

## ORIGINAL ARTICLE

# PREPARATION AND VALIDATION OF AN AURICULAR ACUPUNCTURE POINT PROTOCOL FOR HEADACHES

#### HIGHLIGHTS

- 1. Auricular acupuncture protocol for the treatment of headaches.
- 2. The protocol showed a satisfactory agreement percentage.
- 3. It contributes to the development of methodological studies.

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#### ABSTRACT

**Objective:** To develop and validate the content of an auricular acupuncture point protocol for the treatment of headaches. **Method:** A methodological study, carried out in June 2023 in Montes Claros, Minas Gerais, Brazil. It was structured in three stages: Planning (bibliographic survey and identification of the study variables); Construction of the instruments (characterization of the experts, point protocol and treatment regime); and Content validation in charge of 15 experts. In the data analysis, an absolute agreement percentage equal to or greater than 80% was used. **Results:** The auricular acupuncture protocol for the treatment of headaches that was validated by experts consisted of the following points: "Door of the Mind" (93.3%), Kidney (86.7%), Sympathetic (86.7%), Anxiety (86.7%), Subcortex (86.7%), Brainstem (86.7%), Frontal (86.7%), Occipital (86.7%), Temporal (86.7%) and Liver (80%). **Conclusion:** the auricular acupuncture protocol for the treatment of headaches valid, which will allow its use in the clinical practice and research studies.

**DESCRIPTORS:** Auricular Acupuncture; Headache; Nursing; Methodological Research in Nursing; Complementary Therapies.

#### HOW TO REFERENCE THIS ARTICLE:

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### INTRODUCTION

Acute pain is defined as an "unpleasant sensory or emotional experience associated with an actual or potential tissue injury, or described in terms of such injury; sudden or slow onset, mild to intense intensity, with early or possible termination and lasting less than 3 months. In turn, chronic pain differs in terms of time: it lasts more than 3 months<sup>1</sup>.

Among the different types of pain, headache stands out, characterized by normally bilateral discomfort that fluctuates without associated manifestations, and its crisis can last from 30 minutes to more than 15 days<sup>2</sup>. The etiological determination is related to structural, nervous or extra-nervous and systemic changes or to dysfunctional conditions. Headaches are classified as primary or secondary depending on their etiology. Primary headaches occur without any evident etiology from clinical or laboratory tests. In turn, secondary headaches are those caused by diseases<sup>3</sup>.

In a review of 357 epidemiological studies carried out in Norway in 2022 with the objective of analyzing the estimated global prevalence of active headaches in adults, a result of 52.0% was evidenced: 44.4% in men and 57.8% in women<sup>4</sup>.

Among the global burden of diseases in the age group from 25 to 49 years old, headaches are the fifth most prevalent clinical condition and the tenth specific cause of disability<sup>5</sup>. In Brazil, a study surveying headaches in adults found a mean prevalence of 70.6%<sup>6</sup>.

In the clinical practice, headache control should be a focus of multiprofessional action. In addition to its high prevalence, the problem is also relevant since, when left untreated, it can cause discomfort and disability, threaten quality of life and generate unfavorable economic and psychosocial impacts<sup>7</sup>.

In this sense, pharmacological and non-pharmacological measures must be implemented to control and treat pain. Integrative and Complementary Practices (ICPs) such as Acupuncture stand out among the non-pharmacological interventions,.

Specifically, auricular acupuncture shows effectiveness in treating various clinical situations, especially those with painful symptoms<sup>8</sup>. By stimulating the acupuncture points in the ear, this therapeutic resource helps promote balance and harmony of the body's energies and aims at promoting pain relief<sup>9</sup>.

Needles, crystals or mustard seeds can be used to implement it, for example. These devices stimulate the sensory fibers of the Peripheral Nervous System (PNS), triggering electrical transmissions in neurons that, upon reaching the Central Nervous System (CNS), will result in the release of hormones and of chemical and endogenous substances that help improve the patient's problem<sup>10</sup>.

In addition to being effective in treating pain and representing a technique that many professionals have the competence and autonomy to apply, the encouragement to use auricular acupuncture is highlighted due to its practicality, safety and low cost<sup>8</sup>.

Among the studies found, it was possible to verify lack of consensus on a headache protocol. In addition to that, there was no prior validation of auricular acupuncture point protocols for treating the outcome<sup>8,11-14</sup>. In this context, there is an evident need to establish validated protocols in order to evaluate the effectiveness and safety of the treatments proposed, thus implementing practices based on scientific evidence. In view of the above, methodological studies are a tool that makes it possible to improve interventions and actions, for example, through the preparation and validation of protocols with a positive impact on a given outcome of a person's human response, such as headaches<sup>15</sup>.

At a national and international level, there is scarcity of studies with methodological

robustness that used auricular acupuncture for the treatment of headaches and/or that present validated auricular point protocols for the outcome. Thus, the objective of the current study was to develop and validate the content of an auricular acupuncture point protocol for the treatment of headaches.

#### **METHOD**

This is a methodological study<sup>15</sup> carried out in June 2023 through the evaluation of an experts' committee, to validate an auricular acupuncture point protocol for the treatment of headaches. The validation process consisted of content validity, which referred to the relevance and pertinence degrees<sup>15</sup> of the auricular points suggested in the protocol.

The protocol construction and validation process followed the following stages<sup>16</sup>, adapted for this study: 1. Planning (bibliographic survey and identification of the study variables); 2. Construction of the instruments (questionnaire to characterize the experts, auricular acupuncture point protocol for the treatment of headaches and treatment regime); and 3. Validation of the point protocol content in charge of experts<sup>16</sup>.

In the first stage, conducted between January and May 2023, a bibliographic survey was carried out with the "headache", "auricular acupuncture", "auriculotherapy" and "acupuncture" descriptors, using the AND or OR Boolean operators in the following information sources: Medline via the National Library of Medicine (PUBMED); Biblioteca Virtual de Saúde (BVS) and Biblioteca Virtual em Saúde em Medicinas Tradicionais, Complementares e Integrativas (BVS MTCI).

The literature review was based on the recommendations set forth in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)<sup>17</sup>. The question that guided the study was as follows: Which are the auricular acupuncture protocols (Intervention) for the treatment of headaches (Outcome) in adults (Population), when compared to placebo groups, conventional treatments or no intervention (Comparison)?

Randomized Clinical Trials (RCTs) were included, published in Portuguese, English and Spanish, without delimiting the time period of the publications and studies that had the effect of auricular acupuncture on headaches in individuals over 18 years of age as their research object. Duplicate studies were excluded, as well as opinion articles, letters to the editor, summaries of event annals, unavailable full studies and those that did not present any information regarding the population, interventions or outcome of interest in the current study. A reverse search was carried out by reading the references of the articles selected in the databases.

The articles found were grouped into two *Microsoft Office Excel*® spreadsheets, and duplicates were excluded. Afterwards, they were evaluated independently by two reviewers, who initially read the titles and abstracts to assess compliance with the inclusion criteria. Subsequently, the full texts of the studies selected were retrieved and evaluated in full. Any and all disagreements in these stages were solved by consensus.

In the second stage, the validation process of the auricular acupuncture point protocol for the treatment of headaches was organized. It began with construction of the instrument with the experts' characterization variables, adapted from a previous study<sup>18</sup>, namely: gender; age group; region of the country; training; time since graduation; highest degree; academic production in the area; and performance area.

The auricular acupuncture point protocol to be validated by the experts was organized containing the ear points for the treatment of headaches, based on the clinical experience of the researchers who authored this study, namely: *Shen Men* (Door of the Mind), Kidney, Sympathetic, Anxiety, Subcortex, Brainstem, Liver, Frontal, Occipital, Temporal and

Muscle Relaxation.

To determine the sample of experts, sample calculation was used based on the following finite population formula:  $n=Za^2.P(1-P)/e^2$ <sup>19</sup>, considering a 95% confidence level (Za), an expected proportion from experts who agree with the item evaluated (P) of 90% and an expected difference (e) of 15%. Thus, the number of experts was 15 subjects.

Screening and invitation of the experts were carried out based on the analysis of their CVs on the Lattes Platform belonging to the National Council for Scientific and Technological Development (CNPq).

To participate in the study, the had to meet at least four points based on the sum of the following criteria, which were adapted for the current study: having a *lato sensu* degree in Acupuncture and/or training in Acupuncture (02 points); attending a course in Auricular Acupuncture (02 points); having at least two years of professional experience as an acupuncturist (03 points); and authoring, co-authoring or supervising studies on the topics of Acupuncture, Auricular Acupuncture or Pain (02 points)<sup>20</sup>.

The invitation letter emailed to the experts was accompanied by an online form containing the Free and Informed Consent Form (FICF), the questionnaire to characterize the experts, the auricular acupuncture protocol for the treatment of headaches and the instrument with the treatment variables and materials used in the sessions.

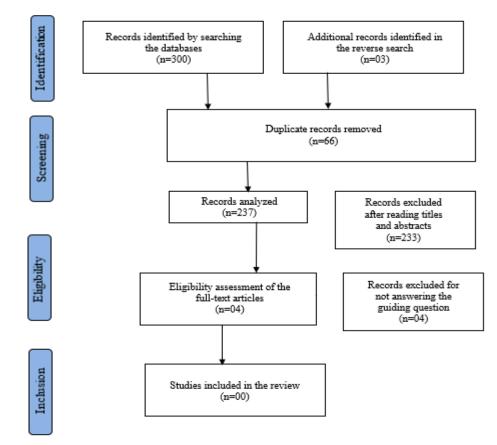
The data collected were entered into the *Statistical Package for the Social Sciences (SPSS)*, version 20. To analyze the results related to the characterization of the experts and the variables regarding the treatment and materials, descriptive statistics were performed using absolute (n) and relative (%) frequencies.

In the third stage in the agreement analysis regarding relevance of the auricular acupuncture point protocol for the treatment of headaches by the experts, the absolute agreement percentage was used, obtained by the following formula: Agreement percentage (%) = (Number of participants who agree/Total number of participants) x 100. The items with rates equal to or greater than 80% were considered adequate<sup>19</sup>. 95% confidence intervals were presented for the agreement relative frequencies.

The current study followed the ethical aspects in accordance with Resolution No. 466/12<sup>21</sup>, being approved by the Ethics and Research Committee of the State University of Montes Claros under number No. 6,058,456.

#### RESULTS

In the literature review, 300 articles were found in the databases and three in the reverse search. Of these, 66 were excluded for being duplicates. Therefore, 237 publications remained and 233 were excluded after reading their titles and abstracts. As a result, 04 articles were read in full and excluded for not answering the guiding question (Figure 1).



**Figure 1** - Review flowchart adapted from PRISMA. Montes Claros, MG, Brazil, 2023 Source: The authors (2023).

All of the studies analyzed obtained positive results with the use of systemic acupuncture. However, there is scarcity of studies using auricular acupuncture in the treatment of headaches in adults.

As for the experts, of the total of 36 contacted, 15 participated and met the inclusion criteria. Of the 15 participants, 80% were female (n=12) and their age varied between 27 and 56 years old, with a mean of 41.1 and a standard deviation of 9.5. The majority lived in the Southeast (n=12; 80%) region; worked in care (n=six; 40%); were nurses (n=10; 66.7%); with more than 10 years since graduation (n=nine; 60%) and specialists in Acupuncture (n=seven; 46.7%) (Table 1).

Variables	n (%)
Gender	
Female	12 (80)
Male	3 (20)
Age group	
25-45 years old	10 (66.7)
≥46 years old	5 (33.3)
Region of the country	

Table 1 - Experts' characterization variables. Montes Claros, MG, Brazil, 2023 (n=15)

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Northeast	1 (6.7)	
Southeast	12 (80)	
South	2 (13.3)	
Training		
Nurses	10 (66.7)	
Pharmacists	2 (13.3)	
Physiotherapists	2 (13.3)	
PICs technologist	1 (6.7)	
Time since graduation		
≤10 years	6 (40)	
>10 years	9 (60)	
Highest degree		
Specialization	7 (46.7)	
MSc Degree	6 (40)	
PhD	2 (13.3)	
Academic production		
Protocols	1 (6.7)	
Articles	1 (6.7)	
Thesis	3 (20)	
Performance area		
Assistance	6 (40)	
Teaching	5 (33.3)	
Management	5 (33.3)	
Source: The authors (2023)		

Source: The authors (2023).

Table 2 presents the auricular points validated for the auricular acupuncture protocol for the treatment of headaches, validated by the experts.

**Table 2** - Auricular points validated for the auricular acupuncture protocol for the treatment of headaches. Montes Claros, MG, Brazil, 2023 (n=15)

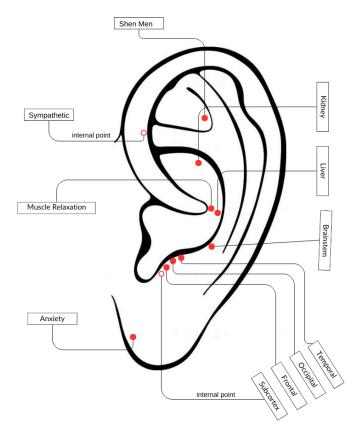
Ear point	n (Agreement %)	95% CI
Shen Men	14 (93.3)	0.70-0.98
Kidney	13 (86.7)	0.62-0.96
Sympathetic	13 (86.7)	0.62-0.96
Anxiety	13 (86.7)	0.62-0.96
Subcortex	13 (86.7)	0.62-0.96

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Brainstem	13 (86.7)	0.62-0.96
Frontal	13 (86.7)	0.62-0.96
Occipital	13 (86.7)	0.62-0.96
Temporal	13 (86.7)	0.62-0.96
Muscle Relaxation	13 (86.7)	0.62-0.96
Liver	12 (80.0)	0.54-0.92
Source: The authors (2023)		

Source: The authors (2023).

Figure 2 presents an illustration of the validated auricular acupuncture protocol for the treatment of headaches.



**Figure 2** - Auricular acupuncture protocol for the treatment of headaches. Montes Claros, MG, Brazil, 2023 Source: The authors (2023).

### DISCUSSION

Headaches are the most prevalent neurological disorder (90%) and are experienced at some point in life by almost the entire population<sup>22</sup>. They can exert negative influences on a person's well-being and cause harms to society.

Previous studies<sup>8,11</sup> have shown the effect of auricular acupuncture in the treatment of pain. However, at the national and international levels, there is scarcity of research evaluating the effect of auricular acupuncture specifically in the treatment of headaches in

adults.

One of the ways to carry out the content validation process is through an evaluation by experts, as they represent a network of professionals with relevant knowledge and skills in a given area or subject matter<sup>15</sup>. Protocols that are validated by experts regarding their content can support the care practice because thy favor clinical and critical thinking<sup>18</sup>.

The profile of the experts that validated the auricular acupuncture protocol proposed by this study is similar to the one used in another research study<sup>23</sup>, as aptitude and expertise in the content are evidenced by the years of training, professional performance, qualifications and productions, and care and academic experience on the topic in question. In the current study, the protocol was validated by experts in an interdisciplinary manner, with nurses standing out.

PICs are developed in a multiprofessional and interdisciplinary context; it is worth highlighting that, in Brazil, Nursing was the first profession to recognize PICs as a care practice, focusing on the person's autonomy over their health<sup>24</sup>. In this context, for being configured as a humanistic science, Nursing can find in these practices new ways to provide comprehensive care to the patients, with an emphasis on health promotion and disease prevention<sup>25</sup>.

Currently, PICs are recognized as a Nursing specialty through COFEN Resolution No. 581 of 2018, ensuring the safety and legal support of these professionals to work in this scenario, as well as to develop research studies with PICs<sup>26</sup>.

Previous studies<sup>8,11</sup> show that the use of auricular acupuncture in care is low cost, highly effective, has no or minimal side effects and is easy to apply by duly trained professionals<sup>8,11</sup>. In addition to that, it favors strengthening of the therapeutic bond and, consequently, greater adherence.

Interdisciplinarity effectively contributes to strengthening a new health care model, which advocates changes in the training strategies of its professionals<sup>27</sup>. This diversity of perspectives can provide greater completeness, reliability and legitimacy to the protocol.

It is noted that the World Health Organization (WHO) has encouraged the implementation of PICs in national health care systems since the 1970s, through the Traditional Medicine Program, which aims at breaking with the fragmentation and hospitalization proposed by the biomedical model. in addition to stimulating research studies, thus expanding scientific evidence on the theme<sup>28</sup>. PICs are important tools that contribute to the implementation of actions aimed at controlling, preventing and treating headaches.

In line with the physiology referring to each point, the protocol validated by the experts consisted of the following points: *Shen Men* (sedative, by releasing endorphins, widely used in the treatment of pain); Kidney (it stimulates blood filtration and circulation and contributes to the elimination of toxins); Sympathetic (it accelerates and regulates neurovegetative activity and acts on sympathetic and parasympathetic functions by promoting rebalance of the autonomic nervous system; it also has analgesic, anti-inflammatory and muscle fiber relaxation effects)<sup>12</sup>; Anxiety (it helps control generalized anxiety, nervous tension, stress with mental fatigue and insomnia<sup>14</sup>; Subcortex (it acts in painful processes)<sup>14</sup>; Brainstem (it acts on emotional problems)<sup>11</sup>; Liver (it promotes good blood assimilation and energy reserve)<sup>13</sup>; and points at the pain site: Frontal, Occipital, Temporal (analgesic action).

To determine the best treatment modalities for patients with headaches, it is first and foremost necessary to scientifically demonstrate the effectiveness of the intervention so that all the evidence can then be applied in the clinical practice<sup>8</sup>.

Considering the theoretical aspects about headaches and Traditional Chinese Medicine, after careful selection and validation by experts, an auricular acupuncture point

protocol for the treatment of headaches was obtained, proving to be a tool that can exert a positive impact on the clinical and scientific practice, representing an innovation for decision-making and control/treatment of this clinical condition.

In the Brazilian context, PICs currently have legal support for their implementation in all health services<sup>26</sup>, thus showing their importance, being shaped as an important tool to meet the comprehensive assistance principle, with potential for expanding access to care and its qualification<sup>25</sup>.

One of the limitations pointed out is the scarcity of studies that apply a validated auricular acupuncture point protocols in the treatment of headaches, as well as studies evaluating the effect of the technique on the aforementioned outcome.

### CONCLUSION

The acupoint protocol used in auricular acupuncture for the treatment of headaches had its content validated by experts, proving to be a tool that might exert a positive impact on the clinical and scientific practice, as it represents a possibility for decision-making and treatment of this clinical condition, requiring subsequent clinical validation.

It is expected that this study will contribute to the development of similar surveys by providing a model for methodological studies on the development and validation of an auricular acupuncture point protocol, in addition to favoring the visibility, protagonism and autonomy of Nursing in the use of PICs, with the implementation of practices based on scientific evidence, positively impacting the comprehensive care and quality of life of the people assisted.

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