UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE ODONTOLOGIA DE PIRACICABA

MARIA JÚLIA CHARAMITARA SUPINO

EFEITOS ANSIOLÍTICOS DA AURICULOTERAPIA EM JOVENS E ADULTOS

ANXIOLYTIC EFFECTS OF AURICULOTHERAPY IN YOUNG PEOPLE AND ADULTS

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Trabalho de Conclusão de Curso apresentado à Faculdade de Odontologia de Piracicaba da Universidade Estadual de Campinas como parte dos requisitos exigidos para obtenção do título de Cirurgião Dentista.

Undergraduate final work presented to the Piracicaba Dental School of the University of Campinas in partial fulfillment of the requirements for the degree of Dental Surgeon

Orientador: Prof(a). Dr(a). Maria da Luz Rosário de Sousa

Coorientador: Prof(a). Dr(a). Talita Bonato de Almeida

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RESUMO

A ansiedade é um distúrbio psiquiátrico que pode se tornar incapacitante. Por possuir alta prevalência entre os brasileiros e manejos seguros de seus sintomas devem ser explorados, como as práticas integrativas. O objetivo deste estudo foi avaliar a efetividade de uma sessão única de auriculoterapia no manejo da ansiedade em jovens e adultos com níveis de ansiedade de moderado a alto. Os voluntários foram randomizados em 2 grupos, sendo que no Grupo Auriculoterapia Real foi realizada uma sessão de auriculoterapia utilizando pontos para controle da ansiedade, e Grupo Auriculoterapia Placebo, o qual recebeu pontos sem valores terapêuticos para ansiedade (linha coluna lombar). Os níveis de ansiedade foram classificados a partir da escala Visual Analogue Scale (VAS) e Inventário de Ansiedade Traço-Estado (IDATE), os quais foram coletados nos momentos inicial (antes da sessão) e tardio (após 4 dias). Os voluntários tiveram sua energia mensurada pelo método Ryodoraku nos momentos inicial, final (após a sessão) e tardio. A análise das medidas do Ryodoraku evidenciou uma regulação da energia especialmente nos meridianos relacionados a terapia escolhida para cada grupo, sendo que no Grupo Real o meridiano em questão foi o do Intestino Delgado (equivalente ao protocolo de pontos escolhidos para ansiedade), e no Grupo Placebo foi o meridiano da Bexiga (relacionado aos pontos da linha lombar). O presente estudo demonstrou que a uma única sessão de auriculoterapia foi capaz de reduzir os escores de ansiedade VAS e IDATE comparando o momento incial e tardio, em voluntários jovens e adultos nos grupos teste e placebo.

Palavras chave: Ansiedade. Auriculoterapia. Medicina Tradicional Chinesa. Meridianos. Terapias Complementares.

ABSTRACT

Anxiety is a psychiatric disorder that can be disabling, causing suffering. As it has a high prevalence among Brazilians, intensified by COVID-19 pandemic, safe management of its signs and symptoms should be explored, such as integrative practices. The aim of this study was to evaluate the effectiveness of a single session of auriculotherapy in the management of anxiety in young people and adults with levels of anxiety classified as moderate to high. The volunteers were randomized into 2 groups: in the Real Auriculotherapy Group, an auriculotherapy session was performed using points to control anxiety, and the Placebo Auriculotherapy Group, which received points without therapeutic values for anxiety (lumbar spine line). Anxiety levels were classified using the Visual Analogue Scale (VAS) and State-Trait Anxiety Inventory (STAI), which were collected at the initial (before the session) and late (after 4 days) moments of the study. The volunteers also had their energy measured by the Ryodoraku method at the beginning, final (after the session) and late of the study. Both real and placebo therapy were able to reduce VAS and STAI anxiety scores comparing early and late times. All volunteers started the study with an average of general energy in deficiency, which still had a reduction in the final and late moments. The Ryodoraku measures showed a regulation of energy especially in the meridians related to the therapy chosen for each group, and in the Real Group the meridian in question was the Small Intestine, and in the Placebo was the Bladder meridian (related to the points on the lumbar line). The present study demonstrated that a single session of auriculotherapy was able to reduce anxiety in young and adult volunteers in both groups, and there was a change in the energy profile in the real and placebo groups.

Keywords: Anxiety, Auriculotherapy, Traditional Chinese Medicine, Meridians, Complementary Therapies.

SUMÁRIO

1 INTRODUÇÃO

Ao final do século XIX, a ansiedade ainda não havia sido reconhecida como uma doença separada. Entretanto, característicos transtornos de ansiedade já eram observados, mas classificados por nomenclaturas diferentes (Crocq, 2015).

A ansiedade se trata de uma resposta natural do organismo humano, proveniente de estímulos que causem apreensão e mal-estar pela antecipação de um perigo, proveniente de uma fonte desconhecida. Quando esse sentimento é persistente, a ansiedade é considerada um transtorno, podendo se tornar incapacitante e passando a interferir na qualidade de vida (Dellovo et al., 2019).

Em escala global, a ansiedade está entre as principais causas que levam a incapacidade funcional e é considerada a condição psiquiátrica de maior prevalência na União Europeia, chegando a atingir 60 milhões de pessoas (Organização Panamericana de Saúde, 2022).

Durante a situação pandêmica do COVID-19 em 2020, Goularte et al. (2021) evidenciam o impacto negativo da pandemia nas pessoas, a partir do aumento dos problemas psiquiátricos na população, que devem ser considerados como um problema de saúde pública no Brasil. O estudo demonstra que 81,9% dos entrevistados relataram ter sintomas de ansiedade, sendo o maior índice em comparação aos demais sintomas psiquiátricos.

Entre os manejos frequentemente adotados para o controle da ansiedade, os ansiolíticos são amplamente utilizados, os benzodiazepínicos são os fármacos mais procurados e sua prescrição para tratamento da ansiedade é comum. Entretanto, as adversidades desses medicamentos, incluem seu uso indiscriminado e a alta prevalência do quadro de dependência entre os usuários, se administrado em períodos superiores a um ano. (Freire et al., 2022)

As práticas integrativas foram legitimadas no Brasil a partir da década de 80, após a criação do Sistema Único de Saúde. São abordagens para o tratamento e prevenção de efermidades, que consideram o ser humano como um ser integral, unindo corpo, mente e espírito. Terapias como a acupuntura, fitoterapia e shiatsu estão englobadas na Medicina Tradicional Chinesa (MTC) e apresentam resultados

eficazes para manejo da ansiedade, além de sua baixa toxidade e baixo custo (Oliveira e Pasche, 2022).

Dentre as terapias integrativas, para este estudo foi utilizada a auriculoterapia, a qual se trata de uma terapia tradicional chinesa a partir da estimulação de pontos auriculares reflexos relacionados a canais energéticos, os meridianos. A aplicação do tratamento se baseia na inserção de pontos terapêuticos na orelha, resultando em pressão de sementes no acuponto auricular desejado. (Zhang et al., 2020). Baseado na Medicina Tradicional Chinesa, tratar desequilíbrios energéticos por meio da estimulação de pontos que tenham a propriedade de restabelecer o equilíbrio do organismo, como na auriculoterapia, resulta no livre fluxo de Qi pelos meridianos e melhora dos sintomas (Wen e Cultrix, 2011).

Dellovo et al. (2019) apontaram em seu estudo sobre pacientes submetidos a extração de terceiro molar, um procedimento odontológico que costuma causar ansiedade nos pacientes, uma comparação entre a auriculoterapia e o ansiolítico midazolam, que foram administrados em grupos diferentes antes do procedimento. O estudo demostrou que a auriculoterapia teve efeito equivalente ao fármaco no controle da ansiedade, sem os efeitos colaterais indesejáveis, como alucinções e amnésia. A auriculoterapia vem demonstrando efetividade e segurança, com poucas contraindicações.

Assim, a busca por tratamentos para ansiedade tem levado cada vez mais pessoas a buscarem por ansiolíticos e nem sempre agir de forma integral para o controle da mesma. A auriculoterapia é uma prática complementar, assim, outros tipos de tratamento também devem ser buscados para resultados satisfatórios. O objetivo desse estudo foi avaliar o efeito de uma única sessão de auriculoterapia e seu impacto na redução dos escores de ansiedade e no perfil energético dos voluntários.

2 ARTIGO: ANXIOLYTIC EFFECTS OF AURICULOTHERAPY IN YOUNG PEOPLE AND ADULTS

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Abstract

Anxiety is a psychiatric disorder that can be disabling, causing suffering. As it has a high prevalence among Brazilians, intensified by COVID-19 pandemic, safe management of its signs and symptoms should be explored, such as integrative practices. The aim of this study was to evaluate the effectiveness of a single session of auriculotherapy in the management of anxiety in young people and adults with levels of anxiety classified as moderate to high. The volunteers were randomized into 2 groups: in the Real Auriculotherapy Group, an auriculotherapy session was performed using points to control anxiety, and the Placebo Auriculotherapy Group, which received points without therapeutic values for anxiety (lumbar spine line). Anxiety levels were classified using the Visual Analogue Scale (VAS) and State-Trait Anxiety Inventory (STAI), which were collected at the initial (before the session) and late (after 4 days) moments of the study. The volunteers also had their energy measured by the Ryodoraku method at the beginning, final (after the session) and late of the study. Both real and placebo therapy were able to reduce VAS and STAI anxiety scores comparing early and late times. All volunteers started the study with an average of general energy in deficiency, which still had a reduction in the final and late moments. The Ryodoraku measures showed a regulation of energy especially in the meridians related to the therapy chosen for each group, and in the Real Group the meridian in question was the Small Intestine, and in the Placebo was the Bladder meridian (related to the points on the lumbar line). The present study demonstrated that a single session of auriculotherapy was able to reduce anxiety in young and adult volunteers in both groups, and there was a change in the energy profile in the real and placebo groups.

Keywords: Anxiety, Auriculotherapy, Traditional Chinese Medicine, Meridians, Complementary Therapies.

Introduction

Anxiety is a natural response of the human organism to a stimulus that causes uncertainty, apprehension, restlessness and discomfort due to the anticipation of a danger, coming from an unknown source. When disabling, anxiety starts to interfere with the individual's quality of life and becomes pathological [1].

Globally, anxiety is listed as one of the top ten causes of functional disability worldwide, being considered the most prevalent psychiatric condition in the European Union, with approximately more than 60 million people affected by this condition [2]. Today it is known that, when untreated, especially in the early stages of life, its sequelae can last into adulthood [3].

Goularte et al. (2021) show the high prevalence of psychiatric symptoms in the population, indicating that the negative impact of the COVID-19 pandemic on the mental health of Brazilians needs to be considered a public health problem in the country. According

to the survey, 81.9% of respondents reported having symptoms of anxiety, which is the highest rate compared to other psychiatric symptoms [4].

As a therapeutic approach, anxiolytics are used on a large scale. Specifically, benzodiazepines are among the most commonly prescribed drugs for anxiety in the world. Its indiscriminate use, for periods longer than one year, was pointed out as a situation of dependence among users [5].

Integrative medicine approaches patients in an integral way, taking into account the biological, psychological, social and spiritual aspects of health and illness. In Brazil, the legitimation and institutionalization of these practices in health care began in the 1980s, after the creation of the SUS. Among the integrative practices, the techniques included within Traditional Chinese Medicine (TCM) stand out, such as: acupuncture, herbal medicine and shiatsu [6], which are considered effective therapies for anxiety control and with better cost-benefit compared to to the side effects caused by benzodiazepines [7].

Auriculotherapy is an ancient technique that treats dysfunctions and promotes analgesia through stimuli in reflex points located in the auricle, which can be used both for prevention and treatment of diseases [8]. Studies involving auriculotherapy demonstrate its effectiveness in controlling anxiety in the most diverse populations, including adults and the elderly [9], in patients before dental procedures [1] and even women in labor [8], in which the results were statistically positive regarding the improvement of anxiety when comparing patients in placebo and control groups.

In addition, a comparative study between auriculotherapy and the anxiolytic midazolam showed that auriculotherapy had an effect equivalent to the drug in the control of anxiety, but without the undesirable side effects, such as hallucinations and anterograde amnesia [1]. Currently, the treatment options available for anxiety present toxicity, risk of dependence, side effects, in addition to limited efficacy [2]. Auriculotherapy has shown high effectiveness for the control of anxiety, in addition to safety, low toxicity and dependence, with few contraindications [9,10].

In view of this, the present study aims to analyze the effectiveness of a single auriculotherapy session in the control of anxiety.

Materials and methods

Randomized, blind clinical study with volunteers who had anxiety, collected at the Faculty of Dentistry of Piracicaba (FOP) and at the Reference Center for Primary Care (CRAB) in the Cecap neighborhood in the city of Piracicaba/SP, approved by the Research Ethics Committee of the FOP under CAAE 48437921.1.0000.5418.

To participate in the clinical study, volunteers must sign the Free and Informed Consent Form, be 18 years of age or older and less than 40 years of age, have a self-reported Visual Analogue Scale (VAS) for anxiety greater than or equal to 4.0 and obtain score of 31 or more on the State-Trait Anxiety Inventory (STAI). Volunteers who used medications with anxiolytic effects or therapies to control anxiety, as well as patients with allergic reactions to tape or micropore, were excluded.

The sample size calculation was performed using the G*Power 3.1.5 software (Universitat Dusseldorf, Dusseldorf, Germany), which determines a sample size considering the distribution of the study design; the statistical test and the power of the analysis method. The following input determinants were considered: sampling power (1-β = 0.80), significance level (α= 0.05), the mean effect size d= 0.60, which was observed in the

comparative study by Klausenitz et al. (2016). The analysis indicated a sample size of 24 participants for each group. In order to reduce the effects of possible losses, a margin of 20% (n=29) was added. Therefore, the estimated sample has 58 patients, who will be randomly distributed into two groups.

Volunteers were randomized into the following study groups:

Real Auriculotherapy Group (Group A): volunteers received a single auriculotherapy session following Dr. Huang (Figure 1, Table 1). After 4 days of the session, the volunteers had to return for the removal of the seeds.

Placebo Auriculotherapy Group (Group B): Volunteers received auriculotherapy at points on the lumbar line (unrelated to treatment for anxiety). After 4 days of the session, the volunteers had to return for the removal of the seeds (Figure 1).

Chart 1: Points used in the auriculotherapy protocol and their respective functions.

Shenmen, Occipital and Subcórtex	Regulation of cerebral cortex function, promoting sleep facilitation.
Liver	Elimination of Qi stagnation, avoiding symptoms such as irritability, insomnia and depression.
Heart	Calms the mind, calms the spirit and reestablishes the balance between Yin (characterized by the overexcitation of the sympathetic system, with symptoms such as palpitation and irritability) and Yang (when in deficiency in the Heart, there are symptoms such as insomnia, memory loss, body weakness and force).
Anxiety	It calms the mind, treating symptoms such as mental agitation, low spirits, insomnia and restlessness.
Happiness	It treats pathologies related to sadness and depression, alleviating symptoms such as fatigue, physical exhaustion and mood swings.

(Garcia, 1999)[11]

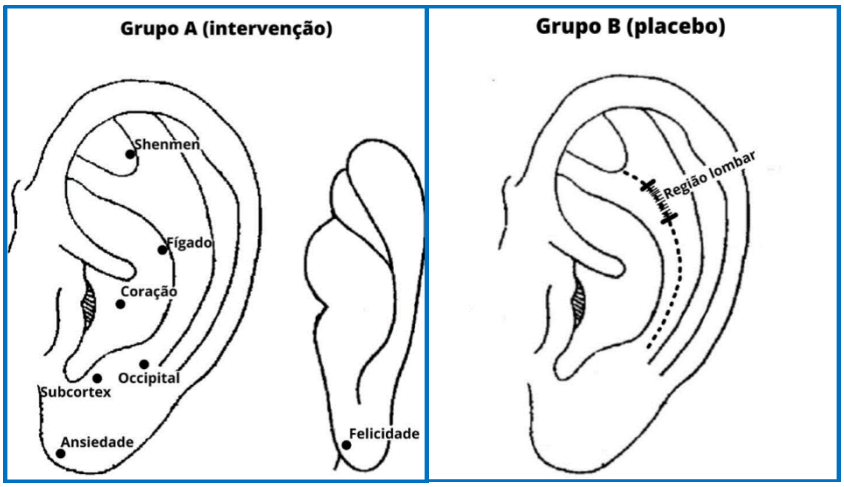

Figure 1: Auricular map with intervention points (Group A) and placebo points (Group B).

Outcomes

In order to know the patients' demographic data, a questionnaire was applied at the beginning of the research to obtain age and sex.

For the analysis of anxiety, the VAS and STAI parameters were used, both applied at the moment before the auriculotherapy (initial moment) and after 4 days of the session (late moment), and Ryodoraku, applied at the initial, final (shortly after the end of the session) and late moment, as shown in Table 2.

Chart 2: Moments of the study of data collection related to VAS, STAI and Ryodoraku.

	VAS	**STAI**	**Ryodoraku**
Initial	X	X	X
Final			X
Late	X	X	X

The subjective measurement of anxiety reported by the patient was performed using the VAS [12], which was applied using the following question: “At this moment, how do you rate your anxiety, with 0 being no anxiety and 10 being maximum anxiety?”. In this study, the scale was analyzed in an absolute and relative way, being divided according to the intensity of anxiety reported by the patient (no anxiety: VAS = 0; mild anxiety: VAS = greater than 0 to 3.9; moderate anxiety: equal or greater than 4 to 7.9; intense anxiety: equal to or greater than 8 [13]).

For the objective assessment of anxiety, the STAI was used, which consists of the individual's self-perception of their state of anxiety and of their personality characteristics, and can be divided into trait anxiety (TA), which refers to the persistent and persistent anxiety state. lasting and may be associated with the individual's personality, being invariable in the face of situations experienced, and state anxiety (AE), which refers to a temporary anxiety condition, usually related to a specific situation or phase of life [14]. Each scale consists of a questionnaire with 20 objective statements, in which each one relates to four alternatives: absolutely not; a little; quite; very much. In the present study, subjects were classified as no anxiety (below 19), mild anxiety (between 20 and 30 points), medium (between 31 and 49 points) or high (above 50 points). Thus, volunteers with VAS greater than or equal to 4.0 and STAI greater than or equal to 31 participated in this study.

And for energy measurement of the patients, the Ryodoraku method was used, which consists of measuring the individual's circulating energy using 24 acupuncture points, twelve on each side of the body, based on the presence of the 12 bilateral meridians [15,16].

The volunteers were randomized according to the order in which they started the study, with the odd-numbered individuals allocated to the Real Group and the even-numbered

individuals to the Placebo Group, and the study was blinded to the volunteers, who did not know which protocol they were receiving. .

Statistical analysis

The effects of auriculotherapy were assessed by the outcome analysis of the VAS, STAI Status and Trait and energy level measures generated by Ryodoraku. The intragroup analysis for each variable was performed using the t test and the analysis between groups was performed using the ANOVA test followed by the post hoc Bonferroni test. The variables were analyzed using the SPSS statistical analysis program, using a significance level of 5%.

Results

The sample consisted of 48 individuals, who were randomized equally among the intervention groups, consisting of 24 people in each group. For the analysis of the VAS and STAI, 3 individuals did not complete the questionnaires at the late stage, so for these variables the statistical analysis was performed with 21 individuals in each group. The average age of the participants was 22 years, and the groups were similar in terms of sex (p=0.146).

There was a reduction in anxiety scores at baseline and late in the study in both groups in the VAS, STAI-State and STAI-Trait variables.

Table 1. Mean of the VAS, STAI-State and STAI-Trace variables in the initial and late intra-group moments. Piracicaba/SP, 2022.

	REAL			**PLACEBO**		
	Initial	**Late**	**p**	**Initial**	**Late**	**p**
VAS	6,60	4,80	**0,000**	5,90	3,80	**0,000**
STAI-STATE	46,00	40,50	**0,004**	41,70	37,90	**0,044**
STAI-TRACE	46,20	42,80	**0,011**	47,20	42,70	**0,001**

T test

Table 2 shows the analysis between groups of VAS, STAI-State and STAI-Trace in the initial and late moments, showing a numerical reduction only in the variables VAS and STAI-State (p>0.09).

Table 2: Means of VAS, STAI-State and STAI-Trace at baseline and end points between study groups. Piracicaba/SP, 2022.

	Initial			**Late**		
	Real	**Placebo**	**p**	**Real**	**Placebo**	**p**
VAS	6,60	5,90	0,090	4,80	3,80	0,082

STAI-State	46,00	41,70	0,165	40,50	37,90	0,504
STAI-Trace	46,20	47,30	0,766	42,80	42,70	0,990

ANOVA

Figure 2 shows the count of the number of cases according to the level of anxiety established by the VAS, STAI-State and STAI-Trait at the beginning of the study, showing that the variables VAS and STAI-State had more severe cases in the Real group.

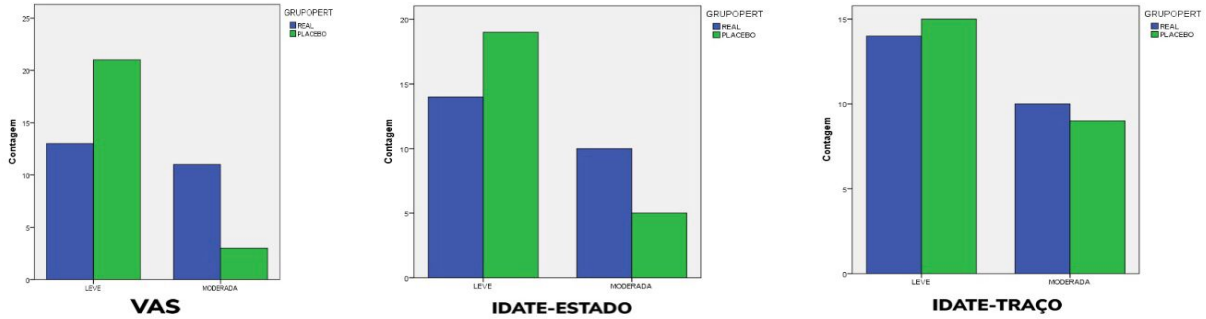

Figure 2: Count of individuals classified by level of anxiety by VAS, STAI-State and STAI-Trait at the beginning of the study, according to the groups.

Figure 3 shows similar reductions in anxiety (without anxiety) in the Real and Placebo groups for the STAI-State and STAI-Trait variables at the late stage of the study.

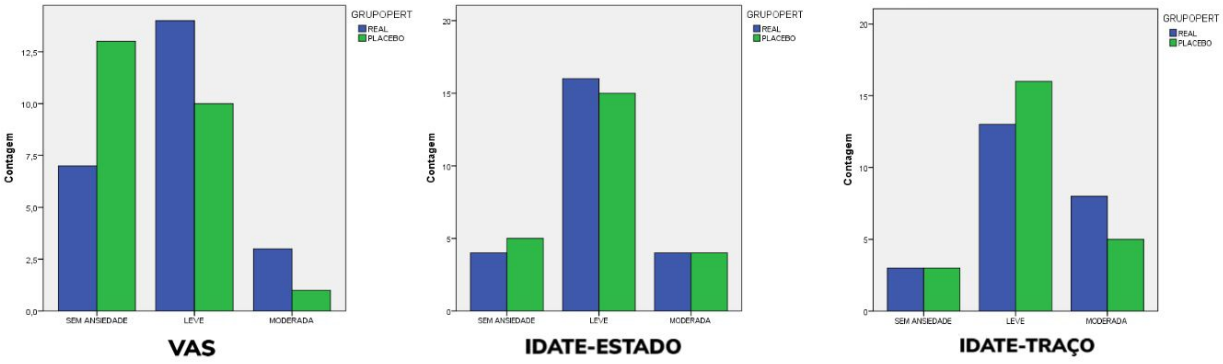

Figure 3: Count of individuals classified by level of anxiety by VAS, STAI-State and STAI-Trait at the late stage of the study, according to groups.

Table 3 shows the analysis of initial, final and late energy averages according to Ryodoraku.

Table 3: Comparison of energy averages in the initial, final and late moments between the study groups, verified by Ryodoraku (in mA). Piracicaba/SP, 2022.

	Initial			**Final**			**Late**		
	Real	**Placebo**	**p**	**Real**	**Placebo**	**p**	**Real**	**Placebo**	**p**

Lung	23,70	28,90	0,250	14,40	19,80	0,099	23,90	25,40	0,771
Pericardium	17,70	17,90	0,952	11,10	12,20	0,597	17,80	15,60	0,523
Heart	14,20	17,20	0,329	9,00	12,30	0,211	14,30	15,90	0,623
Small Intestine	18,10	25,30	0,150	11,00	20,30	**0,019**	16,20	25,20	**0,043**
Triple Energizer	23,60	28,70	0,278	14,90	21,80	0,073	23,10	29,60	0,148
Large Intestine	22,40	27,80	0,289	15,00	23,00	0,064	24,60	29,90	0,353
Spleen	18,90	20,80	0,365	16,00	17,00	0,685	19,80	16,10	0,105
Liver	18,70	20,60	0,494	15,40	16,50	0,639	20,10	18,40	0,565
Kidney	19,50	26,30	0,143	15,40	21,90	0,075	21,70	19,50	0,538
Bladder	9,40	10,80	0,456	12,20	12,50	0,827	13,50	9,60	**0,034**
Gallbladder	12,70	14,90	0,440	9,40	12,80	0,131	12,10	12,10	0,993
Stomach	19,40	24,90	0,134	15,40	21,00	0,088	19,20	20,30	0,769

T test

The analysis of Table 3 shows that, between the groups, the energy averages at the final moment (p=0.019) and late (p=0.043) in the Small Intestine meridian were lower than the initial energy in the Real group. On the other hand, in the Bladder meridian in the Placebo Group, it is observed that the mean energy at the late moment decreased in relation to the energy at the initial moment (p=0.034).

Table 4 shows the energy analysis of each meridian at the early and late times and at early and late times within each study group.

Table 4: Mean energy of the meridians comparing the initial and final and initial and late moments, in the study groups, verified by Ryodoraku (in mA). Piracicaba/SP, 2022.

	REAL						**PLACEBO**					
	Initial	**Final**	**p**	**Initial**	**Late**	**p**	**Initial**	**Final**	**p**	**Initial**	**Late**	**p**
Lung	23,70	14,40	**0,000**	23,70	23,90	1,000	28,90	19,80	**0,000**	28,90	25,40	0,845
Pericardium	17,70	11,10	**0,000**	17,70	17,80	1,000	17,90	12,20	**0,000**	17,90	15,60	0,998
Heart	14,20	9,00	**0,001**	14,20	14,30	1,000	17,20	12,30	**0,002**	17,20	15,90	1,000
Small Intestine	18,10	11,00	**0,001**	18,10	16,20	1,000	25,30	20,30	**0,029**	25,30	25,20	1,000
Triple Energizer	23,60	14,90	**0,000**	23,60	23,10	1,000	28,70	21,80	0,**003**	28,70	29,60	1,000
Large Intestine	22,40	15,00	**0,000**	22,40	24,60	1,000	27,80	23,00	**0,032**	27,80	29,90	1,000
Spleen	18,90	16,00	0,081	18,90	19,80	1,000	20,80	17,00	**0,015**	20,80	16,10	**0,039**
Liver	18,70	15,40	0,101	18,70	20,10	1,000	20,60	16,50	**0,023**	20,60	18,40	0,639
Kidney	19,50	15,40	0,111	19,50	21,70	1,000	26,30	21,90	0,078	26,30	19,50	0,071
Bladder	9,40	12,20	**0,002**	9,40	13,50	**0,022**	10,80	12,50	0,084	10,80	9,60	1,000
Gallbladder	12,70	9,40	**0,010**	12,70	12,10	1,000	14,90	12,80	0,151	14,90	12,10	0,072
Stomach	19,40	15,40	**0,008**	19,40	19,20	1,000	24,90	21,00	0,**009**	24,90	20,30	0,123

T test

The comparison of the average initial and final energy of the Real Group showed that the meridians of the Spleen, Pancreas, Liver and Kidney maintained energy, while the others showed a decrease. Comparing the average of the initial and late energy of the Real Group, it can be seen that all meridians recovered the initial energy, except for the Bladder meridian, which presented higher energy than the initial one (p=0.022).

The comparative analysis of the mean initial and final energy of the Placebo Group showed a reduction in energy in all meridians, with the exception of the Kidney, Bladder and Gallbladder meridians which maintained their initial energies. Comparing the average of the initial and late energies of the Placebo Group, it can be seen that all meridians recovered their initial energies, with the exception of the Spleen Pancreas, which had its energy reduced (p=0.039).

No side effects of auriculotherapy were identified in the present study.

Discussion

The present study demonstrated that a single session of auriculotherapy reduced anxiety in young adult volunteers, when measuring both Trait and State with the VAS and the STAI instrument, both in the test group and in the placebo group.

According to TCM, the treatment of energy imbalances through the stimulation of reflex points that have the property of restoring the balance of the organism, as in auriculotherapy, results in the free flow of Qi through the meridians and improvement of symptoms [17].

The anxiolytic effects promoted by auriculotherapy are widely known in the health area, generating little or no adverse effects [9,10]. In our study, mustard seeds were used because, in addition to being non-invasive, they are more accepted than needles for anxious patients [18].

The analysis of VAS, STAI-State and STAI-Trait showed that the means of these variables reduced equally within each study group, evidencing the reduction of anxiety in both groups in a similar way, leading to questioning the effectiveness of the selected points in the group test and/or influence of other factors on this reduction.

However, when evaluating the distribution of such variables, it was noticed that VAS and STAI-State had more cases classified as moderate in the Real Group, which leads us to suggest that in future studies, the equitable separation of individuals in the groups by severity, so that there is no such disproportionality in the severity of anxiety cases. On the other hand, it can be pondered that, when achieving results of decreasing anxiety, but with higher degrees, this group with real auriculotherapy can be considered with more positive effects than the placebo group.

In our study, the Ryodoraku method was able to detect changes in the energy profile of anxious patients under placebo and real treatment, demonstrating that all volunteers started the study with low general energy averages (deficiency), and that after the therapies there was still a reduction in these averages. , corroborating the findings in the literature [19,20].

In the analysis between the groups, it was identified that the pattern of the Small Intestine meridian is different from the other meridians, because in it the energy averages at the initial and final moments show an energy reduction, but at the late moment the energy recovery did not occur in the Real Group. According to the MTC, the Fire element is what

governs the Small Intestine [21], which is directly related to anxiety, so the results of the study suggest that the Real Group volunteers had a greater energy expenditure, which may indicate a beginning of balance. On the other hand, in the Bladder meridian, the opposite occurred: the average energies were initially equal at the initial moment, with a proportional reduction after the real and placebo therapies. However, in the end, a greater decrease in energy was observed in the Placebo Group, in which points from the lumbar line were used, which are closely linked to the Bladder meridian, presenting a greater energy expenditure in search of balance in the Placebo Group [21].

In the present study, the Placebo Group also presented an anxiolytic effect, as did the Real Group, as documented in the literature, as documented in the literature, probably due to the placebo effect, which may involve several psychological aspects, such as the expectation of treatment [22] and the reinterpretation of stimuli with emotional impact [23], and can contribute to the creation of a biological system and physiological reactions that can be of great importance during a treatment [24]. Considering the variety of existing auricular maps, the stimuli caused by the seeds in the Placebo Group showed therapeutic results, although the points used are for the lumbar line and are not directly related to the reduction of anxiety. However, we can admit that blinding the volunteers was successful because, although points with different analgesic effects and in different regions were used, the volunteers recruited were laymen on the subject and did not know how to identify the exact location of the points. As all volunteers were treated in the same way, one cannot deny the effect of the reception and treatment of all who presented with anxiety, which may have contributed to the placebo effect of this therapy.

Thus, the present study brings an innovation in the field of integrative and complementary practices, presenting results of measures already used to measure anxiety in the literature, such as VAS and STAI, and energy measures that are still little used, captured by Ryodoraku. Both the Placebo Group and the Real Group showed a reduction in anxiety, however more studies should be carried out to explain the placebo effect. As a limitation of the present study, we could highlight the possibility of expanding the sample size of the study and dividing the intervention groups according to the severity of anxiety.

Interesting analyzes on the energy patterns of the volunteers were observed in this study, being able to detect the body's energy expenditure in search of balance and bringing data that may have subsequent interpretations regarding the study of the energy profile of anxious volunteers in the face of integrative therapies.

Competing interest

The authors declare that they have no competing interests.

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3 CONCLUSÃO

De acordo com os resultados obtidos nesse estudo foi possível concluir:

- A partir da análise das medidas do Ryodoraku, uma regulação da energia especialmente nos meridianos relacionados a terapia escolhida para cada grupo foi evidenciada, sendo que no Grupo Real o meridiano em questão foi o do Intestino Delgado (equivalente ao protocolo de pontos escolhidos para ansiedade), e no Grupo Placebo foi o meridiano da Bexiga (relacionado aos pontos da linha lombar.

- Uma única sessão de auriculoterapia foi capaz de reduzir a ansiedade em voluntários jovens e adultos tanto no grupo teste como no grupo placebo, e houve alteração do perfil energético nos grupos real e placebo.

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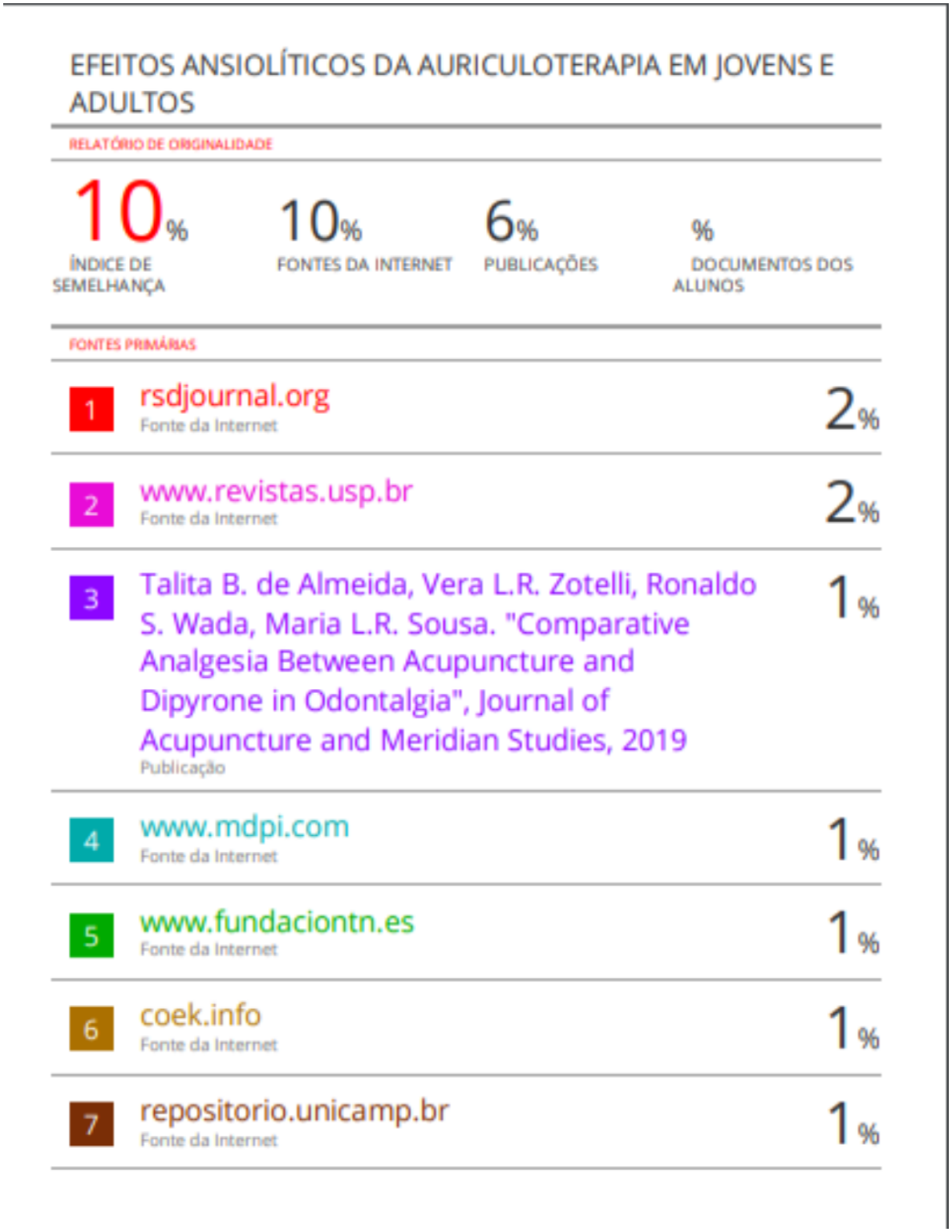
ANEXOS

Anexo 1 – Verificação de originalidade e prevenção de plágio



EFEITOS ANSIOLÍTICOS DA AURICULOTERAPIA EM JOVENS E ADULTOS

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Anexo 2 – Comitê de Ética em Pesquisa

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Continuação do Parecer: 4.934.867

Considerações Finais a critério do CEP:
Parecer de aprovação de Protocolo emitido "ad referendum" conforme autorização do Colegiado na reunião de 03/02/2021. O parecer será submetido para homologação na reunião de 01/09/2021.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1776810.pdf	20/08/2021 09:23:02		Aceito
Outros	Outros.pdf	20/08/2021 09:22:34	TALITA BONATO DE ALMEIDA	Aceito
Outros	Respostaparecer.pdf	11/08/2021 10:19:32	TALITA BONATO DE ALMEIDA	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	11/08/2021 10:19:12	TALITA BONATO DE ALMEIDA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	11/08/2021 10:19:00	TALITA BONATO DE ALMEIDA	Aceito
Declaração de Pesquisadores	DeclaraPesquisadores.pdf	05/08/2021 08:16:11	TALITA BONATO DE ALMEIDA	Aceito
Declaração de Instituição e Infraestrutura	DeclaraInstituicao.pdf	23/06/2021 17:02:34	TALITA BONATO DE ALMEIDA	Aceito
Folha de Rosto	Folhaderosto.pdf	23/06/2021 17:02:09	TALITA BONATO DE ALMEIDA	Aceito
Outros	Altinfra.pdf	22/06/2021 14:46:34	TALITA BONATO DE ALMEIDA	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

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Anexo 3 – Iniciação Científica

Relatório Final

Efeitos Ansiolíticos da Auriculoterapia em Jovens e Adultos

Versão enviada em 13/09/2022 23:22:58 ver relatório

— **Parecer do orientador emitido em 14/09/2022 19:23:51**

Desempenho do aluno no projeto: A aluna se empenhou muito na coleta dos dados e mesmo nestes tempos de reposição de aulas e clínicas conseguiu cumprir o cronograma de coleta e ter tempo para digitação, análise e discussão de seus resultados, o que demonstrou maturidade e responsabilidade da aluna e um ótimo desempenho.

Desempenho acadêmico do aluno: A aluna manteve suas atividades e teve muito bom desempenho acadêmico

— **Parecer do Assessor dado em 27/09/2022 16:30:05**

O relatório está bem estruturado e os resultados apresentados de forma adequada.

● Aprovado

Anexo 4 – Comprovante de submissão do Artigo

Universidade Estadual de Campinas
Faculdade de Odontologia de Piracicaba

Prof. Yuan Shiun Chang
Editor-in-Chief
Journal of CAM Research Progress

November, 2022

Subject: Submission of a manuscript for evaluation

Dear Editor,

I would like to submit the manuscript entitled "Anxiolytic Effect of Acupuncture: a randomized clinical trial in comparison with phytotherapy" by Maria Júlia Charamitara Supino, Gabriela Cateb Ramos, Talita Bonato de Almeida, Maria Lúcia Bressiani Gil, Maria Imaculada de Lima Montebello and Maria da Luz Rosário de Sousa to be considered to publication as an original article in Journal of CAM Research Progress.

We declare that this manuscript is original, has not been published before and is not currently being considered for publication elsewhere.

We declare that this manuscript do not have conflits of interest.

All authors have approved the manuscript for submission.

The manuscript sent for evaluation demonstrates that a single session of auriculotherapy was able to reduce anxiety in young and adult volunteers and this reduction was captured by an objective method (using State-Trait Anxiety Inventory), a subjective method (using Visual Analogue Scale) and a energetic method (Ryodoraku), which demonstrated that auriculotherapy can be used in integrative and complementary treatments.

Thank you for your consideration.

Maria da Luz Rosário de Sousa