject so desires.

Excluded cases

Those who with any of the following should be excluded: (1) subjects with incomplete case information that affects the analysis of the trial results; (2) subjects with poor compliance during the trial due to subjective or objective factors of their own or family members; (3) subjects who uses other interventions for myopia outside the protocol.

Randomization

The random sequence will be designed and processed by the research team of Beijing University of Chinese Medicine. SPSS 20.0 (SPSS Inc., Chicago, Illinois, United States) software will be used to generate serial numbers for the subjects; the 1140 random numbers and the allocation sequence table with the unit are saved as blind codes. Subjects will be assigned to the experimental (n=760) and control groups (n=380) at a ratio of 2:1.

Allocation concealment

The randomization lists will be kept in opaque envelopes by the non-investigator on the team which are ordered, identical, and sealed with adhesive.

Implementation

The participants will be consecutively enrolled and distributed into experimental and control groups by researchers according to the randomized sequences generated who will not participate in assessing outcomes. Another group of researchers responsible for analyzing results will be blind to the grouping of subjects and will not participate in the treatment. The executors of this trial and subjects will not be blinded to the treatment assignment.

Interventions

Explanation for the choice of comparators

The choice of the comparator is based on the current treatment of myopia in clinical.

Intervention description

The vision acuity training of this study is conducted in the schools, and school leaders are fully aware of this project, support and cooperate with the research work. Relevant teachers will be designated by the schools to be responsible for this project with respect to the specific matters concerned. The study will be conducted in two phases over a period of 8 months, with a training period of 30 days in each phase and a follow-up of 3 months. No interventions will be conducted during the treatment period and follow-up period. One visual acuity examination will be performed in each of the two phases at months 1, 2, and 3 of the follow-up.

Phase 1

Experimental group

Two sets of vision acuity training movement verbal commands will be applied in the experimental group. In order to facilitate the subjects to follow the verbal commands in a uniform, standardized way, the related audio and standard movements will be recorded.

The first set of audio and video content are relatively rich, lasting about 1 hour, and the audio and video will be projected in the classroom on the first and eighth day of training, with the subjects following the verbal commands and the movement demonstrations in the video. Visual training tutors (trained in procedures and methods) will be responsible for audio and video presentations.

The second set of audio and video content are relatively concise, approximately 15-20 minutes in length, and the subjects will be trained under the schools' uniform deployment for the remaining 28 days.

Due to the uninterrupted daily vision acuity training for 30 days, it is recommended to use the last self-study class at the schools to ensure that the students' normal studies are not interrupted; students will still be required to come to get trained at their school or a designated location confirmed with the schools on Saturday.

First training

The first set of audio and video training exercises will be projected in the classroom by the vision acuity training tutor, and the students will be guided by the audio-visual movements and verbal commands to perform the following exercises.

- (1) Abdominal breathing: Inhale through the nose, exhale through the mouth, bulge abdomen while inhaling, tighten abdomen while exhaling; start doing abdominal breathing when hearing the words of "adjust your breath and inhale.
- (2) Eye-warming exercise: Rub your hands more than 30 times, cover your eyes with the palms, place thumbs on the temples, clasp four fingers on your forehead, and leverage the temperature of your palms to warm eyes; after the temperature gradually dissipates, use Yuji acupoints of the palms to gently press your eyes 5 times, with moderate intensity; start eye-warming exercise when you hear the words "get ready to press "and" quickly rub your hands" during training.
- (3) Healthy vision exercise: Press both hands palms on your ears, place fingers on the back of your head; do not move the palms, and use fingers to gently tap the back of your head. During the training, when you hear "healthy vision exercise", start doing it.
- (4) Activate Shixuan acupuncture point: Tap your fingers on your palm, shake your palm, and make an arrow shape.
- (5) Play the "1-Audio", turn off the lights in the classroom, close the curtains, and try to create a dark environment. Remain quiet the entire time. Close your eyes until the audio says to open them. Follow the

audio to imagine and do movements, e.g., "Use the fingertips of one hand to gently touch the center of the palm of the other, and then shake your hand vigorously.

(6) Play the "C-video", a video about lotus flowers to stimulate the imagination and match the 2-Audio with the images that appear in the video. For example, "On a calm lake, you can definitely see the vivid color of the lotus flowers and the greenish-blue leaves of the lotus"

(7) Demonstration and correction. Make a hollow bowl shape with your hands (thumbs on the second knuckle of your index finger) and clasp them over your eyes, with palms facing your eyes.

(8) Play "2-Audio" and do the eye stretches: Close your eyes and move them from front to back as if a train is moving back and forth in a tunnel.

(9) Play "3-Audio" and listen to the audio with your hands in a hollow bowl shape over your eyes the whole time. When the audio says "in", put pressure on your eyes for one second, and when it says "out", relax your eyes and perform the related imagery and actions. When the audio say "pull" in future exercises, let your eyes enter a state just like going into a tunnel, hold for 1 second, and then relax.

(10) Play "D-Video (Ball of Light)" to stimulate imagination and introduce natural light.

(11) Play "4-Audio" to build up the confidence of myopia sufferers to restore their eyesight.

The above training will be repeated on the 8th day to intensify the effect, for 1 hour.

Daily vision acuity training

Guided by the second set of audio and video movement verbal commands, the subjects perform self-rehabilitation exercises.

(1) Ocular exercises: keep body and head still, torso upright, move only eyes, four 8-tempos per part.

In the first part, both eyes look up and down to the left. In the second part, both eyes look up and down to the right. In the third part, both eyes look to the left to the right. In the fourth part, both eyes turn clockwise. In the fifth part, turn both eyes counterclockwise. In the sixth part, close your eyes hard and then open them to look up. In the seventh part, close your eyes for a moment to control the time.

(2) Eye-warming exercises: same movements as before, 12 movements per day.

(3) Vision acuity exercise: same movements as before, 24 movements per day.

(4) Character card stretching: 10 minutes of training, with results recorded on an observation chart. Character cards (Chinese characters of different sizes) are placed on a well-lit wall at the subject's eye level. Find the farthest place where you can see the card clearly, that is, about 10-15cm back where you cannot see the card clearly. Let your eyes stretch 6 times for 1.5 seconds each (eye movement, stretching backwards), without blinking, stare at the characters for 10 seconds, step back 15cm, and repeat the

above movements until you are unable to see the location of the character card after stretching. If the training time is less than 10 minutes, switch to a second character and repeat the above steps; if it has reached 10 minutes, end the exercise and take notes.

Control group

The control group will be given Chinese eye exercises in the first stage of the trial. On the first day and the eighth day of the trial, the school teachers who has received training in Chinese eye exercises will give instructions on finding the positions of acupoints, massage intensity, direction and frequency according to the standard Chinese eye exercises Assessment Form to ensure that the students can perform the eye exercises independently and with high quality. For the remaining 28 days, subjects will be in a uniform classroom for 15-20 minutes of daily Chinese eye exercises. Acupoints: Jingming, Zanzhu, Yuyao, Tongziliao, Sizhukong, Taiyang, Chengqi, Sibai.

Second phase

After the completion of the first phase of the randomized controlled study, data will be collected and compared between the vision acuity training group and the Chinese eye exercises group. If the data show that the vision acuity training is not significantly better than the Chinese eye exercises, the trial will be terminated; if the data show that the vision acuity training is significantly better than the eye exercises, the trial will enter the second phase, and the 3-month follow-up period of the first phase will be used as an elution period before the second phase. In the second phase, the experimental group will end the trial, and the control group will switch to a 30-day vision acuity training method based on meditation and concentration, with a follow-up period of 3 months.

The subjects in this study are adolescent students with simple myopia and no other comorbidities of chronic diseases. If the subjects need to combine medication due to cold or other reasons, they should be recorded promptly.

Basic Information Collection

Information will be collected from the subjects before the start and after the trial is completed, and the main information is as follows.

- a. Basic information: age, nation, grade, height, weight, family history of myopia, parents' high myopia, etc.
- b. Myopia: duration of myopia, possible causes of myopia, naked eye visual acuity, corrected visual acuity, diopter of both eyes, astigmatism and so on.
- c. Time allocation for daily activities: including close range activities (<50 cm): such as drawing, homework, reading and using electronic screen terminals such as mobile phones; outdoor activities: including playing outdoors, cycling, hiking, etc.

Primary observation indexes

vision acuity training aims to improve the visual acuity of the naked eye that affects life and work, so this study will use distance visual acuity as the primary observation index. After the start of the training, visual acuity tests will be performed before and after daily training for the first 7 days; after 7 days of training, visual acuity tests are performed once a week; and the tests will be performed at the 1st, 2nd, and 3rd months of follow-up.

The specification for visual acuity testing is based on the "Expert Consensus on Workflow of Myopia Screening in Children and Adolescents (2019)" [21]. Measurements are taken under adequate lighting conditions and the subjects are measured 5 meters away from the visual acuity meter. All visual acuity examinations in this study will be performed by a regular person who will not undergo vision acuity training or clinical examinations. Specific details of subjects will be not disclosed to this measurer.

Secondary observation indexes

Ocular symptoms, diopter and astigmatism are secondary indexes. Ocular symptoms will be evaluated before and after 30 days of training, respectively. Diopter will be obtained from the subjects after testing at the same hospital before and after the training.

Ocular symptoms

a. Ocular symptom scores are developed based on the "Visual Fatigue Test and Evaluation Method (VFTEM)" and principally cover eye fatigue, dryness, pain, visual double vision, neck pain, thought disorders, and lags in response.

b. Collective Insufficient Symptoms Survey (CISS): the CISS is a valid tool in quantifying near visual acuity symptoms in adolescents [22] and consists of 15 items, each with five options of varying degrees, scored as follows: never (0), rarely (1), sometimes (2), often (3) and always (4). The sum of the 15 items' scores (ranging from 0 to 60) is the total score.

All of the above information and scales need to be completed with the help of the subject student's parents and professional staff.

Diopter and astigmatism

The diopter (after pupil dilation by tropicamide) and astigmatism will be obtained from the students after examination at a local first-tier public hospital or public eye hospital accompanied by their family members, and the data will be recorded in the entry of "Information Collection - Visual Acuity".

Data Entry and Statistical Analysis

Data collection

A paper version of the Case Report Form will be developed for data collection. The data will be collected using standardized entry terms and structured registration contents as much as possible, which will facilitate post-processing and analysis of the data and minimize the burden on the researcher. According to the original observation records of the subjects, the data manager will load the data into the case report form in a timely, complete, correct and clear manner. When amending a case, the original record should be clearly visible, and corrections should be signed and dated by the investigator.

Data entry and storage

The paper-based data should be entered by a dedicated data manager using a dual-track entry to reduce the error rate, and any problems or unexpected matters found in the entry process should be registered and reported promptly so that problems can be dealt with quickly. Observation forms should be subject to random inspections at the end of data entry to understand the quality of the entry and to analyze and address any problems. Once data entry is completed, all original case report information should be kept. The original case report forms, after completion of data entry and verification as required, should be filed in a numbered order, and a dedicated person should be assigned to manage the files and complete the search directory, etc. Also, the entered data should be backed up regularly to prevent loss of data and other unexpected occurrences. Particular attention should be paid to the security of data storage and the protection of the privacy of the subjects and related personnel. All research documents will be stored in special filing cabinets that are locked to ensure the security of the stored documents. In any case, only authorized staff will have access to the data.

Statistical analysis

Sample size

The sample size of this superiority trial will be estimated based on the past research [23] and early observations. According to the references and professional judgment, it is assumed that the effective rates of the control group and the experimental group will be 40% and 51%, respectively. Under 20% dropout rate, if the two-tailed $\alpha=0.05$ and $\beta=0.1$ test efficacy of 0.9, experimental group: control group = 2:1, and the dropout rate is 20%, then it will be calculated through the following formula:

$$n1=n2 = \frac{(Z_{\alpha}+Z_{\beta})^2 \times 2\sigma^2}{\delta^2} \times 120\%$$

It's finally confirmed there will be 1140 cases in total, with 760 cases in the experimental group and 380 cases in the control group.

Statistical analysis

Statistical analysis using SPSS 20.0 will be performed, and data management software will be used to construct the database. Dedicated staff will be assigned to oversee the management of electronic data,

and a clinical research team will be deployed for data entry, validation, reporting, and answering questions. Measurement data will be described statistically using mean \pm standard deviation and counts will be described statistically using frequency. Measurement data conforming to a normal distribution will be compared between groups using two independent samples t-test in randomized controlled study and paired samples t-test in pre-post controlled study. $P \leq 0.05$ will be considered a statistically significant difference.

Primary and secondary observation indexes will be analyzed by the superiority test depending on the treatment, using Per Protocol Set (PPS) and Full Analysis Set (FAS) datasets. The indices of safety evaluation will be analyzed using the Save Set (SS) dataset.

Monitoring

A Data Monitoring Committee (DMC) will be instituted during the study, which is consisted of project researchers, ethics committee members, statistical analysis personnel, and implementation teachers. Who have no competing interests. It is the responsibility of the DMC to review the trial design and trial documentations prior to the commencement of the study to identify issues that may affect data analysis or patient safety. And identify problems during project implementation and take timely intervention measures. The collected data will be checked again at the end of the study.

Adverse events

In case of any adverse event, subjective discomfort (dizziness, nausea, etc.) or abnormal laboratory parameters of subjects should be treated seriously, the cause should be carefully analyzed, and immediate measures should be taken to maintain the safety of the subject's life. Procedures: Detailed records should be made on the case report form, and retesting should be performed within 24 hours, 7 days, and 14 days as appropriate. Records of persistence, prognosis and disappearance should be kept.

Treatment of serious adverse events: If there is any serious adverse event in the course of the study, it must be reported immediately to the ethics committee of the organization, and the sponsor, and the "Serious Adverse Event Report Form" must be filled; if there is a serious adverse reaction, it should be reported to the National Medical Products Administration within 24 hours, and the contact person should be notified according to the telephone number and home address listed in the case report form.

(1) Treatment measures: When the subject has an accident or emergency, the investigator should make corresponding treatment according to the experimental therapy and its symptoms, and pass the treatment results to the clinical examiner. The institute should record the treatment and results on the case report form and sign it.

(2) Follow-up of unmitigated adverse events: all adverse events should be tracked for their cause until they can be appropriately resolved.

Frequency and plans for auditing trial conduct

The DMC and the ethics committee will meet annually during the trial to review the conduct of the study, Good Clinical Practice(GCP), compliance with the protocol standard operating procedures and applicable regulatory requirements.

Quality control

Quality control is crucial to the reliability and accuracy of the research results, mainly conducted over the implementation process and data management aspects to achieve quality assurance. Quality control principally covers the following aspects: 1. investigator training: before the implementation of the study, a detailed research protocol and the SOPs should be developed, participants of the study should be trained and documented; 2. data quality control: investigators should be trained, and the way in which data are collected, the list of all data elements and definitions, and the treatment methods for missing values, invalid entries, incorrect entries, and logically inconsistent data should be clarified during training. To prevent data bias, data entry and statisticians should be masked during the trial.

Confidentiality

This study will fully comply with the relevant provisions of the data protection legislation. All appropriate and necessary precautions will be taken to keep medical data and personal information permanently confidential.

Discussion

The eyes do not exist in isolation, but are an integral part of what makes up the human body, influencing the body, mind and emotions in a unique way. Western medical research has shown that the visual system is considerably sensitive to any form of stress, tension and mental state, and that vision problems usually occur along with chronic stress and incorrect eye habits. Nearsightedness, farsightedness and astigmatism are symptoms that are resulted from this underlying stress and imbalance. A better holistic model of vision includes the following three components: Physical Eyesight, Inner Vision, and Emotional Seeing [24].

The book "Zhu Bing Yuan Hou Lun", also known as "General Treatise on Etiologies and Manifestations of All Diseases" from Traditional Chinese Medicine (TCM) states: "The injury to the visceral organs caused by fatigue, deficiency of liver vitality (qi), and exposure to exopathic evil (wind-evil) make the essence of qi or vitality weak, causing vision problems", pointing out the causalities and characteristics of myopia in a systematic way. The liver is the main reservoir of blood and one of the major sources for vitality, associating strongly with blood capillary supplement for extraocular muscle. Emotion fluctuation as well as excessive use of eye will compromise liver qi (vitality) or cause it to be stagnant, thereby affecting blood or qi supply to the eye, leading to vision problems. "The Chapter of Discussion on the Generation of Five Zang (visceral) Organs in Su Wen" states: "the heart governs blood vessels, all vessels connect to the eyes."; spleen is the origin of acquired constitution and the source of qi and blood production; if the spleen qi suffers from deficiencies lasted, blood is difficult to nourish eyes, compromising the visual

acuity. According to Zhang Jingyue, an ancient TCM master, "lung governs qi, and when qi is coordinated, deficiencies in nutritive qi and protective qi as well as lower vitality in zang (visceral)-organs are all cured"; The whole body's blood converges at the lung, and lung regulates the whole body's vigor of qi; when the qi of the lung is harmonized, blood can form a steady flow into the eyes, thus benefiting the vision; Thus, the deficiency of essence of visceral organs will dampen the vigor qi for blood flow and make it unable to nourish eyes, thereby weakening the vision; from the clinical perspective of Chinese medicine, the causalities of vision problems are related to liver, heart, spleen, lung and kidney, the five zang (visceral) - organs[25]; Therefore, vision rehabilitation training should not be limited to the adjustment of the visual system only, but extend to internal, external treatments, as well as physical and physiological regulation holistically.

Meditation is vital for "mental condition adjustment" and "health improvement" in TCM, and has been advocated and practiced by medical practitioners in ancient China. It is also one of the populated approaches for self-health management. Meditation is often coordinated with the adjustment of posture, breathing and consciousness to motivate self-healing capacity. It means to build a peaceful and perceptive mind to overcome the judgmental thoughts or emotions; This helps to eliminate unhealthy muscle memories and psychological preconceptions, potentially creating new ways to cope with illness [26]. Studies have shown that during meditation, parasympathetic activity increases, sensory and perceptual changes occur. These physiological changes are a state of self-healing relaxation that may have preventive and therapeutic effects on human health [27]. Meditation is also a positive mental exercise that alters brain and mind function and facilitates the regulation of attention, cognition and mood. It is well documented that mental state affects physical condition, and its imbalance affecting hormone release, attributing to diseases.

The incorporation of meditation elements into vision acuity training is a multifaceted combination of movement, breathing and imagination, which may enhance vision by strengthening the eye muscle regulation functions.

This project will be conducted in two phases, using two research designs. The first phase will be a multicenter randomized controlled study, and the second phase will be a single-arm pre-post controlled study. The aim is to compare the differences in the effects of the training based on guided meditation and Chinese eye exercises on vision regulation in adolescents. If the significant clinical efficacy and safety are uncovered, a novel non-pharmacological physical therapy will be provided for the treatment of adolescent myopia. The study will also help to promote and disseminate the vision acuity training method, which is infused with the TCM rehabilitation concept, and provide a reference plan and basis for solving the myopia problem among adolescents.

Declarations

Trial status

At the time of submission, the formative research has been completed and recruitment is ongoing. The first participant will be enrolled in December 2020. Patient recruitment is estimated to be completed around September 2022. The current protocol is version 2.0 of 19-6-2020.

Acknowledgements

The authors would like to thank the Medical Ethics Review Committee of Beijing University of Chinese Medicine and all the staff involved in this study.

Dissemination policy

The results of this study will be published in a peer-reviewed manuscript and will be presented to health system and community stakeholders as well as relevant local, national and international meetings. Access to the study protocol will be provided through an open access protocol.

Funding

Professor Tao Lu., Beijing Municipal Commission of Education, Double First-Class, personnel department, High-caliber talents (NO. 1000041510156). The funding is internal to Beijing University of Chinese Medicine. The funder plays an important role in the study design, collection, analysis, and interpretation of data, and in revising the manuscript and the decision to submit the report for publication.

Availability of data and materials

The datasets generated or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

LT, ZLL and LYB designed and compiled the protocol. LT is the team leader in charge of the project. ZLL completed the randomized controlled trial of the project. ZLL and LYB provided written materials such as inclusion criteria, exclusion criteria and objective indicators to check the medical record form, and participated in the process of ethical review. LYB completed the writing and revision of the article, and was responsible for data management. WRY participated in the submission of this article and additional files. JXQ contributed to the investigation and summary of the literature. Co-first authors are equally important in their contributions to this paper. All authors have read and approved the final manuscript.

Consent for publication

All authors consent to publication of this research.

Ethics approval and consent to participate

The Ethical Review Committee of Beijing University of Chinese Medicine has approved the ethical approval of this study. (4 June 2020, Approval Number: 2020 BZYLL0306) Written informed consent will

be obtained from all participants or their authorized representatives.

Author details

1 Beijing University of Chinese Medicine, 11 Beisanhuan Dong Lu, Chaoyang District, Beijing, China.

Competing interests

The authors declare that they have no competing interests.

References

1. Morgan IG, Ohno-Matsui K, Saw SM: Myopia. *Lancet* 2012, 379 (9827): 1739-1748.
2. Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P, Wong TY, Naduvilath TJ, Resnikoff S: Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology* 2016, 123(5):1036-1042.
3. Yu L, Li ZK, Gao JR, Liu JR, Xu CT: Epidemiology, genetics and treatments for myopia. *International journal of ophthalmology* 2011, 4(6):658-669.
4. Bai JF: The number of people with myopia in our country has exceeded 450 million. In: *People's Daily*. 2018.6.5.
5. Hargrave BK: Accommodation: The role of the external muscles of the eye: A consideration of refractive errors in relation to extraocular malfunction. *Medical hypotheses* 2014, 83(5):607-613.
6. Ruiz-Medrano J, Montero JA, Flores-Moreno I, Arias L, García-Layana A, Ruiz-Moreno JM: Myopic maculopathy: Current status and proposal for a new classification and grading system (ATN). *Progress in retinal and eye research* 2019, 69:80-115.
7. Li FF, Yam JC: Low-Concentration Atropine Eye Drops for Myopia Progression. *Asia-Pacific journal of ophthalmology (Philadelphia, Pa)* 2019, 8(5):360-365.
8. Torun N, Bertelmann E, Klamann MK, Maier AK, Liekfeld A, Gonnermann J: Posterior chamber phakic intraocular lens to correct myopia: long-term follow-up. *Journal of cataract and refractive surgery* 2013, 39(7):1023-1028.
9. Vestergaard AH, Hjortdal J, Ivarsen A, Work K, Grauslund J, Sjølie AK: Long-term outcomes of photorefractive keratectomy for low to high myopia: 13 to 19 years of follow-up. *Journal of refractive surgery (Thorofare, NJ : 1995)* 2013, 29(5):312-319.
10. Tang YY, Hölzel BK, Posner MI: The neuroscience of mindfulness meditation. *Nature reviews Neuroscience* 2015, 16(4):213-225.
11. Van Gordon W, Shonin E, Dunn TJ, Garcia-Campayo J, Demarzo MMP, Griffiths MD: Meditation awareness training for the treatment of workaholism: A controlled trial. *Journal of behavioral addictions* 2017, 6(2):212-220.
12. Dossett ML, Fricchione GL, Benson H: A New Era for Mind-Body Medicine. *N Engl J Med* 2020, 382(15):1390-1391.

13. Sedlmeier P, Eberth J, Schwarz M, Zimmermann D, Haarig F, Jaeger S, Kunze S: The psychological effects of meditation: a meta-analysis. *Psychological bulletin* 2012, 138(6):1139-1171.
14. Goyal M, Singh S, Sibinga EM, Gould NF, Rowland-Seymour A, Sharma R, Berger Z, Sleicher D, Maron DD, Shihab HM *et al*: Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. *JAMA internal medicine* 2014, 174(3):357-368.
15. Cherkin DC, Sherman KJ, Balderson BH, Cook AJ, Anderson ML, Hawkes RJ, Hansen KE, Turner JA: Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain: A Randomized Clinical Trial. *Jama* 2016, 315(12):1240-1249.
16. Black DS, O'Reilly GA, Olmstead R, Breen EC, Irwin MR: Mindfulness meditation and improvement in sleep quality and daytime impairment among older adults with sleep disturbances: a randomized clinical trial. *JAMA internal medicine* 2015, 175(4):494-501.
17. Carlson LE, Doll R, Stephen J, Faris P, Tamagawa R, Drysdale E, Specia M: Randomized controlled trial of Mindfulness-based cancer recovery versus supportive expressive group therapy for distressed survivors of breast cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2013, 31(25):3119-3126.
18. Hartmann M, Kopf S, Kircher C, Faude-Lang V, Djuric Z, Augstein F, Friederich HC, Kieser M, Bierhaus A, Humpert PM *et al*: Sustained effects of a mindfulness-based stress-reduction intervention in type 2 diabetic patients: design and first results of a randomized controlled trial (the Heidelberger Diabetes and Stress-study). *Diabetes care* 2012, 35(5):945-947.
19. Guidelines for prevention and treatment of myopia. *China Glasses Science-Technology Magazine* 2018:98-102.
20. Wei RH, Lu DQ, Jin N, Du B: Interpretation of the International Myopia Institute white papers focusing on myopia prevention and control. *Recent Advances in Ophthalmology* 2019, 39:701-713.
21. Expert consensus on the workflow of myopia screening for children and adolescents(2019). *Chinese Journal of Optometry Ophthalmology and Visual Science* 2019:1-4.
22. Marran LF: Validity and reliability of the revised convergence insufficiency symptom survey in children aged 9 to 18 years. *Optometry and vision science : official publication of the American Academy of Optometry* 2004, 81(7):489; author reply 489-490.
23. Kang MT, Li SM, Peng X, Li L, Ran A, Meng B, Sun Y, Liu LR, Li H, Millodot M *et al*: Chinese Eye Exercises and Myopia Development in School Age Children: A Nested Case-control Study. *Sci Rep* 2016, 6:28531.
24. Sussman M: The Program for Better Vision; 1998.
25. Yongchen ZYZ: Analysis on Treatment of Oculopathy in "Acupuncture DaCheng". *Journal of Zhejiang Chinese Medical University* 2016, 40(8).
26. Krisanaprakornkit T, Krisanaprakornkit W, Piyavhatkul N, Laopaiboon M: Meditation therapy for anxiety disorders. *The Cochrane database of systematic reviews* 2006(1):Cd004998.

27. Wu SD, Lo PC: Inward-attention meditation increases parasympathetic activity: a study based on heart rate variability. *Biomedical research (Tokyo, Japan)* 2008, 29(5):245-250.

Figures

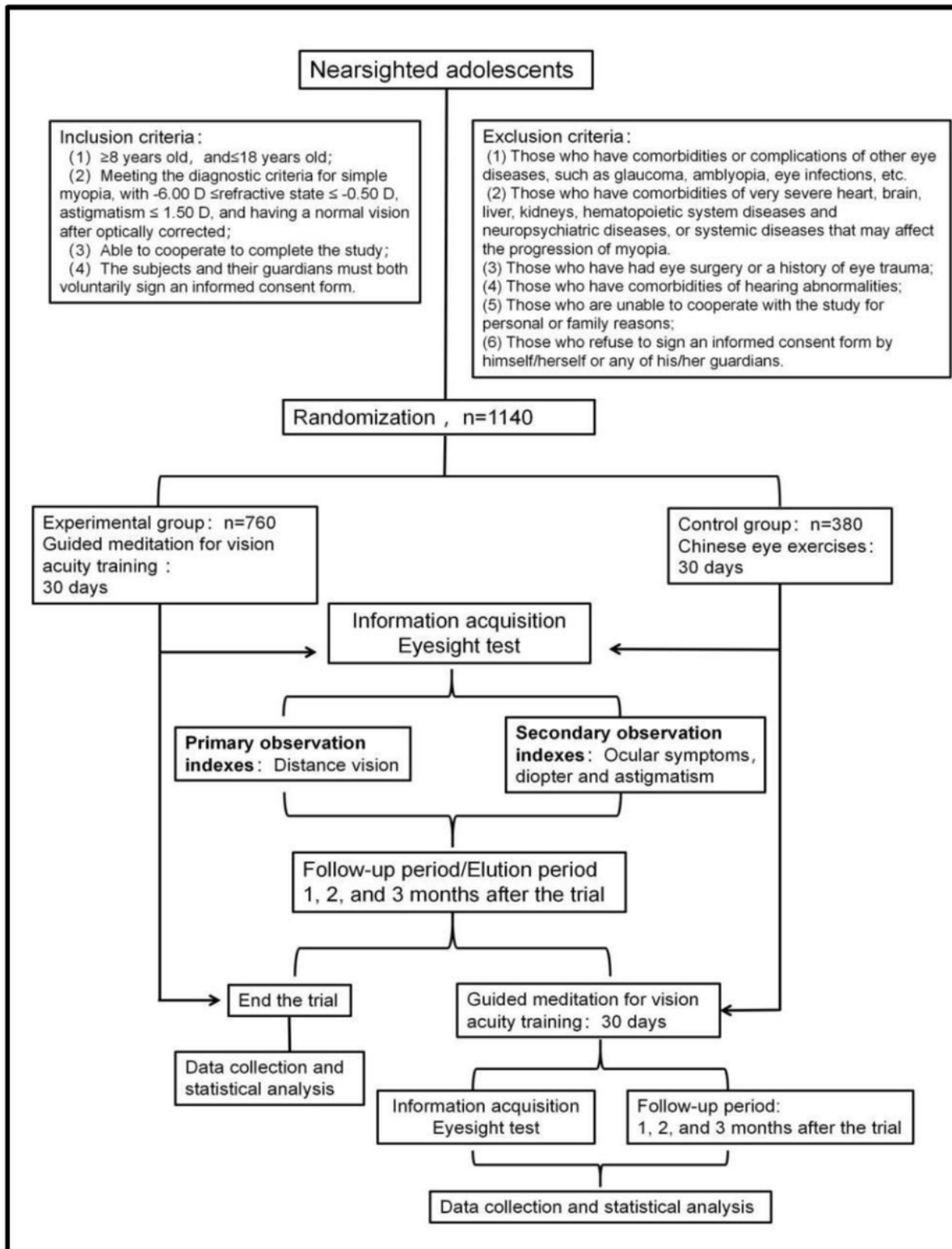


Figure 1

Study design

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRIT.doc](#)