



## Clinical trial

## Clinical effect of auricular acupuncture in anxiety levels of students prior to the exams: A randomized controlled trial

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## ABSTRACT

**Introduction:** Students are exposed to various challenges that trigger anxiety in relation to their academic requirements. Some studies suggest that auricular acupuncture, may improve anxiety. This study aimed to evaluate the clinical effect of Auricular Acupuncture (AA) on the anxiety-levels of university students.

**Methods:** An experimental, prospective, randomized, controlled and single-blinded study was conducted. The sample included university students (N = 69), unfamiliar to acupuncture, under no psychotropic medication, with no known psychiatric or thyroid disorders. Individuals were randomly allocated to the Experimental Group (EG, n = 25): verum AA points; Placebo Group (PG, n = 22): sham AA points in neurological segments distinct from the verum AA and the Control group (CG, n = 22): without any AA treatment. One week prior to the examination period at the University, subjects were treated with AA using semi-permanent needles placed for 48 h. Anxiety assessments were conducted using the State Anxiety Inventory (STAI), the Visual Analogue (VAS) for anxiety, and a scale on the neurovegetative status based on a scored analysis of the tongue according to the principles of Traditional Chinese Medicine (SN-TCM)

**Results:** 69 students (49 women; 20 men) participated in this study, 15,5% showing moderate to severe states of anxiety, and 12% some trace of anxiety. We found a significant reduction of the anxiety levels in the experimental group, according to STAI-form Y1 (p = 0,031), VAS (p = < 0.01) and SN-TCM (p = < 0.01).

**Conclusion:** AA seems effective in reducing exam-related anxiety in university-level students, as corroborated by an SN-TCM and VAS for anxiety tests.

## 1. Introduction

Anxiety is one of the most frequent clinical behavioural disorders, affecting both physical and emotional states and inducing changes in behaviour and cognition [1,2]. In respect of emotional states, individuals can express feelings of fear, insecurity, apprehensive anticipation, catastrophic thinking and increased time of alert [1,2]. Anxiety is a natural response, resulting in a sign of fundamental alert in humans to respond a given danger [3]. However, anxiety can become pathologic when excessive and uncontrollable. In this sense, physical health is also compromised due to hormonal changes and consequent decrease of the immune system activity, which may promote the development of various conditions such as cancer, chronic musculoskeletal pain, respiratory diseases, cardiovascular and infectious [4,5].

In order to treat anxiety, conventional medicine relies on medicines such as benzodiazepines [6], antidepressants [7], barbiturates [8] and

antihistamines [9]. However, Western medicine cannot resolve all anxiety diseases and the risk of side effects and resistance to pharmacological treatment affects approximately one in three patients with anxiety disorders [10,11].

Auricular Acupuncture (AA) is a technique similar to reflexology. It is speculated that this technique might work in anxiety because groups of pluripotent cells contain information from the whole organism and create regional organization centres representing different parts of the body, through the recruitment of more cortex cells dedicated to specific areas of the body [12]. Thus, stimulation of a reflex point in the ear may relieve symptoms of distant pathology by the stimulation responses of reticular formation and the sympathetic and parasympathetic nervous systems [13]. The information that comes from the thermal, algic and proprioceptive stimuli are transmitted from the auricular pavilion by the fibers of the trigeminal nerve, auricular magnum and minor occipital (sensitive branch of the cervical plexus), and the vagus nerve

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[14,15,12]. The vagus nerve is responsible for the parasympathetic innervation of the lung, heart, stomach and small intestine, as well as the pharynx and larynx muscles, and it also sends information to important brain regions in the regulation of anxiety (locus coeruleus, orbitofrontal cortex, hippocampus and the amygdala) George et al., 2008. In turn, the trigeminal nerve mainly controls the mastication muscles and the facial sensitivity. Finally, the cervical plexus innervates muscles of the neck, diaphragm and thorax [16,17].

As we shown in a preliminary study, there was a tendency for a reduction of anxiety levels after 30 min, with AA treatment [18]. The effect was even more effective and significant after 48 h of the experimental session. In this sense, we run a new study with a larger sample and new variables. It aimed at exploring the clinical effect of AA on the anxiety-levels of university students as assessed by the State Anxiety Inventory (STAI), the Visual Analogue (VAS) for anxiety, and a scale on the neurovegetative status based on a scored analysis of the tongue according to the principles of Traditional Chinese Medicine (SN-TCM). Therefore, we expect a reduction in anxiety in the experimental group, but not in the placebo and control groups.

## 2. Methods

### 2.1. Participants

This study was approved by the Ethics Committee of Abel Salazar Biomedical Sciences Institute (ICBAS), University from Porto, Portugal. Written informed consent was obtained from all students before study enrollment.

The sample in this study included university students (N = 69; 49 women; 20 men; age (mean ± s.d.): 20.8 + 4.71 years; weight: 62.1 + 9.16 kg; height: 1.69 + 0.07 m; body mass index: 21. 73 + 2. 25 kg/m<sup>2</sup>), unfamiliar to acupuncture, under no psychotropic medication, and with no psychiatric or thyroid disorders. Initially, informed consent, questionnaire evaluation of the criteria for participation, inventory psychopathological symptoms (BSI); Inventory trait-state anxiety (STAI) were delivered to all those interested in participating in this study. From these 69 students, 15,5% showed moderate to severe states of anxiety, and 12% showed some trace of anxiety (Figs. 1 and 2).

Prior to the formation of experimental groups, and to ensure greater uniformity, students selected for the study were divided into four groups according to the level of trait anxiety achieved by one of STAI (Y2 form): a group of students not anxious at all, a group of students a little anxious, a group of moderately anxious students, and a group a very anxious students. Assessments were made 5 min before (T2), 30 min (T3) and 48 h after (T4) the needling (Fig. 4).

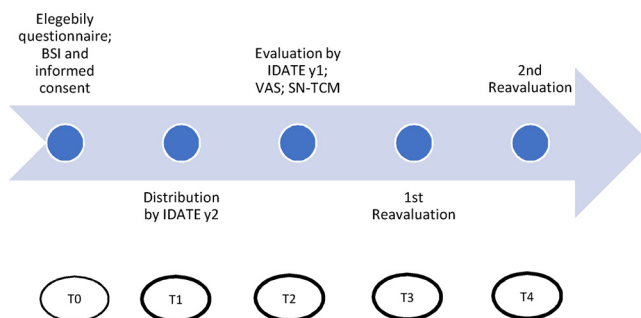


Fig. 2. Diagram of the experimental study procedures 2 weeks prior the examinations. Time: T0 to T1 – 4 days; T1 to T2 – 3 days; T2 to T3 – 5 min and T3 to T4 – 48 h.

### 2.2. Study design

An experimental, prospective, randomized, controlled and single-blinded study was conducted [19]. Participants were randomly allocated to the Experimental group (EG, n = 25), Placebo group (PG, n = 22) and Control group (CG, n = 22). Prior to the formation of experimental groups, and in order to ensure the highest homogeneity, the students selected for the study were divided into four groups according to the level of anxiety-trait obtained through one of the forms of the IDATE (form Y2) in: group of students not at all anxious, group of students not very anxious, a group of moderately anxious students, and a group of very anxious students. Subsequently, the students were divided into 3 groups: control group (students who did not receive auricular acupuncture treatment); placebo group (students receiving placebo acupuncture treatment); experimental group (students who received acupuncture treatment for anxiety). It should be noted that the distribution of students by these three groups was not totally random in that homogeneous groups were used in terms of trace-anxiety. Thus, each student extracted a random paper of an opaque envelope corresponding to his group of anxiety. In the opaque envelope were papers defined with the letter A, B and C, referring to experimental treatment, placebo treatment and control treatment, respectively. The EG consisted in auricular acupuncture with semi-permanent needles (ASP) 3 mm, sterilized, including toning needles (ASP gold), dispersive needles (ASP silver) in points: i) diazepam, II) lung parenchyma, III) anxiety, IV) psychosomatic and V) joy. per 48 h. In the Placebo group the ASP were applied on auricular acupuncture points in neurological segments distinct from the EG: i) articulation of the right hand, ii) foot joint right, iii) left hand joint, iv) joint of the left foot and v) shoulder joint per 48 h. Lastly, the control group without any auricular acupuncture treatment. For more details, please consult Vieira et al. [18].

In respect of the placebo group, criteria for point selection included: auricular acupuncture in points without any influence on anxiety, according to TCM; two points located on the non-dominant ear and 3 points in the dominant ear, to cover the nerve trigeminal irrigation zone, i.e., outside the dermatomes of auricular points of the study group. The group of auricular points selected in the study: “Diazepam” “anxiety,” ‘psychosomatic’ and “joy” are located in the pinna at the cervical plexus irrigation zone; on the other hand the point “pulmonary parenchyma” is in the dermatome of the vagus nerve of the ear, rather than regular acupuncture needles, once the effects of the puncture can be maintained for several days of stimulation, prolonging the treatment effect [18]. At the end of the study, participants of the placebo and control groups had the opportunity to receive the same AA treatment then the study group.

### 2.3. Anxiety measures

Anxiety level was assessed using the STAI form Y1, the VAS for anxiety and the SN-TCM (Gretten [32]). The students' level of anxiety

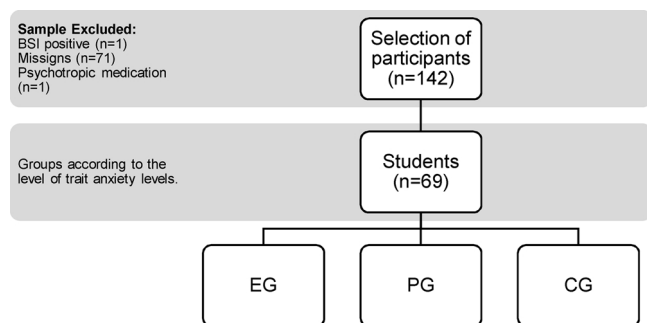


Fig. 1. Sample selection and distribution across the different experimental conditions. EG – experimental group: auricular acupuncture session for the treatment of anxiety n = 25; PG – placebo group: auricular placebo acupuncture session n = 22. CG – Control group: without auricular acupuncture session n = 22.

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