Original Article

Immediate Effect of Auriculotherapy on Exam Anxiety among Naturopathy Medical Students: A Protocol for Randomized Controlled Trial.

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ABSTRACT

Background: Anxiety characterized by tension, worries, resulting unfavorable reactions in the physical body. Educational institutions use examinations to evaluate students' learning and comprehension, this may hamper their scholastic performance because of anxiety, which leads to psychosomatic disturbance before, during, and sometimes after tests resulting in exam anxiety. Medical students reported higher rates of anxiety and depression. Extreme anxiety can hinder their ability to manage the stress response during examinations. Anxiety can be effectively managed through complementary and alternative medicines. Auriculotherapy is a less invasive method effectively reducing the anxiety through stimulation of vagus and trigeminal nerves of the ear. **Objectives:** Primary objective is to assess the immediate effect of auriculotherapy in reducing anxiety levels, heart rate and blood pressure among medical students. **Materials and method:** This study adapts randomized controlled design. 60 subjects will be recruited by using convenient sampling technique from Naturopathy medical college, Tamil Nadu and randomized into study and control group. Study group will receive auriculotherapy on ear Shenmen and Point Zero for 3 hours whereas control group will not receive any intervention. The assessment will be done 30 mins before the exam and after the completion of the exam (3 hours). **Results:** The outcome variables are Hamilton Anxiety Rating Scale (HMA-A), Blood pressure (BP) and Heart rate (HR). We have framed the strong hypothesis based on which we expecting positive results on HMA-A scale, HR, and BP. **Conclusion:** The study will confirm the effect of auriculotherapy on exam anxiety among university exam appearing naturopathy students.

Key words: Anxiety, Traditional Chinese medicine, Auriculotherapy, Alternative medicine, Complementary therapy, Blood pressure

Anxiety is an irrational fear of an unbalanced future accompanied by muscle tension and caution when facing potential hazards according to Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Anxiety leads to unfavorable physiological reactions in the body. In severe condition, disrupting physical symptoms are triggered in daily life [1-2]. Educational institutions use examinations to evaluate students' learning and comprehension, this may hamper their scholastic performance because of anxiety, which leads to psychosomatic disturbance before, during, and sometimes after tests resulting in Exam anxiety [3]. Medical students reported higher rates of anxiety and depression, while compared to students in other professional courses. Their mental state is influenced by the large amount of clinical and academic overloads [3, 4].

Although some levels of anxiety are necessary for academic success, extreme anxiety such as overthrowing emotions, negative thoughts about the exams can hinder their ability to manage the stress response during examinations [4]. This condition is based on the individual's perception on situation, this perceived anxiety symptoms and its intensity can be assessed through various anxiety rating scales. Hamilton anxiety rating scale is valid and dependable for use in educational institutions for assessing anxiety levels of the students [5]. Anxiety can be managed through several therapies like conventional medicine, psychotherapy, complementary and alternative medicines, or integrative treatments. In that acupuncture can effectively alleviate situational and other types of anxieties [6]. Acupuncture is a simple and cost effective Chinese medical treatment involving in insertion of fine needles at precise points in the body [7].

Auriculotherapy is a branch of acupuncture and it is a less invasive method to stimulates nerves innervating the ear (i.e. Vagus and Trigeminal nerve) [8, 9]. This send si to central nervous system through the cranial/spinal nerves, and it also helps to balances the energy flow by stimulating the specific points this inhibits inappropriate reflexes and modulates the

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physiological response through release of certain neurotransmitters (norepinephrine and serotonin) [10, 11]. This can activate or deactivate certain brain structures, belongs to the anxiety's neurobiology [2].

Previous studies observed that auricular acupuncture at tranquilizing points induced the parasympathetic activation and maintains the lower frequency /higher frequency ratio of heart rate variability at lower levels in post operative patients [12]. Thereby we hypothesis that auriculotherapy at Shenmen and Point Zero will alleviate the exam anxiety immediately after few minutes of needling. From our search knowledge, there are many research study emphasizing the effect of auriculotherapy on anxiety till today, this is the first of its kind to evaluate the immediate effect of auriculotherapy on anxiety. Hence, the aim of this study is to investigate the immediate effect of auriculotherapy on alleviating exam anxiety among medical students. The objective is to assess the immediate effect of auriculotherapy in reducing anxiety levels among medical students and to evaluate the immediate impact of auriculotherapy on heart rate and blood pressure among medical students.

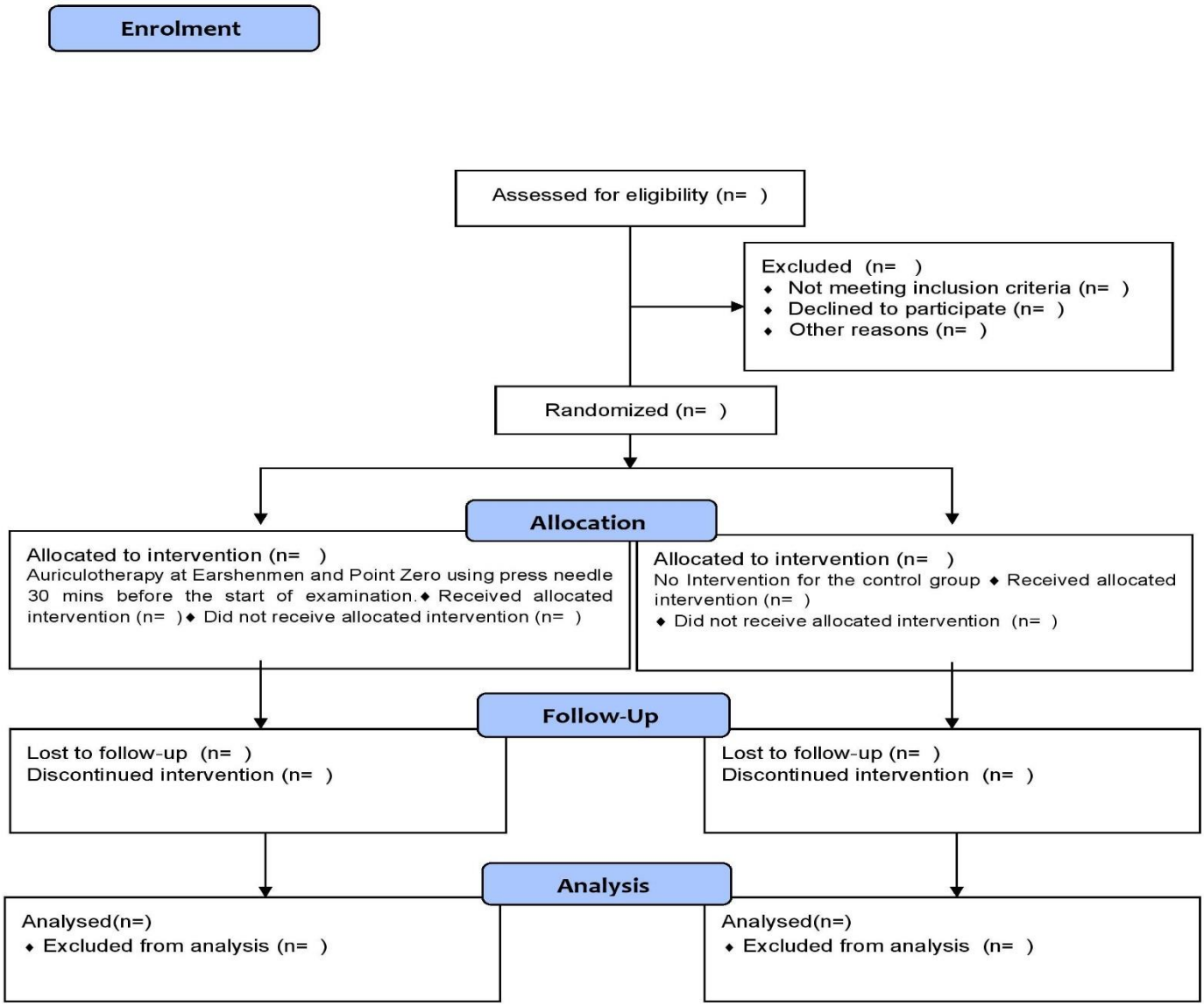

Fig 1: CONSORT flow diagram

MATERIALS AND METHODS

Trial design: A randomized control study design will be adopted for this study. All the eligible subjects will be divided into 2 groups. The study group will undergo needling at Shenmen and Point Zero with press needles on bilateral ears, while the control group will be only observed without any intervention. Questionnaire assessments, heart rate and blood pressure will be assessed 30minutes before the start of exam and after the completion of exam. The detailed trial design illustrated in the figure 1 [13].

Study setting

Around 60 Participants will be recruited from International Institute of Yoga and Naturopathy Medical Sciences,

Chengalpattu, Tamil Nadu, India. A detailed symptomatic assessment history will be taken to collect information on in- and exclusion criteria one day before examination. After which the participants will be recruited and randomized into study and control group. The inclusion criteria of the participants are of age group: 18- 20 years, first year Undergraduate Naturopathy medical students appearing for university examinations, without alcohol abuse or use of opioid or psychotropic medication within 24 hours prior to the study, students who are willing to give their consent. Participants with open wounds, burns or scalds in the ears, who had alcohol or psychotropic medication within 24 hours prior to the study, infection and inflammation in the ear, who have needle phobia, allergic to adhesive tape will be excluded from the study.

Intervention

Study group: We have used auricular press needling based on Traditional Chinese Medicine theory to improve the exam anxiety among university exam appearing students for the first time. Participants will receive needles at ear shenmen and point zero bilaterally, using PCS PINPAI size 0.22mm diameter, 1.5mm length auricular press needle just 30minutes prior to the university exam, the needles will be retained in situ for (3 hours- duration of the exam) till the completion of the exams and they will be advised to avoid touching or pressing the needles. The acupuncture will be performed by a trained doctor licensed from Tamil Nadu Medical Registration Board with 3 years of clinical experience. The location of the auricular points and needles used for this study are given in table 1 [14] and figure 2.

Table 1: Location of the auricular points

Points	Auricular Zone	Location	Rationale
Shenmen	TF 2	Located in the triangular fossa of the ear.	Tranquilizing the mind, Homeostasis, pain relief, relaxation.
Point Zero	HX 1/CR 1	Found in a notch on the helix root at LM_0, where the vertically ascending helix root rises from the more horizontal concha ridge.	Homeostasis, producing a balance of energy, hormones, and brain activity.

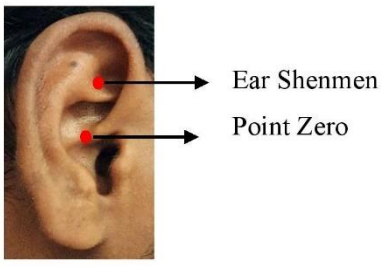

Fig 2: Location of the points used in the study

Control group: Control group participants were observed without giving any intervention and the assessment will be done before and after the study.

Outcomes

Primary outcome: The Hamilton anxiety rating (HMA-A) Scale will be used to measure the severity of anxiety symptoms. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item is scored on a scale of 0 (not present) to 4 (severe), in the total score of less than 17 indicates mild, 18-24 moderate, 25-30 moderate to severe [5].

Secondary outcome: Blood pressure (BP) and heart rate (HR) will be assessed in sitting position 30 mins before the exam by using a non-invasive arm type automatic blood pressure monitor (Accusure AS9 Autometic BP monitor). Minimum of two- measurements with the rest period of 3-min between the measurements and averaged to get a final value. In case of difference between the two-measurements by >10- mmHg, a third measurement will be taken after 3-min of rest period followed by the second measurement and the average of the two- measurements which did not differ >10-mmHg were averaged to get a final value.

Participant timeline

Participants will be randomized into two groups after screening. Both study and control group assessed for baseline test using self-reported HMA-A scale questionnaire, heart rate, and blood pressure. After which they will receive intervention based on group they were allocated and post assessment will be done after university completion of university examination. The detailed participant timeline illustrated in the figure 3.

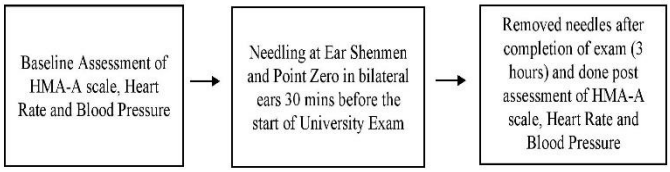

Fig 3: Participant timeline

Sample size calculation

Among 390 students at International Institute of Yoga and Naturopathy Medical Sciences, about 100 students are in first year of their academic study. A power analysis was conducted using G*Power version 3.1.9.7 to calculate the sensitivity of effect size for the study. Assuming a standard alpha of 0.05 and a power 95%, as it is preliminary study we have taken n=30 in group 1, and n=30 in group 2 and an initial calculation yielded 96% of effect size, so we finalize sample size as 60.

Recruitment

The subjects will be recruited from International Institute of Yoga and Naturopathy Medical Sciences using convenient sampling method after registration in the clinical trial registry India.

METHODS

Allocation & Sequence generation

Participants will be randomly divided (1:1 ratio) into either study group or control group using simple random methods with the use of lottery randomization. A simple randomization procedure will be performed for 60 subjects with 1:1 ratio to get a sample size of (n=30) in each group. Allocation concealment will be done using Sequentially Numbered Opaque Sealed Envelope (SNOSE) technique.

Blinding

The subjects, investigator will not be blinded.

Data collection

Data collection will be performed after getting approval from Institutional Ethical Committee (IEC) and after registration of clinical trials registry – India (CTRI). Study protocol will be explained to the subjects and a signed consent will be obtained from each subject. Collected informed consent form will be stored by principal investigator with due care. Primary outcome variable Hamilton anxiety rating scale data will be collected, Secondary data blood pressure and heart rate will be collected by primary investigator at baseline and 3 hours after of intervention (completion of the exam).

Data management

All participants are assessed after recruitment. The collected data will be set up in Excel spreadsheets with concealment of participant identification and all relevant data will be coded. Administration, coordination, and monitoring (including setting up and data entry) will also fall under the scope of data managers. The analysis's findings must be kept confidential until the publication of the results.

Statistical methods

R statistical version 3.4.2 will be intended to use for the statistical analysis. Extracted data will be analyzed for its mean and standard deviation with confident interval (CI) of 95%. P value of >0.05 will be indicated as normal for Gaussian distribution. The Wilcoxon test will be used to analyze the normality of study, and point-biserial correlation will be used to measures the strength and direction of the association between a continuous variable and a binary variable.

Data monitoring

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

Research studies reported severe adverse reactions associated with acupuncture needle are rare. However, some minor effects take place rarely at the site of needling like infection, inflammation, pain, brushing and bleeding while removing the needles. 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 International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu, Tamil Nadu, India.

RESULT

This study intended to evaluate the effect of ear Shenmen, Point Zero on exam anxiety among exam appearing naturopathy students. Study group participants HAM-A score may reduce upto 40-50% in the post intervention. Their reduced anxiety level might be maintained for certain period of time till they experience next hike of anxiety situation. The intergroup difference in the parameters can be anticipated with the p value less than 0.05. The detailed Pre and Post assessment of data will be provided in table 2. We have framed the strong hypothesis based on which we expecting positive results on HMA-A scale, HR, BP.

Table 2: Pre and Post assessment of the study

Parameters		Pre-test	Post-test
Date and time of assessments		***	***
HAM-A Scale		***	***
Heart Rate (cpm)		***	***
Blood pressure	Systolic BP (mm/hg)	***	***
	Diastolic BP (mm/hg)	***	***

DISCUSSION

The study result anticipates that auriculotherapy at ear Shenmen and Point Zero will reduce the anxiety level of the participants in the study group. This can also lower the heart rate and blood pressure of the individual's undergoing intervention.

Based on theories of Traditional Chinese Medicine (TCM), Auriculotherapy mechanism of action explained through somatotropic function by the presence of pluripotent cells in the ear that contain information about the entire organism, the rich

innervation and blood supply of the auricular region, and it has relation with organs and meridians [15]. Ear shenmen acupoints innervated by a branch of the vagus nerve, which associated with anti-inflammatory and calming actions by altering the concentrations of neurotransmitters and 5 hydroxytryptamine and adrenocorticotropic hormone in nerve cells [16]. Auricular shenmen and point zero modulate the functional connectivity amygdala-prefrontal, anterior cingulate cortex, and cerebellum which plays key role in modulate the psychiatric, neuromuscular and functional disorders [17] by above mentioned mechanism of action these points may affect the exam anxiety positively.

Previous research studies showed, acupuncture at ear Shenmen and Brainstem points reduced the symptoms of stress in nursing students [18]. Auriculo-acupuncture reduces the symptoms of anxiety and levels of the salivary cortisol immediately after the intervention [19]. Mahboubeh Valiani et, al. (2018) showed that auriculotherapy decreases the levels of depression, anxiety and stress in patients with Multiple sclerosis by needling at Shenmen, Zero point, and 10 other points [20]. Another research study showed auriculotherapy on Shenmen and 5 other points reduced the levels of anxiety [21].

The limitation of the study would be the non-blinded study design, with small sample size, without heterogenicity of the participant group. This might affect the generalizability of the study. The future direction of the study can be done with large sample size with double blinding, assessing the levels of salivary cortisol and stress levels for warrant the effect of auriculotherapy in reducing the exam anxiety to a better extent.

CONCLUSION

Auriculotherapy at Ear Shenmen and Point Zero will reduce the exam anxiety among university exam appearing naturopathy students. Thereby, it will reduce the heart rate and blood pressure due to the parasympathetic activation by stimulation of vagus nerve. Hence auriculotherapy could be used in managing the stress, anxiety levels and other psychological issues of the individuals in academic, professional field due to sympathetic hyperactivation. This study addresses a specific gap in complementary therapy literature by examining the immediate impact of auriculotherapy on exam anxiety and serves as a foundation for further exploration in immediate effect of naturopathic stress management.

Ethics and dissemination

Research ethics approval

This study protocol follows SPIRIT 2013 and CONSORT 2010 guidelines. Received Institutional ethics committee (IEC) clearance from International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu-603001, IEC/IIYNMS/Approval/ 066/2024, dated 28-6-2024.

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 get signed in the written format.

Consent

Study protocol will be explained to the subjects and a signed informed consent will be obtained from each participant before recruitment.

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 analyst 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

Dissemination policy: Results will be published online along with statistics code open access for all including common public.

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