REVISTA DA ESCOLA DE ENFERMAGEM DA USP

JOURNAL OF SCHOOL OF NURSING · UNIVERSITY OF SÃO PAULO

ORIGINAL ARTICLE

Effectiveness of auricular acupuncture in the treatment of cancer pain: randomized clinical trial*

Efetividade da acupuntura auricular no tratamento da dor oncológica: ensaio clínico randomizado

Efectividad de la acupuntura auricular en el tratamiento del dolor oncológico: ensayo clínico aleatorizado

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ABSTRACT

Objective: To evaluate the effectiveness of auricular acupuncture in the pain of cancer patients receiving chemotherapy and to verify if there were alterations in the use of analgesics after the application of this intervention. **Method:** Randomized controlled trial with cancer patients with complaints of pain greater than or equal to four in the Numerical Pain Scale. Two parallel groups were created, an Experimental group, which received auricular acupuncture at energy balance points and at points indicated for the treatment of pain, and a Placebo group, in which fixed placebo points were used. Both groups received the application of semipermanent needles in eight sessions. **Results:** 31 cancer patients participated in the study. After the eight auricular acupuncture sessions, there was a significant difference between the groups regarding the reduction of pain intensity ($p < 0.001$) and of the use of medications ($p < 0.05$). **Conclusion:** Auricular acupuncture was effective in reducing the pain of patients receiving chemotherapy. Brazilian Registry of Clinical Trials: RBR-6k3rqh.

DESCRIPTORS

Acupuncture, Ear; Complementary Therapies; Pain; Neoplasms; Oncology Nursing.

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INTRODUCTION

Cancer cases have increased in recent years, as have the prevalence of the symptoms presented by patients during the disease, especially the occurrence of pain[1-2].

Cancer pain is a symptom related to multiple factors and defined as simultaneous sensations of acute and chronic pain at different levels, associated with the spread of cancerous cells in the body. It is a consequence of cancer treatment, including chemotherapy, or cancer-related conditions such as wound pain. Cancer pain is usually described as imprecise, hurtful, painful, frightening or as an unbearable pain, with episodes of intense pain that appear along with difficulties sleeping, irritability, depression, suffering, isolation, despair and helplessness[3]. It is considered a challenge for health services and for the multi-professional team.

Despite having received more attention in recent years, especially after the approval of the WHO Analgesic Ladder[4], about 40% to 50% of the cases of cancer pain receive inadequate treatment, since they depend on a combination of factors, such as evaluation and the treatment itself, and require complex decisions for its management[5-6]. This international method supports the use of accessible drugs, prescribed according to the intensity of pain reported by each individual[7].

However, even with simple strategies available for managing cancer pain, its prevalence indicates the urgency of developing actions that lead to more favorable patient outcomes[8]. Health services can incorporate complementary and safe techniques in an attempt to provide better pain management, especially when conventional treatments become limited[9].

In this context, we highlight Auricular Acupuncture (AA), which has shown satisfactory results in the management of cancer pain[10-11]. This technique, originated in Traditional Chinese Medicine (TCM), has been described for about 2,500 years and seeks the harmony and balance of the body through stimuli at specific points of the auricle, which have direct effects on the central nervous system (CNS)[12-14].

For TCH, Qi (energy or life force) flows throughout the body through channels that pass through specific points connected to the functions of each organ. Thus, when Qi is unbalanced, these points can be stimulated, altering the flow of energy and recovering the health of the individual[15]. According to this theory, when the auricular acupoints are stimulated, they cause changes in Qi and restore balance in the body[16].

However, the evidence supporting the use of AA for the management of cancer pain is still incipient, due to the methodological commitment of studies available in the scientific literature, which present a high risk of bias[9,17]. Thus, studies that prove the effectiveness of AA for the treatment of this symptom are necessary to strengthen the evidence and encourage the use of the technique.

This study aimed to evaluate the effectiveness of Auricular Acupuncture in the pain of cancer patients receiving chemotherapy and to verify if there were alterations in the use of analgesics after the application of this intervention.

METHOD

Randomized controlled trial, with a 1:1 parallel design.

The inclusion criteria for participation in the study were: receiving chemotherapy treatment and being mentally oriented; presenting pain ≥ four in the Numerical Pain Scale (EN); being followed up in the High Complexity Care Unit; accepting the needle treatment and being at least 18 years old. The exclusion criteria were the presence of lesions and/or edema on the ear, absence of the auricle or alterations that would contraindicate the insertion of needles, allergy to micropore tape, terminal patients and/or patients with head and neck cancer, due to possible alterations in the transmission of AA stimuli, and anticoagulant users, due to the risk of bleeding after needle placement.

The study was carried out in the city of Alfenas, located in the state of Minas Gerais. The participants were cancer patients who received chemotherapy treatment at the UNACON of the House of Charity Nossa Senhora do Perpétuo Socorro – Santa Casa of Alfenas, which authorized the study.

An intervention protocol based on previous studies was established[10,18]. There were nine meetings, and eight sessions of AA with all participants, one session per week, with a 7-day interval between sessions. Seven days after the last session, participants returned to the ninth meeting, in which final evaluations, needle removal and inspection of the ear occurred.

Due to the scarcity of studies determining the ideal size of auricular needles for the treatment of cancer pain, sterile, disposable, semi-permanent auricular needles, size 0.20 mm x 1.5 mm were chosen. In the first session, the application of the needles in the right auricle was standardized for both groups, alternating the auricle in the other sessions.

Participants were allocated into two groups, an Experimental Group and a Placebo Group. In the Experimental Group the acupoints used were *Shenmen*, Kidney, Sympathetic, Muscle Relaxation and the energy balance points, defined through the Five Elements theory. The Eye and Trachea points were applied to the Placebo Group.

The *Shenmen* stimulates the brainstem and the cortex to receive, decode, modulate and condition the reflexes of the next acupoints, avoiding imbalances in the patient's body and preventing new diseases. This point calms the heart and mind and has an analgesic function, through the release of endorphins[13-14]. It is one of the most used points in pain treatments[11-12].

The Kidney Point stimulates the filtration of blood, releasing toxins and improving circulation. This point improves the function of the respiratory system, the endocrine glands and the excretory organs. The Sympathetic point accelerates and regulates the neurovegetative activity, balancing the sympathetic and parasympathetic functions by rebalancing the autonomic nervous system, which promotes the general balance of the organism. This point has an important analgesic, anti-inflammatory and relaxation action of muscle fibers[13-14]. The Muscular Relaxation point is indicated for pain, muscular tension, anxiety, depression, among others[13].

The Five Elements theory (pentagram) is part of the essence of TCM and is one of the principles and tools used to diagnose a person's energy imbalance[19]. The design of the Five Elements is based on the elements of nature (Wood, Fire, Earth, Metal and Water) and how they interrelate[14], according to the functions, energy and qualities of each element to establish the balance of the organism[19].

Each element is represented by an organ and a viscera (hollow organ) of the body, composing the Five Elements. This way, the Wood is associated with the liver and the gallbladder, the Fire with the heart and the small intestine, the Earth with the spleen/pancreas and the stomach, the Metal with the lungs and the large intestine and the Water with the kidney and the bladder[19]. The elements exchange energy with each other, providing harmony to the person.

When the elements are balanced, there is no disharmony in the pentagram, and the person is in the state of "health". When there are energy changes caused by the exchange of altered energy between the elements, this relationship is compromised and the "disease" process, which can be slow and progressive, is established[14]. Unbalance in the pentagram is diagnosed through anamnesis and the symptoms reported by each individual, evaluated according to the principles of CTM. Thus, according to this evaluation, the energy balance points are defined individually and correspond to the organ and the viscera that represent the element in which the body imbalance begins. From this, the points of the pentagram are used to restore the harmony and health of the individual[19].

The application of the points in the Experimental Group respected the following order: *Shenmen*, Kidney, Sympathetic, energy balance points and Muscle Relaxation. The minimum number of needles applied per session was five when there was imbalance of the element Water (*Shenmen*, Kidney, Sympathetic, Bladder and Muscle Relaxation), and the maximum was seven when the result indicated unbalance of the Earth element (*Shenmen*, Kidney, Sympathetic, Spleen/Pancreas, stomach and muscle relaxation). In this group, the mean time per session was 40 minutes.

In the Placebo Group, two fixed sham points, unrelated to pain, were used: Eye point and Trachea point[13-14], applied in that order. For this group, the mean time per session was 20 minutes.

The needles remained in the auricle for 7 days, except in specific cases where the session was rescheduled for particular reasons, such as malaise and tests. In these cases, there were variations of 2 to 3 days in the application of AA.

After the intervention, the participants were informed about the hygiene and maintenance of the needles in the ear. The manual stimulation of the needles was not recommended because the researchers would not have control of this action. The participants followed the orientations, and the needles remained fixed on the points until they returned to the next session.

In cases of doubts or adverse reactions that could be related to AA, participants were instructed to contact the investigator. At the end of the study, those in the Placebo Group were invited to receive the same treatment offered to the Experimental Group, and one participant accepted the treatment.

The AA was conducted by a researcher, who has the necessary certification, guaranteeing the homogeneity of the technique. The evaluations were performed by a trained evaluator who was blinded to the allocation and who had no knowledge on AA treatment, and no participants were informed as to which group they belonged.

The characterization of the participants occurred at the first meeting through, an instrument developed by the researchers. The AA was applied in a reserved place, in a calm and safe environment, and the participants remained in the supine position due to the risk of dizziness or lipothymy[14].

Pain intensity was evaluated in the first and ninth meetings, using the 11-point version of the EN, chosen because of its reliability in evaluating cancer pain[20]. Participants chose score that best represented their pain. The pain level was compared at the beginning and at the end of the study. When assigning a score for pain, the symptom was classified as absent (0), mild (1-4), moderate (5-7), or severe (8-10)[21].

The use of analgesics was evaluated in the first and ninth meeting, through the participant's report regarding the use of this medication in the previous 3 days. They were questioned about: the daily number of medications, the dosage used and the name of the medication, for confirmation of its class. After this, the medication was classified according to the medications defined for each step of the WHO Analgesic Ladder, determining the participant's position on the steps. Each participant was instructed to seek the appropriate physician before reducing any medication.

The follow-up evaluation was scheduled for 20 days after the final evaluation. However, the number of deaths that occurred next and the non-attendance of participants for the evaluation, due to health issues or without justification, made this evaluation impossible.

Participants were divided into the groups by simple randomization (biased coin method), and the researcher responsible for the intervention was also responsible for the randomization process, and did not participate in the evaluations.

The collected data were stored and arranged in a database. Subsequently, they were transferred to the statistical program Statistical Package for Social Sciences (SPSS), version 17.0, the software used for the statistical analysis of the study. For all analyzes, the level of significance was <0.05.

For the homogeneity test, the Pearson's Chi-square test, the Fisher's exact test and the Mann-Whitney test were applied according to the variable. To verify if there was a significant difference between the groups, the Mann-Whitney test was applied.

The statistical power and effect size of the tests were analyzed using the programs GPower® 3.1 and PASS® 11, depending on the variable. In addition, a statistical power of 95% was considered for all effect size analyzes.

Participants signed an Informed Consent Form and received a copy. The study was registered in the Brazilian Registry of Clinical Trials (REBEC) portal: RBR-6k3rqh and approved by the Research Ethics Committee of UNIFAL-MG protocol no. 1330960, complying with Resolution 466/2012.

RESULTS

The study population was approximately 1,070 people undergoing cancer treatment at UNACON. The sample was collected by active search divided in two stages, with two weeks each. The first stage occurred in December 2015, and the second in February 2016. Patients who were in this sector and who had no apparent lesions in the head and neck region were approached.

Thus, 70 individuals were assessed for eligibility to participate in the study. Of these, 31 met the inclusion criteria and were part of the initial sample. After randomization, 16 participants were allocated in the Experimental Group and 15 in the Placebo Group. During follow-up, there were losses, and at the end of the study, 11 participants were analyzed in the Experimental Group and 12 in the Placebo Group. The final sample was composed of 23 participants, as shown in Figure 1.
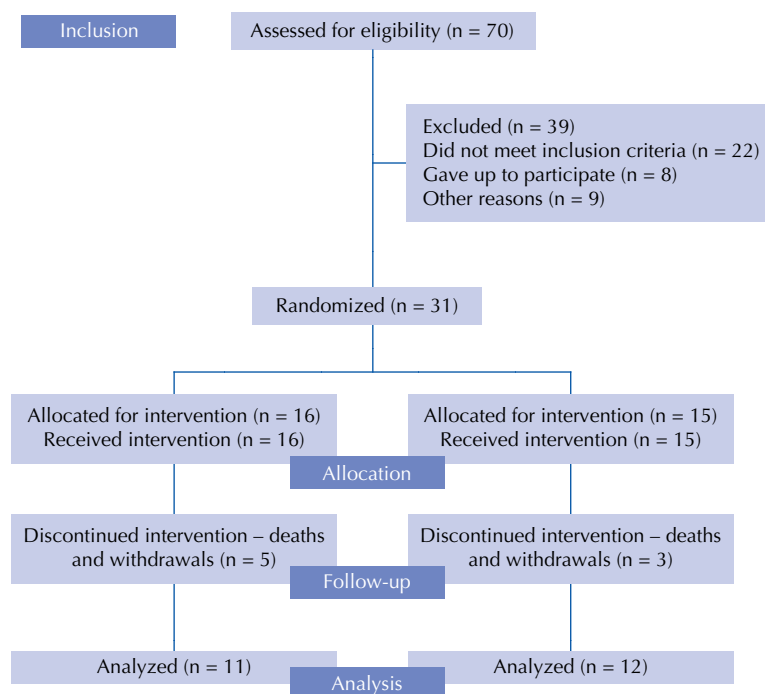

Figure 1 – Flowchart of allocation, follow-up and analysis of the participants of the Experimental Group and the Placebo Group.

The participants were characterized according to quantitative socio-demographic variables (Table 1) and qualitative clinical variables (Table 2), and the groups were homogeneous in relation to the variables age, education, gender, type of cancer, cancer stage, time of treatment and number of analgesics used.

Table 1 – Characterization of quantitative socio-demographic variables – Alfenas, MG, Brazil, 2016.

Variables	Experimental Group (n = 11) Mean ± SD (Median)	Placebo Group (n = 12) Mean ± SD (Median)	p-value
Age (years)	58.27 ± 10.09 (59.00)	52.08 ± 7.99 (53.00)	0.116
Level of education (years)	8.55 ± 3.44 (6.00)	9.92 ± 3.91 (10.50)	0.391

Note: SD: standard-deviation. Application of the Mann-Whitney test.

After the application of AA, a statistically significant difference in pain intensity between the groups (p <0.001) was observed and confirmed by the analysis of the statistical power and effect size.

Table 2 – Characterization of qualitative clinical variables – Alfenas, MG, Brazil, 2016.

Variables		Experimental Group (n = 11) (%)	Placebo Group (n = 12) (%)	p-value
Gender[F]	Male	18.2	25.0	1.000
	Female	81.8	75.0	
Type of cancer[F]	Breast	63.6	41.7	0.414
	Others	36.4	58.3	
Cancer stage[P]	II	18.2	16.7	0.278
	III	27.3	58.3	
	IV	54.5	25.0	
Time of treatment (in months)[F]	0-12	63.6	25.0	0.100
	> 12	36.4	75.0	
Number of analgesics used[F]	0-1	63.6	58.3	1.000
	≥ 2	36.4	41.7	

Note: [F]: Application of Fisher's Exact Test; [P]: Application of the Chi-square Person's test.

The comparison between the mean pain intensity in the first and in the last evaluation showed that the Experimental Group started the study with moderate pain (mean ± SD: 7.36 ± 1.74), as did the Placebo Group (6.00 ± 1.5).

However, at the end of the study, the group receiving true AA had pain classified as mild (2.09 ± 1.44), while the group receiving sham AA maintained the mean pain at baseline level (6.33 ± 2.14) (Table 3).

Table 3 – Intergroup evaluation related to pain intensity – Alfenas, MG, Brazil, 2016.

Ev.	Experimental Group (n = 11) Mean ± SD (Median)	Placebo Group (n = 12) Mean ± SD (Mediana)	p-value	Statistical power (1 – error β)[1] Effect size[2]
Initial	7.36 ± 1.74 (7.00)	6.00 ± 1.5 (6.00)	0.090	0.462[1] 0.837[2]
Final	2.09 ± 1.44 (2.00)	6.33 ± 2.14 (5.50)	<0.001*	0.999[1] 2.324[2]

Note: Ev.: Evaluation; *: p-value < 0,05. Application of Mann-Whitney test.

In addition to reduction of pain intensity, the comparison between the groups also showed significant differences in daily doses of analgesics (p = 0.010), number of analgesics used (p = 0.019) and position in the WHO Analgesic Ladder (p = 0.026). All these values are confirmed by the statistical power and effect size of the test (Table 4).

Table 4 – Intergroup evaluation of analgesics dosage, number of analgesics used and positions on the steps of the WHO Analgesic Ladder – Alfenas, MG, Brazil, 2016.

Variable	Ev.	Experimental Group (n = 11) Mean ± SD (Median)	Placebo Group (n = 12) Mean ± SD (Median)	p-value	Power of the test (1 – error β[†])[1] Effect size [2]
Daily doses	1	1.36 ± 1.02 (2.00)	1.50 ± 0.79 (2.00)	0.732	0.063[1] 0.153[2]
	2	0.36 ± 0.50 (0.00)	1.41 ± 0.99 (2.00)	0.010*	0.846[1] 1.338[2]
Number of analgesics used	1	1.27 ± 1.10 (1.00)	1.33 ± 0.88 (1.00)	0.797	0.052[1] 0.060[2]
	2	0.36 ± 0.50 (0.00)	1.33 ± 1.07 (1.00)	0.019*	0.734[1] 1.161[2]
Step of the WHO Analgesic Ladder	1	1.00 ± 0.83 (1.00)	1.33 ± 1.07 (1.00)	0.742	0.119[1] 0.344[2]
	2	0.36 ± 0.50 (0.00)	1.33 ± 1.15 (1.00)	0.026*	0.683[1] 1.093[2]

Note: Ev.: Evaluation; *: p-value < 0.05; [†] β-Error. Application of the Mann-Whitney Test.

During the study, there were no reports of major adverse reactions that required medical evaluations or any specific intervention. Some participants reported pain at the site of application of the needles, of slight intensity, with a maximum duration of 3 days.

DISCUSSION

AA caused changes in the intensity and classification of pain. It also led to intergroup statistical differences in relation to medications. These changes are related to the reduction of the daily doses of analgesics, the number of medications used by the participants and their position in the steps of the WHO Analgesic Ladder.

In this study, the majority of the sample was composed by women affected by breast cancer, which is in line with world statistics that point to this type of cancer as the most prevalent among the female population[1]. In addition, stages III and IV represent the most severe forms of the disease. Thus, delayed diagnosis and treatment leads to more aggressive therapies, poor prognosis and potential reduction of survival rates[22-23]. It is concerning to note that 43.5% of the participants had a stage III tumor and were undergoing treatment for less than 1 year, which may indicate delayed diagnosis of the cancer and, consequently, an unfavorable prognosis.

Another fact observed is that, in general, participants had less than 10 years of education. According to authors[24], low schooling may influence the perception of pain in cancer patients, since many believe that pain is part of the illness process, and thus take too long to seek help, which can make the symptom worse.

It should be noted that, at baseline, the mean pain intensity of the Experimental Group and of the Placebo Group was classified as moderate. However, 60.9% of the participants reported using one or no analgesics for pain management. In this context, it is important to note that, in Brazil,

pain management is ineffective and health professionals give little attention to complaints of pain, treating it in a less effective way[25]. Therefore, cancer patients are increasingly seeking complementary or alternative measures to manage symptoms during the disease[26].

Pain is a symptom whose origins vary according to the experiences of each individual. Thus, its treatment requires a comprehensive and individualized approach. However, in many cases, conventional or complementary therapy, when used in isolation, provide ineffective results when compared to the treatments that associate the two options[27].

Thus, with the application of AA in energy balance points that took into account the participant's complaint in an individual way, there was a reduction in pain intensity after the eight sessions. This result resembles that of a previous study[10], in which the researchers compared the effects of AA on the relief of cancer pain and found a significant difference between the group that received AA at personalized points and the groups that received the intervention in sham points. This supports the evidence that treatment with the use of specific and personalized points is what promotes pain relief.

Pain management, from the perspective of CTM, must be performed through individual assessment, according to medical history, symptoms and diagnosis, directing the therapy according to the patients' complaints. This pain management, which considers the individual in a comprehensive manner, has shown good results[10,28]. The present study, in agreement with these findings, found a significant reduction of pain. The individualized treatment, selected according to the energetic changes of each participant, was fundamental to obtain the final result, since, even though the two groups received the insertion of needles in the auricle, only the group that received the treatment from the perspective of the CTM obtained more satisfactory results.

With pain relief, there is a possibility of decreasing medication use, reducing the adverse effects caused indirectly by medications. In this context, since AA is a complementary treatment that does not use drugs and offers minimum risks to the patient, it can contribute to the treatment of patients who are sensitive to analgesics or who, even with conventional treatment and high doses of medication, still complain of pain[17].

Current studies evaluating the association between complementary therapies and analgesics and its effect on the relief of cancer pain can be found. These studies demonstrate satisfactory effects when these treatments are used in a combined manner. Their combined use decreases the time of pain relief and potentializes the reduction of pain intensity, while the isolated treatment is not very effective[29-30]. A study[30] has raised the possibility that the analgesia provided by acupuncture can be more significant than the outcomes of the medications indicated in the WHO Analgesic Ladder. In addition, it causes fewer adverse effects and dependence. This fact can be explained by the fact that the complementary treatment seeks an energetic balance of the individual, treating not only physical pain, but other aspects, such as psychological factors, that can influence the intensity of the symptom.

In the present study, there was a significant difference between the groups in relation to the daily doses of analgesics and the number of analgesics used. In addition, with the reduction of pain, there was a possibility that the analgesic treatment and, consequently, the classification of the patient on the WHO Analgesic Ladder, would change. This fact was verified, which demonstrates the effectiveness of AA, as found by other studies[29-30].

However, regardless of the choice of therapy for the management of cancer pain, this symptom should be treated and assessed in an individual and holistic manner, because it is a particular process influenced by different factors[31].

During the development of this study, some factors were considered as limitations. The scarcity of literature on the efficacy of AA in the treatment of cancer pain was an obstacle to the design of the study, a limitation that is also found by other authors[9,17,29]. Another difficulty was the resistance of the population to accept the needle treatment. The adverse effects of chemotherapy and the complementary tests required during the treatment of cancer led to rescheduling of some sessions. The expressive number of deaths since the beginning of the study caused a considerable sample loss. There were also difficulties with languages of Eastern countries during literature search, which may have limited the comparison of findings. The existence of different views of AA impaired the elaboration of the treatment protocol, since the authors disagree on the use of the technique. Finally, although the follow-up evaluation was a limitation, the results obtained showed the importance of AA as a complementary treatment of cancer pain. In addition, studies with larger samples are suggested.

CONCLUSION

Auricular acupuncture was effective in reducing the pain intensity of cancer patients receiving chemotherapy. In addition, it was associated with reduction in the consumption of analgesics. The technique was safe, effective, inexpensive and with minimal risk to participants.

However, new studies are necessary to provide new evidence on the use of auricular acupuncture in the treatment of cancer pain and to strengthen the acceptance of the technique by health professionals, especially nurses, in the planning of their care.

RESUMO

Objetivo: Avaliar a efetividade da acupuntura auricular na dor de pacientes oncológicos em tratamento quimioterápico e possíveis alterações no consumo de analgésicos após a aplicação da intervenção. **Método:** Ensaio clínico randomizado com portadores de câncer que apresentavam queixa de dor maior ou igual a quatro na Escala Numérica da Dor. Foram criados dois grupos paralelos, um Experimental, o qual recebeu a aplicação da acupuntura auricular em pontos do equilíbrio energético e em pontos indicados para o tratamento da dor, e um Placebo, em que foram aplicados pontos placebos fixos. Ambos os grupos receberam a aplicação de agulhas semipermanentes em oito sessões. **Resultados:** Participaram 31 portadores de câncer. Depois das oito sessões de acupuntura auricular,

houve diferença significativa entre os grupos na redução da intensidade da dor (p < 0,001) e no consumo das medicações (p < 0,05). **Conclusão:** A acupuntura auricular foi efetiva na redução da dor de pacientes em tratamento quimioterápico. Registro Brasileiro de Ensaios Clínicos: RBR-6k3rqh.

DESCRITORES

Acupuntura Auricular; Terapias Complementares; Dor; Neoplasias; Enfermagem Oncológica.

RESUMEN

Objetivo: Evaluar la efectividad de la acupuntura auricular en el dolor de pacientes oncológicos en tratamiento quimioterápico y posibles alteraciones en el consumo de analgésicos después de la aplicación de la intervención. **Método:** Ensayo clínico aleatorizado con portadores de cáncer que se quejaban de dolor mayor o igual a cuatro en la Escala Numérica del Dolor. Se crearon dos grupos paralelos, un Experimental, el cual recibió la aplicación de la acupuntura auricular en puntos del equilibrio energético y en puntos indicados para el tratamiento del dolor, y un Placebo, en que se aplicaron puntos placebos fijos. Ambos grupos recibieron la aplicación de agujas semipermanentes en ocho sesiones. **Resultados:** Participaron 31 portadores de cáncer. Después de las ocho sesiones de acupuntura auricular, hubo diferencia significativa entre los grupos en la reducción de la intensidad del dolor (p <0,001) y en el consumo de las medicaciones (p <0,05). **Conclusión:** La acupuntura auricular fue efectiva en la reducción del dolor de pacientes en tratamiento quimioterápico. Registro Brasileño de Ensayos Clínicos: RBR-6k3rqh.

DESCRIPTORES

Acupuntura Auricular; Terapias Complementarias; Dolor; Neoplasias; Enfermería Oncológica.

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