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Effectiveness of auriculotherapy for urinary incontinence in adults and older people: a systematic review protocol

Efetividade da auriculoterapia para incontinência urinária em pessoas adultas e idosas: protocolo de revisão sistemática

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ABSTRACT

Objective: To analyze the effectiveness of auriculotherapy for urinary incontinence in adults and older people, compared to placebo, control, or usual treatment groups. **Method:** systematic review protocol with meta-analysis, following the recommendations of the Joanna Briggs Institute (JBI). Searches will take place in seven sources of information. Experimental and/or observational studies that used auriculotherapy as an intervention for urinary incontinence in adults or elderly people will be included. The stages of selection, data extraction, and critical evaluation will be developed by two independent reviewers. The methodological quality of the studies will be evaluated as directed by the JBI. It is proposed to develop a statistical synthesis with meta-analysis, if appropriate; otherwise, a narrative synthesis will be applied. Protocol with registration in the International Prospective Register of Systematic Reviews (PROSPERO), code CRD42023445508.

Descriptors: Auriculotherapy; Urinary Incontinence; Adult; Elderly; Systematic Review.

RESUMO

Objetivo: analisar a efetividade da auriculoterapia para incontinência urinária em pessoas adultas e idosas, comparada a grupos placebo, controle ou de tratamento habitual. **Método:** protocolo de revisão sistemática com metanálise, seguindo as recomendações do *Joanna Briggs Institute* (JBI). As buscas ocorrerão em sete fontes de informação. Serão incluídos estudos experimentais e/ou observacionais que utilizaram auriculoterapia como intervenção para incontinência urinária em pessoas adultas ou idosas. As etapas de seleção, extração de dados e avaliação crítica serão desenvolvidas por dois revisores independentes. A qualidade metodológica dos estudos será avaliada conforme orienta o JBI. Propõe-se desenvolver uma síntese estatística com metanálise, se apropriado; caso contrário, uma síntese narrativa será aplicada. Protocolo com registro no *International prospective register of systematic reviews* (PROSPERO), código CRD42023445508.

Descritores: Auriculoterapia; Incontinência Urinária; Adulto; Idoso; Revisão Sistemática.

INTRODUCTION

According to the International Continence Society (ICS), the symptoms of the Lower Urinary Tract (STUI) are among the most reported by the general population, and urinary incontinence (UI) is one of the most prevalent among adult and elderly people[1]. It is estimated that the prevalence of this disease in the population concerned varies from 9.9% to 36.1%[2].

UI is defined as any involuntary loss/exit of urine, self-reported or verified[1]. This condition can be classified as stress incontinence (abrupt increases in intra-abdominal pressure, for example, by cough), urgency (involuntary loss of urine after urgent and uncontrollable need to urinate), overflow (when the bladder is excessively full), functional (loss of

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urine resulting from cognitive/physical deficits) or mixed (there is a combination of more than one UI type) [1].

The presence of IU increases the complexity of the clinical management of the patient and compromises its autonomy and independence for the activities of daily life (ADL)[3-4]. Thus, to promote a better quality of life for the individual, it is necessary to have early identification and adequate management, of factors that contribute positively to the prognosis of this condition, as well as assist in the integral care of affected patients[5]. Therefore, interventions to control, reduce and/or treat IU are relevant[5-6]. Thus, auriculotherapy is effective for the treatment and/or reduction of UI symptoms[5-8]. It is a practice applied mainly with the use of needles, spherical crystals, and seeds. When used, auriculotherapy stimulates reflex points of the ear that are associated with the central nervous system and favor body homeostasis[9-10]. Studies point out as a safe, non/non-invasive technique, with minimal side effects (such as local pain and itching), and its application is fast, with characteristics that provide better therapeutic adherence[9-11].

Moreover, this technique can be applied alone or combined with other conventional therapeutic procedures in the control of UI, which favors it as a therapy for this condition[5,7]. However, as a rule, treatment for UI includes pelvic floor muscle training (TMAP), use of medications, and behavioral changes[5,7], i.e., approaches that require adherence, changes in attitudes, changes in attitudes, and changes in behavior. availability of time and physical fitness, which sometimes makes them challenging for people who live with this disease.

Aiming at appropriation in the theme, preliminary research was carried out in the International Platform for the Registration of Systematic Reviews (PROSPERO), the Open Science Framework (OSF), and the Cochrane Database of Systematic Reviews, and systematic analyses were not identified. to date, directed strictly to evaluate the effectiveness of auriculotherapy for IU in adults and elderly people. Investigations were identified on the efficacy of complementary therapies for the management of symptoms of the lower urinary tract of the male[12]; the efficacy and safety of acupuncture and moxibustion for urinary retention in patients after the cerebral vascular accident [13] and the effectiveness of electroacupuncture for female patients with IU[14]; different from the present proposal.

In addition, evidence-based practice (PBE) is constantly growing, in particular by assisting clinical and care decision-making[15]. Given the above, and depending on the gap of technical-scientific knowledge in the area, it becomes pertinent to investigate the subject in question. Therefore, the objective is to analyze the effectiveness of auriculotherapy for urinary incontinence in adults and the elderly, compared to placebo, control, or usual treatment groups.

METHOD

Type of review study

Systematic Review of Effectiveness (RSE)[16]. The recommendations of the Joanna Briggs Institute (JBI)[16], the Preferred Reporting of Items to Include When Reporting a Systematic Review Involving a Network Meta-Analysis (PRISMA NMA) will be followed[17] and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for acupuncture studies[18]. CSR will follow the steps of: Formulation of the review question; definition of selection criteria; location of studies; selection of studies for inclusion; evaluation of the quality of studies; data extraction; analysis and synthesis of relevant studies; presentation and interpretation of results[16].

For the formulation of the CSR question, MNEMONIC peak (population; intervention; comparison; outcomes) was used, in which it was defined: P = adult and elderly people; I = auriculotherapy; C = control group, placebo or usual treatment; and O = control and/or reduction of UI symptoms. Therefore, the search will be carried out to answer the following question: What is the effectiveness of auriculotherapy for the control and/or reduction of urinary incontinence symptoms in adults and elderly, comparing the intervention with the control group, placebo and/or usual treatment?

Selection criteria of studies

Studies from randomized clinical trials will be prioritized (RCTs), to answer the review question. In the absence of productions with this design, almost experimental or observational designs will be considered. It will not be delimited temporal, or idiomatic. Figure 1 elucidates other details of the selection criteria, according to the PICO strategy[16].

Mnemonic element	Detail of the inclusion criteria
P opulation	Studies that include adult and elderly people with diagnosis and/or symptoms of urinary incontinence (by effort, urgency, by overflow, functional or mixed), under treatment/follow-up at home, outpatient or hospital.
I ntervention	Studies that include the use of auriculotherapy by pressure, acupuncture, or electrical stimulation, with the use of seeds, spherical devices or micro needles.
C omparation	Studies comparing the use of auriculotherapy with other therapies may be: absence of intervention (control), placebo (*sham points*) or usual treatment (use of pelvic floor muscle therapy; re-education of life and health habits; symptomatic medications).
***O**utcomes*	Primary: effects (positive or negative) of auriculotherapy on symptoms and prevalence of urinary incontinence. Secondary: Improvement of quality of life.

Figure 1 – Detailing the selection criteria according to the PICO mnemonic. Santa Maria, RS, Brazil, 2023

The lists of references of the included articles will be evaluated, as will be made contact with authors, or with the journal, if necessary; a period of 30 days will be expected for returns. Duplicate articles will be considered once.

Sampling and definition of the sources of primary studies

The search for references in the databases will be carried out: Medical Literature and Retrieval System Online (MEDLINE), via PubMed; SCOPUS(Elsevier); EMBASE (Elsevier); Latin American and Caribbean Health Sciences Literature (LILACS), through the Virtual Health Library (VHL); Web of Science Core Collection (Clarivate analytics); Cochrane Library; and, on Google Scholar (Gray Literature). The Journal Portal of the Coordination for the Improvement of Higher Education Personnel (CAPES) will be used for remote access to the bases.

Search strategies in databases

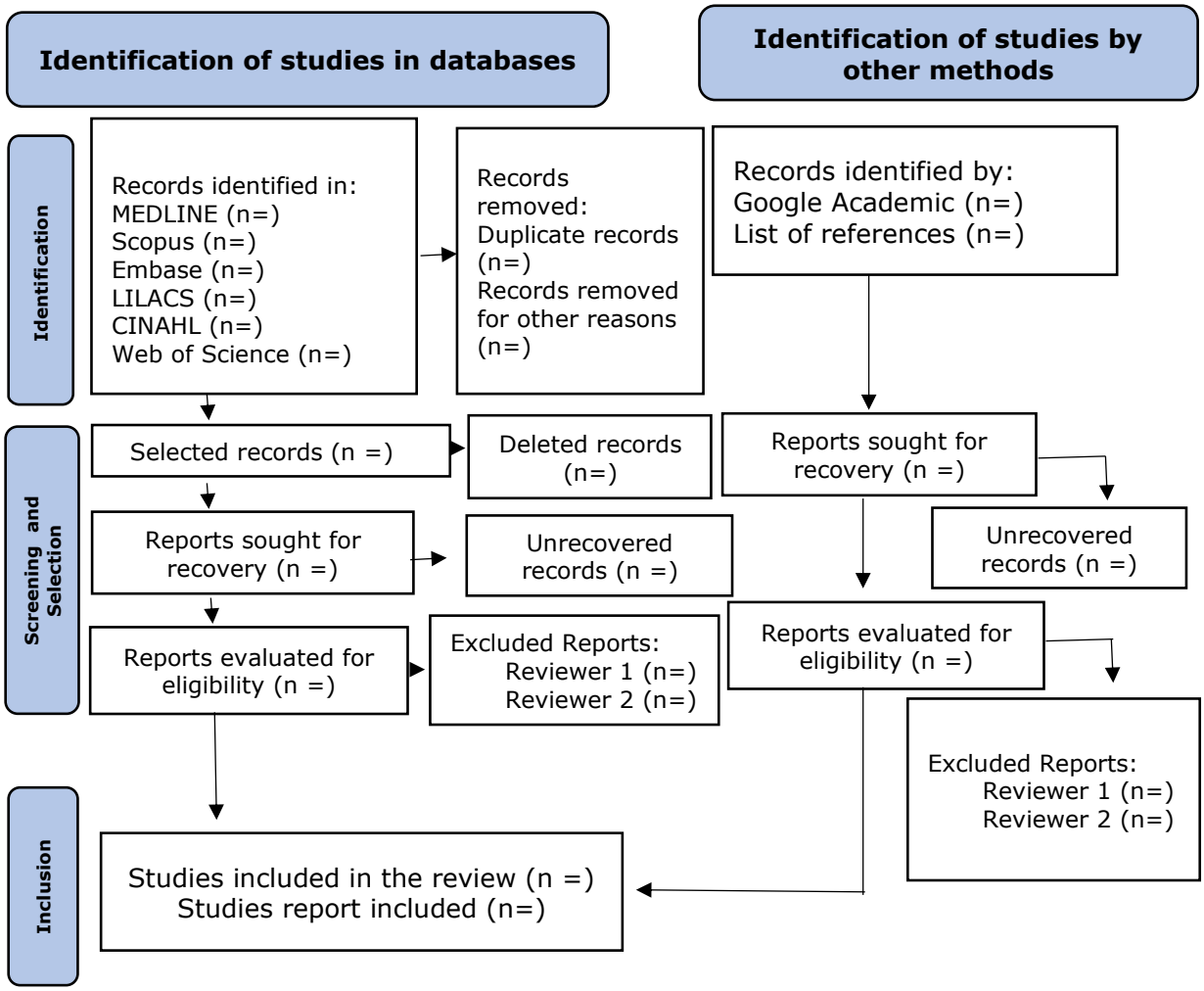
A specific strategy will be defined for each database, using Health Science Descriptors (DeCS), Medical Subject Headings (MeSH Terms), keywords, and entry terms, combined with the Boolean operators "AND "and" OR" for the location of the studies. Thus, the details of the advanced strategy of the MEDLINE database are presented (Figure 2). From this, the adjustments to the other bases will be made.

Search	Search strategy	References retrieved
#1	((((“auriculotherapy”[MeSH Terms]) OR (“acupuncture, ear”[MeSH Terms])) OR (“auriculotherapy”[All Fields])) OR (“acupuncture ear”[All Fields])) OR (“nada protocol”[All Fields])	738
#2	(((((((incontinence, urinary[MeSH Terms]) OR (“urination disorders”[MeSH Terms])) OR (“urinary retention”[MeSH Terms]))) OR (lower urinary tract symptoms[MeSH Terms]) OR (“incontinence, urinary”[All Fields]) OR (“urination disorders”[All Fields])) OR (“urinary retention”[All Fields]))) OR (“lower urinary tract symptoms” [All Fields]))))	155,041
#3	(((adult[MeSH Terms]) OR (aged[MeSH Terms])) OR (Adults[All Fields])) OR (Elderly[All Fields]))	8,998,451
#4	#1 AND #2 AND #3	7
	Search date: July 05th, 2023	

Figure 2 – Search strategy for systematic review of effectiveness according to the MEDLINE database. Santa Maria, RS, Brazil, 2023

Selection of primary studies

The studies will be elected by two reviewers, being a main reviewer (with experience in the subject of auriculotherapy) and a secondary one, with experience in the subject of auriculotherapy. First, the reading of titles and abstracts will take place, for later reading in full of those included. The reviewers will examine the productions independently; after, a comparison of the banks will be made to verify possible differences, with a consensus between the parties. In case of divergences, a third reviewer will be consulted. As for the management of references, Rayyan software will be used. The results will be reported following the PRISMA guidelines[17-18] using a flowchart (Figure 3).



Source: Adapted from Hutton et al., 2015.
Figure 3 – Flowchart PRISMA of selection of studies. Santa Maria, RS, Brazil, 2023

Critical evaluation of selected primary studies

A critical evaluation will be made to verify the methodological quality and to identify to what extent a study excluded (or minimized) design bias, conduct, and analysis[16]. The evaluation will take place in a double independent way, with subsequent consensus and consultation of the third reviewer for the divergences. In addition, reviewers will report in a narrative manner and through tables the results of the evaluation for the risk of bias and methodological quality of the included studies. The instruments used will be those recommended by JBI[16].

Extraction of the data found

After data extraction, a table will be prepared in the Excel software to extract the following

information: identification of the manuscript (year, authorship, journal, language, country of origin of the study, and research groups), objective, and methodological characteristics (design, sample and collection instruments); sociodemographic and clinical variables (sex, age, diagnosis); auriculotherapy used (characteristics of the intervention, location form and applied points, sessions and intervals, ear application, place – physical structure – intervention application); main results (size of intervention groups, follow-up losses, effects on health conditions, size of effects, statistical differences, side effects); conclusions. These data were defined to be extracted by the recommended by the Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA)[19].

Also, this step will be carried out by two reviewers and with the consultation of a third party in cases of disagreements. The authors of the included studies will be contacted in cases of need of clarification of results or request for additional information.

Synthesis of evidence

It is proposed that a statistical synthesis will be developed with meta-analysis, if appropriate, and, otherwise, a narrative synthesis[16].

As for the statistical model for meta-analysis, the random effects model will be used, in which it is assumed that the size of the effect is approximated to the average distribution of real effects[16] .

The effect sizes will be verified considering the results of risk ratio (RR), risk difference (RD), odds ratio (OR), weighted, and standardized mean difference. For meta-analysis of dichotomous data, odds ratio logarithm calculation will be used. Also, the effect size results will be expressed with RR and RD; for meta-analysis for continuous data, the effect size will be calculated using data referring to mean, standard deviation, and number of participants, emphasizing differences between means of intervention and control group. Cohen's d index will be applied for this calculation.

The conduct of the meta-analysis will be through *the software Review Manager 5.3*. Statistical heterogeneity will be tested using the square of I (I^2), being that: values I^2 of 25% = low heterogeneity; I^2 of 50% = moderate, and 75% = high. For results of heterogeneity greater than or equal to 50%, a random effects model will be used for the combination of the results. In case of lower values, the fixed effects model will be applied.

Sensitivity analysis will be performed, aiming to explore the impact of excluding or including studies in the meta-analysis based on sample size, methodological quality, or variation of effects.

It is assumed that subgroup analyses will be performed. Subgroups will include the following: auriculotherapy with seeds versus auriculotherapy with micro needles; auriculotherapy with seeds versus auriculotherapy with crests or spheres; auriculotherapy versus conventional drugs; and type of control. If feasible, studies containing participants with the same clinical characteristics will form another subgroup.

It is worth mentioning that a network meta-analysis[17,20-21] can be considered, considering that auriculotherapy is an intervention that can be applied with different techniques and materials. The objective is to develop direct comparisons (between similar interventions) and/or indirect (between different interventions compared to a common control group and tested in different clinical trials), with a combination of different interventions in a single analysis. The transitivity of interventions will also be considered, in which interventions will be considered compared simultaneously in a single randomized multi-arm trial.

Record of the systematic review protocol

The RSE protocol was evaluated by a librarian with expertise in search strategies, with subsequent referral to PROSPERO, obtaining code CRD42023445508.

Expected results

To verify the effectiveness of auriculotherapy for IU in adults or elderly people; to understand the factors associated with this condition; to identify the biosocial characteristics, work, and health profile of adult or elderly people affected by IU; obtain subsidies to propose an interventional protocol with specific ear points for the reduction of UI in adult or elderly people.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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