



Experimental and placebo auriculotherapy for stressed nurses: randomized controlled trial

Auriculoterapia verdadeira e placebo para enfermeiros estressados: ensaio clínico randomizado
Auriculoterapia verdadera y placebo para enfermeros estresados: ensayo clínico randomizado

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ABSTRACT

Objective: To compare the efficacy of experimental auriculotherapy and placebo auriculotherapy with sham points for the treatment of stress in nurses of a charity hospital in São Paulo. **Method:** Randomized, single-blind, controlled trial. The sample consisted of 168 nurses with medium and high stress levels according to the List of Stress Symptoms (LSS). The participants were randomized to three groups: Auriculotherapy (G1), Placebo (G2) and Control (G3). Groups 1 and 2 received 12 sessions, twice a week. The points used in Group 1 were: Shenmen and Brainstem; in Group 2 the points were: External Ear and Face Area. The three groups were evaluated at baseline, after eight sessions, 12 sessions and in a follow-up (after 15 days). **Results:** Group 1 achieved a 43% reduction and a 1.81 Cohen d index (high effect), presenting statistical difference after eight sessions, maintained in the follow-up evaluation ($p < 0.001$), according to Analysis of Variance. Group 2 achieved a 26% reduction, with Cohen's d index of 0.86 (great effect), achieving a difference after 12 sessions ($p < 0.001$), maintained in the follow-up ($p < 0.05$). The G3 did not present stress reduction. **Conclusion:** Experimental auriculotherapy achieved greater stress reduction among nurses, but there was no statistical difference between the two intervention groups. Brazilian Registry of Clinical Trials: RBR-req2792

DESCRIPTORS

Auriculotherapy; Burnout, Professional; Nursing; Placebos; Complementary Therapies.

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INTRODUCTION

In the early twentieth century, the endocrinologist Hans Selye called “General Adaptation Syndrome” the set of similar non-specific responses in people who are experiencing distressing situations⁽¹⁾. In 1936, he began to use the word stress to define the physiological reactions of the organism when facing a situation that requires effort, triggered by a threatening stimulus. In his conception, stress consists of three successive stages: alarm stage, resistance and exhaustion. Stress is understood as a real or perceived threat to a person’s physical and psychological integrity, resulting in biological and behavioral responses. Situations considered new, unpredictable, ego threatening and/or uncontrollable can lead to physiological responses to stress, which are activated by the autonomic nervous system (ANS) and neuroendocrine system trying to find an adaptation to the stressful situation⁽²⁾.

Stress influences the psychosocial well-being of individuals, especially of workers. It can have negative consequences for the performance of Nursing professionals, affecting the institution and the work process with absenteeism, high turnover and low quality care⁽³⁾. Besides the physical, chemical and biological risks that exist in the workplace of nursing professionals, there are also psychosocial risks related to work, which have been identified as one of the major current challenges for the health of workers and are related to problems such as stress, violence and harassment at work⁽⁴⁾.

In Brazil, researchers have been interested in the study of work stress in Nursing since the 1990s, and strategies to minimize occupational stress among nurses need to be discussed. Research has shown that complementary health practices can be used as coping strategies for stress situations, improving quality of life⁽⁵⁻⁶⁾.

Auricular acupuncture or Chinese auriculotherapy, along with body acupuncture, is part of a set of therapeutic techniques based on the precepts of Traditional Chinese Medicine (TCM). It is an integrative and complementary practice approved as a specialty for health professionals in the Unified Health System (SUS – *Sistema Único de Saúde*), Ordinance No. 971⁽⁷⁾. The Federal Nursing Council established it as a Nursing specialty in Resolution No. 326/2008⁽⁸⁾.

Auriculotherapy presents some important advantages over other complementary practices, since it can be done with non-invasive materials, it is easy to apply, has minimal side effects, and can occur along with the Nursing care in the workplace itself⁽⁹⁾.

A randomized controlled trial (RCT) with nurses was proposed to evaluate the applicability and the effects of this technique, with a methodological design that would allow evaluating experimental and sham auriculotherapy. RCT is considered the gold standard for ascertaining the effectiveness of an intervention and for obtaining evidence for health care⁽¹⁰⁾. Regarding RCTs of acupuncture and auriculotherapy, several types of control groups have been proposed: waiting list, untreated control group, conventional treatment and sham interventions, which allow comparing the expected

outcome with the placebo effect and other non-specific effects⁽¹¹⁾. As for placebo in auriculotherapy, sham interventions usually include: superficial needling, insertion at non-points, non-penetrating sham needles, sham interventions without needling, minimal acupuncture, and insertion at irrelevant real points⁽¹²⁾. This last type of intervention was the one proposed in the present study for the placebo group, along with an untreated control group (waiting list), for evaluation of the two intervention groups compared to the control group.

There is controversy regarding the placebo effect, especially in acupuncture. A comparative study of placebo pills and acupuncture has estimated that the latter has a much stronger effect on pain management than a placebo pill⁽¹³⁾. Psychological mechanisms can influence the results of the procedure, including variables such as personal motivation, belief, previous experiences, memory and possible conditioning mechanisms. Considering this, the bond established between therapist and patient in frequent encounters can also be considered, since it can generate an increase in positive expectations about the treatment⁽¹⁴⁾. The placebo effect is a beneficial outcome of a treatment or procedure arising not from the treatment itself, but from the positive expectations of the patient about the treatment.

There are many auricular points and different charts used to determine them, so it is no simple task to find non-reactive sham points in the ear. This study was based on a protocol of auricular points that were previously tested for stress among nursing students and whose effects were positive for both true and sham auriculotherapy⁽⁶⁾. These results raised the question whether the beneficial effect of the sham points previously tested were due to an inadequate protocol or a response to placebo.

Thus, a new sham protocol was proposed and the RCT was repeated, not with Nursing students, but with nurses, changing one of the sham points used, the wrist point. Therefore, the objective of the present study was to compare the therapeutic efficacy of experimental and sham auriculotherapy for the treatment of stress levels identified in the nurses of a large Charity Hospital in São Paulo, comparing with a control group without intervention.

METHOD

This is a randomized, single-blind, controlled trial with three groups: experimental auriculotherapy (with points indicated for stress), sham auriculotherapy (with sham points), and control group (without any treatment). The study was conducted with nurses of the Hospital Beneficência Portuguesa in São Paulo, São Joaquim Unit, in 2014. The control group without intervention was a waiting list, and the participants of this group later received the auriculotherapy intervention for the same time and number of sessions.

For the definition sample size, an epidemiological survey with application of the stress level questionnaire and the socio-demographic data sheet was conducted for the characterization of the nurses. Approximately 290 nurses

from the three shifts and from various sectors were invited to participate in the study. Of these, 257 accepted to answer the stress and socio-demographic questionnaires. As shown in the flowchart (Figure 1), 89 people were excluded, 82

because they had a stress level below the inclusion criteria, five people with stress level above maximum and two people reported that they would be on vacation during the data collection period.

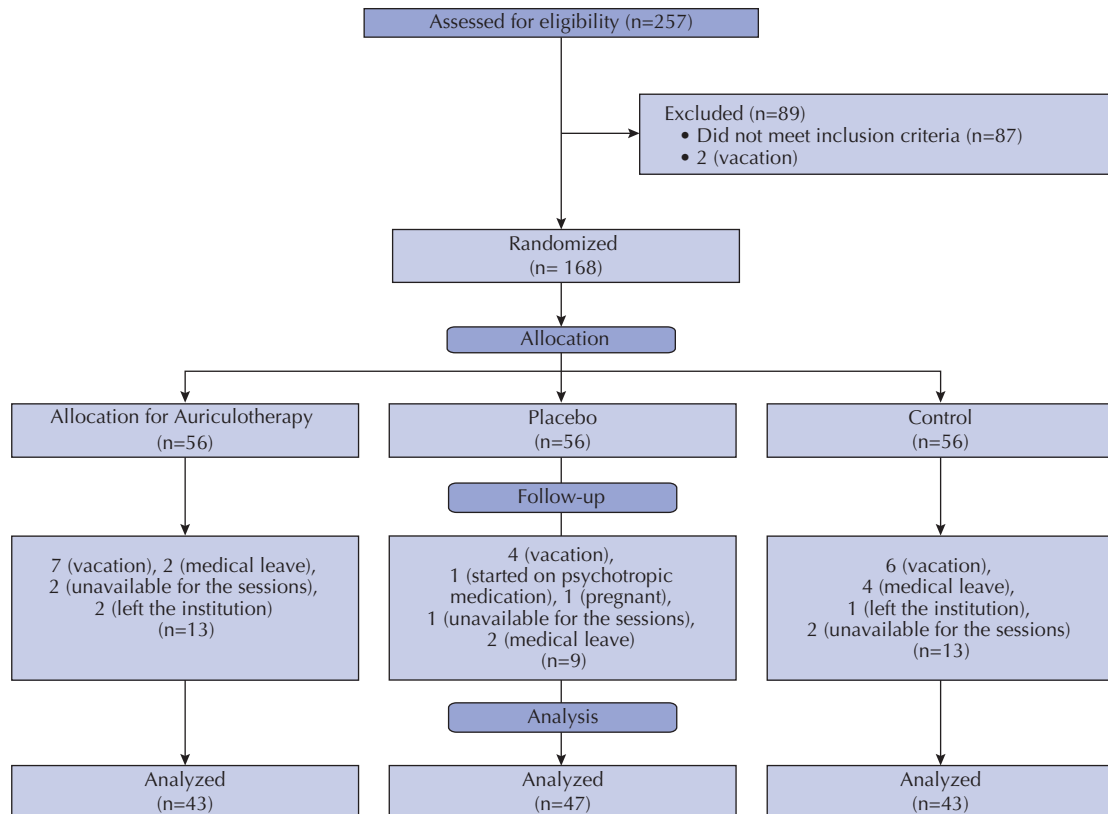


Figure 1 – Flowchart of participants involved in the study – São Paulo, SP, Brazil, 2014.

The sample consisted of 168 nurses who presented a stress score between 40 and 110 points on the List of Stress Symptoms (LSS). Since few people presented very high stress level, the level was limited to medium and high in order to obtain homogeneous samples. Other inclusion criteria were voluntary participation and availability for the auriculotherapy sessions.

From the inclusion criteria, the participants were randomized to the three groups by the Random Allocation Software, each group receiving 56 participants. Thirty-five people left the study. Because it involved human beings, the study complied with Resolution 466/2012 of the National Health Council and was approved by the Research Ethics Committees of the Universidade de São Paulo, Nursing School, protocol number 252.931 and CAAE 12449413.9.0000.5392 (04/09/2013) and by the Real e Benemérita Associação Portuguesa de Beneficência (cooperating institution) protocol 408.748 (9/25/2013). Data collection only began after explanation of the study and consent of the subjects, given by signing the Informed Consent Term (TCLE).

The Stress Symptom List (LSS) was used for data collection. It is a list of 59 psychophysiological and psychosocial

stress symptoms, in which the subject must associate one of four responses for each symptom: never (0), few times (1), often (2) or always (3). In this questionnaire, a score from 0 to 11 is considered null, from 12 to 29 low stress level, from 30 to 59 medium level, from 60 to 120 high level and above 120, very high level. This instrument is the result of an association between a list elaborated and validated at the Max Planck Institute in Germany and the Professional Psychologist's Stress Questionnaire⁽¹⁵⁾. A socio-demographic data questionnaire was also used to assess the following variables: age, gender, shift, sector, position, previous diseases and marital status.

All nurses who accepted to participate in the study had their stress levels evaluated after eight sessions (LSS1), at the end of 12 sessions (LSS2) and 15 days after the end of the applications (*follow-up*) (LSS3). The control group was also evaluated with the same frequency as the others. The auriculotherapy and placebo groups received 12 auriculotherapy sessions, twice a week.

For the auriculotherapy group, two points with calming properties were used, the Shenmen point and the Brainstem. As for the placebo group, the sham points chosen were External Ear and Face Area, as shown in Figure 2.

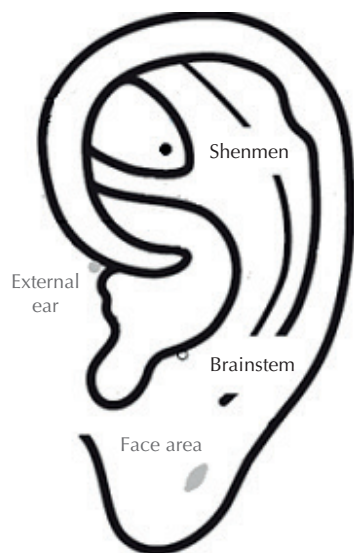


Figura 2 – Protocol of experimental and sham auriculotherapy – São Paulo, SP, Brazil, 2014.

DATA ANALYSIS

The data were submitted to descriptive statistical analysis using the Fisher’s exact test, with the statistical software R v 2.12.2. The mean and standard deviation values were calculated for the quantitative variables and the repeated measures analysis of variance (ANOVA) was used, with Tukey’s post-hoc test for inferential analysis, using the SPSS v.19. The size of the treatment effect was also verified by Cohen’s d index.

RESULTS

The mean age of the participants was 35 (\pm 8.4) years, and the distribution in the three groups was normal ($p=0.617$). The overall mean score in the baseline LSS for the 133 participants was 69.39 (\pm 17.7) points, corresponding to a high stress level, with homogeneity of distribution for the three groups ($p=0.317$), according to the Analysis of Variance (ANOVA).

Table 1 shows the frequencies and percentages of socio-demographic variables in the three groups.

Table 1 – Descriptive of frequency and percentages of socio-demographic variables in the three groups – São Paulo, SP, Brazil, 2014.

Variable	Factor	Auriculotherapy (n=43)		Placebo (n=47)		Control (n=43)		Total (n=133)		P (Fisher)
		N	%	N	%	N	%	N	%	
Gender	Female	40	93	44	93.6	42	97.6	126	94.7	0.700
	Male	3	7	3	6.4	1	2.3	6	5.3	
Shift	Morning	17	39.5	19	41.3	20	46.5	56	42.4	0.814
	Afternoon	11	25.6	17	37	13	30.2	41	31.1	
	Night	7	16.3	5	10.9	4	9.3	16	12.1	
	Commercial	8	18.6	5	10.9	6	14	19	14.4	
Sector	Management	11	25.6	6	12.8	9	20.9	26	9.5	0.462
	Open unit	21	48.8	29	61.7	20	46.5	70	52.6	
	Closed unit	11	25.6	12	25.5	14	43.6	37	27.8	
Position	Management	11	25.6	6	12.8	9	20.9	26	19.5	0.333
	Care	32	74.4	41	87.2	34	79.1	107	80.5	
Disease	No	19	44.2	27	57.4	22	52.4	68	51.5	0.463
	Yes	24	55.8	20	42.6	20	47.6	64	48.5	
Marital Status	Single	18	41.9	21	44.7	21	48.8	60	45.1	0.587
	Married	22	51.2	20	42.6	20	46.5	62	46.6	
	Divorced	2	4.7	6	12.8	2	4.7	10	7.5	
	Widow	1	2.3	0	0	0	0	1	0.8	

Nurses who did not directly work in patient care were classified as management of personnel, that is, coordination and supervision positions in sectors such as Hospital Infection Control Service, Continued Education, Nursing School, Graphic Methods and External and Internal Clinics. All the nurses who provided direct or indirect care to the patients were classified as care personnel.

Among all the shifts analyzed, in a total of 132 respondents, 89 had high levels of stress (67.4%). In the morning shift, out of the 56 participants, 35 (62.5%) had a high level

of stress; in the afternoon, of 41 participants, 26 (63.41%) had high stress level; of the 16 people working night shifts, 14 (87.5%) had high stress level; and in the commercial shift, of the 19 participants, 14 (73.7%) reported high levels of stress ($p=0.245$), according to Fisher’s exact test.

Of the 68 people who did not present a previous disease, 42 (61.8%) presented high stress level, and among the healthy ones, 47 had high stress level (73.4%), with $p=0.194$ (Fisher’s test). The most frequent diseases were Musculoskeletal Pain, followed by Migraine/Headache,

Systemic Arterial Hypertension, Hypothyroidism, Gastritis, Dyslipidemia, Diabetes Mellitus, among others.

As for the results of the ANOVA test for repeated measures, there were statistical differences in the analysis between the three groups ($p=0.000$) in the four moments. In Tukey's post hoc, a difference for the auriculotherapy group between the baseline and the second assessment (after eight

sessions) was found and maintained in the third evaluation (12 sessions) and in the follow-up ($p=0.000$) after 15 days.

In the placebo group, a statistically significant difference occurred between the baseline assessment and the third assessment, after 12 sessions of sham auriculotherapy ($p=0.001$), and was kept in the follow-up ($p=0.01$). Figure 3 illustrates the evolution of the three groups regarding stress levels.

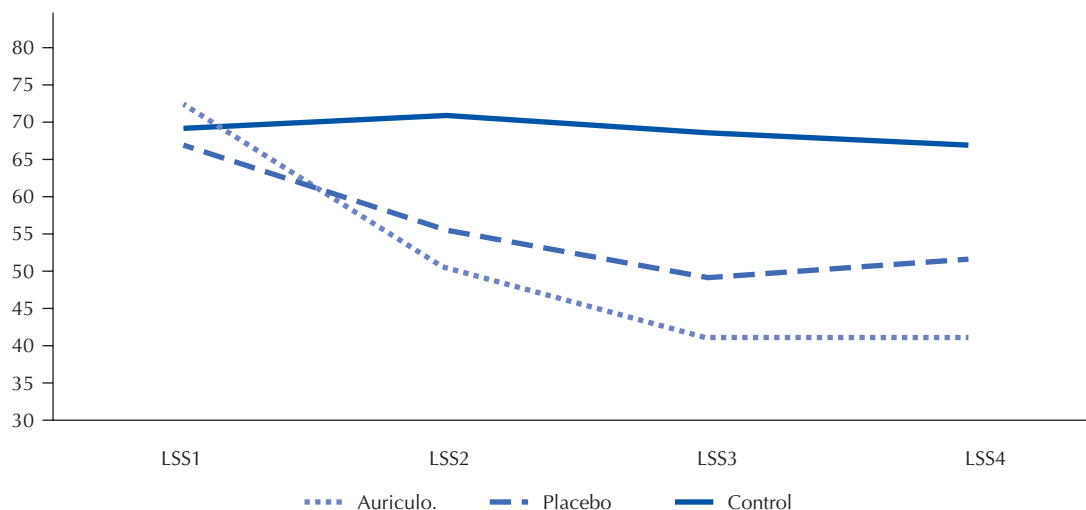


Figure 3 – Evolution of the stress score in the groups in the four moments – São Paulo, SP, Brazil, 2014.

The evaluation of the effect size by the Cohen's index and the percentage change showed that the auriculotherapy group presented a better result, with a 43% reduction of the

stress levels after 12 sessions, against 26% in the placebo group, a result maintained in the follow-up evaluation of the auriculotherapy group, according to Table 2, below.

Table 2 – Mean and standard deviation of stress levels in the four moments, Cohen's d index and percentage of change in the three groups – São Paulo, SP, Brazil, 2014.

	N	LSS1		LSS2		LSS3		LSS4		
		Mean(SD)		Mean(SD)		Mean(SD)		Mean(SD)		
Auriculotherapy	43	72.4(±17.9)		50.7(±20.2)		41.2(±17)		41.3(±16.4)		
Placebo	47	66.7(±17.3)		55.7(±23.6)		49.1(±23.6)		51.8(±27)		
Control	43	69.3(±17.8)		70.9(±25.8)		68.6(±25.7)		66.8(±27.6)		
	Cohen'd	LSS2-1			LSS3-1			LSS4-1		
		Classif	%		Cohen'd	Classif	%	Cohen'd	Classif	%
Auriculotherapy	1.15	VLE	-30		1.81	HE	-43	1.83	HE	-43
Placebo	0.54	ME	-17		0.86	LE	-26	0.67	ME	-22
Control	0.08	NE	2		0.03	NE	-1	0.11	NE	-4

NE= negligible effect; ME= medium effect; LE = large effect; VGE=very large effect; HE= huge effect.

DISCUSSION

Of the nurses participating in the study, 67.4% had a high stress level. In all the work shifts there was predominance of high stress levels. In fact, the hospital environment is recognized as a place conducive to illness, an unwholesome, distressing and risky environment for those who work there.

In addition to the risks of accidents and physical illnesses to which these professionals are exposed, psychological suffering is also quite common due to the high pressure to which they are subjected⁽¹⁶⁾. Working in shifts can have negative effects on the health of nursing professionals, damaging their mental and physical health. It impacts social and family life, due to

the difficulty these professionals find to participate in social activities and plan their life⁽¹⁷⁾.

Sixty-four nurses (48.5%) presented a health complaint. The most frequent problem was musculoskeletal pain. Among the occupational diseases, musculoskeletal disorders are the most serious health problems. In fact, a study verified that the main complaint of nursing professionals was related to the musculoskeletal system⁽¹⁸⁾. The main risk factors are related to the organization of work and possible overuse of body parts in certain movements, such as excessive strength to perform some tasks, repetitiveness and inadequate postures⁽¹⁹⁾.

Regarding the treatment for stress, the present study found that the group that received auriculotherapy had a statistically significant reduction in stress in the second evaluation, after eight sessions, which was maintained in the follow-up after 15 days. The points used in the auriculotherapy group, Shenmen and Brainstem, reduced the stress levels by 43%.

Other studies used the Shenmen and Brainstem points for reducing stress and anxiety. One of them, conducted with professionals of the Nursing team in an Intensive Care Unit of a private hospital in the city of São Paulo, managed to improve the symptoms of 85.4% of the participants after treatment⁽⁵⁾. The Shenmen and Brainstem points were also used for stress management in Nursing professionals in a protocol with five points (Shenmen, Brainstem, Kidney, Liver Yang 1 and 2). The intervention group was compared to a group without this protocol, with points chosen according to the diagnoses of Traditional Chinese Medicine. The Shenmen point was used in 100% of the participants of the group without the protocol and the Brainstem was used in 93% of these participants⁽²⁰⁾, reaffirming the relevance of these points in the treatment of mental and emotional problems.

In the present study, the placebo group also achieved positive results after 12 sessions and in the follow-up evaluation. The two main hypotheses that arose to try to understand these results were: (1) the sham auricular points chosen were not inert as expected, or (2) the effect could have been due to other factors associated with the placebo effect, as had already occurred in the previous study with nursing students⁽⁶⁾.

In the present investigation, the previous sham protocol was modified. The External Ear point was kept and the Wrist point was replaced by the Face Area point. These points, in theory, are not indicated for stress management. However, since there are many auricular points and the method for locating points was painful palpation, future studies should use other methods of locating points that can minimize this bias.

Some methodologies have been suggested for the detection of auricular points: observation of the auriculocardiac reflex on the radial artery when the auricular points are stimulated⁽²¹⁾, and devices: the electrical device for the location of auricular points *Pointer Plus*⁽²²⁾, Auricular Electrodermal Test⁽²¹⁾ and the *Ryodoraku (Acuspointer)* device for searching reactive electropermeable points (REP) in the skin of the external ear⁽²³⁾.

The sham points chosen had no indication of being useful for stress treatment, but produced a placebo effect. For a better understanding of the placebo effect and its potential to produce clinically significant improvement in the patient, it must be understood as a real phenomenon, as one of several ways through which healing can occur. The positive results of a treatment can be attributed to some possibilities: the improvement can be induced by a treatment that is real; by placebo effect when there is positive result without real treatment; by the interaction between the person applying the treatment and the patient; by the self-healing properties of the organism and by the natural regression of the disease symptoms⁽²⁴⁾. There is evidence of the role of psychological traits on the therapeutic outcome, including optimism, pessimism, and the patients' expectations and beliefs. Placebos can mimic, improve, and even prevent the beneficial responses of pharmacological agents⁽²⁵⁾. This is the reason for a great interest in studying its effect.

The placebo effect seems to be malleable and depends on behaviors incorporated into treatment routine⁽¹³⁾. It is possible that the ritual involved in the acupuncture treatment and the regular encounters were responsible for the placebo effect. Experimental research on placebo effects demonstrates that interventions such as acupuncture or auriculotherapy contain an important ritualistic dimension. In this sense, ritual healing not only represents changes in affect, self-awareness and self-appraisal of behavioural capacities, but involves modulations of symptoms through neurobiological mechanisms⁽²⁶⁾. Researchers noted that placebo had already been studied, and the results provided a distinction between the actual and ritual effects of acupuncture on the brain. The most extensively investigated physiological reaction to the actual effects has been the release of substances in the brain, such as endorphins, a subtype of neuropeptide called endogenous opioid, part of the mechanism of pain suppression. Sham acupuncture would act on a cognitive component in the dorsolateral prefrontal cortex, a prefrontal region associated with the placebo effect and cognitive modulation of pain⁽²⁷⁾.

The main limitation of the present study was not using electrical devices or other more accurate methods of locating active and non-reactive auricular points for the definition of sham points. Another study should be carried out taking this aspect into account, in order to reassess whether the effect achieved by the sham protocol was actually due to a placebo effect or other associated non-specific effects.

CONCLUSION

When compared to the control group (without intervention), experimental auriculotherapy (Shenmen and Brainstem points) was effective for reducing stress in nurses after eight sessions, 12 sessions and in the follow-up after 15 days. As for the intervention performed with Sham points (External Ear and Face Area), there were positive results after 12 sessions, but with less reduction of stress levels. Further studies are recommended to better evaluate the placebo effect of sham auriculotherapy.

RESUMO

Objetivo: Comparar a eficácia da auriculoterapia verdadeira e placebo com pontos *sham* no tratamento de estresse em enfermeiros de um hospital beneficente em São Paulo. **Método:** Ensaio clínico controlado randomizado, simples-cego. A amostra foi constituída de 168 enfermeiros que apresentaram níveis médio e alto de estresse pela Lista de Sintomas de *Stress* (LSS) e foram randomizados em 3 grupos: Auriculoterapia (G1), Placebo (G2) e Controle (G3). Os grupos 1 e 2 receberam 12 sessões, 2 vezes por semana. Os pontos utilizados no Grupo 1 foram: *Shenmen* e Tronco Cerebral; no Grupo 2 foram: Ovido Externo e Bochecha. Os três grupos foram avaliados no início, após oito, 12 sessões e *follow-up* (15 dias). **Resultados:** O grupo 1 conseguiu 43% de redução e 1,81 de índice d de Cohen (alto efeito), apresentando diferença estatística a partir de oito sessões, com manutenção no *follow-up* ($p < 0,001$), segundo Análise de Variâncias. Já o grupo 2 atingiu 26% de redução, com d de Cohen de 0,86 (grande efeito), conseguindo diferença após 12 sessões ($p < 0,001$), com manutenção no *follow-up* ($p < 0,05$), comparativamente ao G3, que não obteve redução em nenhum momento. **Conclusão:** A auriculoterapia verdadeira conseguiu maior redução de estresse entre enfermeiros, mas não houve diferença estatística entre os dois grupos de intervenção. Registro Brasileiro de Ensaios Clínicos: RBR-req2792

DESCRIPTORIOS

Auriculoterapia; Esgotamento Profissional; Enfermagem; Placebos; Terapias Complementares.

RESUMEN

Objetivo: Comparar la efectividad de la auriculoterapia verdadera y placebo con puntos *sham* en el tratamiento de estrés en enfermeros de un hospital benéfico en São Paulo. **Método:** Ensayo clínico controlado aleatorizado, simple ciego. La muestra estuvo constituída de 168 enfermeros que presentaron niveles mediano y alto de estrés por el Inventario de Síntomas de Estrés (ISE) y fueron randomizados en 3 grupos: Auriculoterapia (G1), Placebo (G2) y Control (G3). Los grupos 1 y 2 recibieron 12 sesiones, 2 veces por semana. Los puntos utilizados en el Grupo 1 fueron: *Shenmen* y Tronco Cerebral; en el Grupo 2, fueron: Oído Externo y Mejilla. Los tres grupos fueron evaluados en el inicio, después de ocho, 12 sesiones y *follow-up* (15 días). **Resultados:** El grupo 1 logró el 43% de reducción y 1,81 de índice d de Cohen (alto efecto), presentando diferencia estadística a partir de ocho sesiones, con mantenimiento en el *follow-up* ($p < 0,001$), según el Análisis de Varianzas. En el caso del grupo 2, este alcanzó el 26% de reducción, con d de Cohen de 0,86 (gran efecto), obteniendo diferencia después de 12 sesiones ($p < 0,001$), con mantenimiento en el *follow-up* ($p < 0,05$), comparativamente con el G3, que no logró reducción en ningún momento. **Conclusión:** La auriculoterapia verdadera consiguió mayor reducción de estrés entre enfermeros, pero no hubo diferencia estadística entre ambos grupos de intervención. Registro Brasileño de Ensayos Clínicos: RBR-req2792

DESCRIPTORIOS

Auriculoterapia; Agotamiento Profesional; Enfermería; Placebos; Terapias Complementarias.

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