Study Protocol

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Auricular acupuncture for compassion fatigue in nursing professionals: a randomized clinical trial protocol

Acupuntura auricular para fadiga de compaixão em profissionais de enfermagem: protocolo de ensaio clínico randomizado

Acupuntura auricular para la fatiga por compasión en profesionales de enfermería: protocolo de ensayo clínico aleatorizado

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ABSTRACT

Objective: To present a study protocol to evaluate the efficacy of auricular acupuncture on compassion fatigue scores in nursing professionals, compared to the placebo group and control group.

Method: Randomized, controlled, double-blind, three-arm parallel clinical trial protocol, conducted with nursing professionals from a teaching hospital who present compassion fatigue. Volunteers will be randomly assigned to three groups to receive eight sessions of auricular acupuncture or follow-up. The primary outcome will be the compassion fatigue score, and the secondary outcome will be compassion satisfaction, measured by the Brazilian version of the Professional Quality of Life scale, and the depression, anxiety, and stress scores, measured by the Depression, Anxiety, and Stress scale, Brazilian version.

Expected results: The results may strengthen the validity of auricular acupuncture to mitigate compassion fatigue, enabling its incorporation as a mental health care strategy for the nursing team in the workplace.

Final considerations: This protocol aims to test the efficacy of auricular acupuncture for compassion fatigue in hospital nursing professionals. In addition, it may contribute to the management of these professionals' quality of life and support future research on the application of this therapy by nurses. Record identifier RBR-28xttdt.

Descriptors: Compassion fatigue; Auricular acupuncture; Nursing team; Randomized Controlled Clinical Trial; Mental health.

RESUMO

Objetivo: Apresentar um protocolo de estudo para avaliar a eficácia da acupuntura auricular nos escores de fadiga de compaixão em profissionais de enfermagem, comparados ao grupo placebo e grupo controle.

Método: Protocolo de ensaio clínico randomizado, controlado, duplo-cego, de três braços paralelos, realizado com profissionais de enfermagem de um hospital escola que apresentam fadiga de compaixão. Os voluntários serão distribuídos aleatoriamente em três grupos para receberem oito sessões de acupuntura auricular ou acompanhamento. O desfecho primário será o escore de fadiga de compaixão e o secundário será a satisfação por compaixão, aferidos pela versão brasileira da escala de Qualidade de Vida Profissional, e escores de depressão, ansiedade e estresse, aferidos pela *Depression, Anxiety and Stress scale*, versão brasileira.

Resultados esperados: Os resultados podem fortalecer a validade da acupuntura auricular para mitigar a fadiga de compaixão, possibilitando a sua incorporação como estratégia de cuidado à saúde mental da equipe de enfermagem no ambiente laboral.

Considerações finais: Este protocolo objetiva testar a eficácia da acupuntura auricular para fadiga de compaixão em profissionais de enfermagem hospitalares. Além disso, poderá contribuir para o manejo da qualidade de vida desses profissionais e em pesquisas futuras acerca da aplicação desta terapêutica por enfermeiros. Registro identificador RBR-28xttdt.

Descritores: Fadiga de compaixão; Acupuntura auricular; Equipe de enfermagem; Ensaio Clínico Controlado Aleatório; Saúde Mental.

RESUMEN

Objetivo: Presentar un protocolo de estudio para evaluar la efectividad de la acupuntura auricular en las puntuaciones de fatiga por compasión en profesionales de enfermería, en comparación con el grupo placebo y el grupo control.

Método: Protocolo de ensayo clínico aleatorizado, controlado, doble ciego, de tres brazos paralelos, realizado con profesionales de enfermería de un hospital universitario que presentan fatiga por compasión. Los voluntarios serán distribuidos aleatoriamente en tres grupos para recibir ocho sesiones de acupuntura de oído o seguimiento. El resultado primario será la puntuación de fatiga por compasión y el resultado secundario será la satisfacción por compasión, medida por la versión brasileña de la escala de Calidad de Vida Profesional, y puntuaciones de depresión, ansiedad y estrés, medidas por la *Depression, Anxiety and Stress scale*, versión brasileña.

Resultados esperados: Los resultados pueden fortalecer la validez de la acupuntura auricular para mitigar la fatiga por compasión, posibilitando su incorporación como estrategia de atención a la salud mental del equipo de enfermería en el ambiente laboral.

Consideraciones finales: Este protocolo tiene como objetivo probar la eficacia de la acupuntura auricular para la fatiga por compasión en profesionales de enfermería hospitalarios. Además, puede contribuir a la gestión de la calidad de vida de estos profesionales y en futuras investigaciones sobre la aplicación de esta terapia por parte de las enfermeras. Registro identificador RBR-28xttdt.

Descriptores: Desgaste por Empatía; Acupuntura Auricular; Grupo de Enfermería; Ensayo Clínico Controlado Aleatorio; Salud Mental.

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INTRODUCTION

Hospital healthcare professionals who worked during COVID-19 were intensely exposed to work-related stress, which led to an increase in mental suffering among this population[1,2]. The impact was greater among nursing professionals, due to the characteristics of their work nature, such as the greater workload and the time in direct contact with patients' pain and suffering. Thus, these professionals were more subject to emotional distress, including compassion fatigue (CF)[2,3].

CF is defined as a syndrome of emotional exhaustion associated with the complexity of the healthcare work environment and the empathic bond with the patient, understood within the model of professional quality of life (ProQoL)[3–5]. In Brazil, studies conducted in a hospital context during COVID-19 indicate evidence of CF among nursing professionals[6,7], while international studies indicate a high prevalence of this condition among nurses, with a progressive increase since 2010[3].

Other studies indicate that nursing professionals who experience CF often have reduced empathic capacity after repeated exposure to traumatic situations faced by people under their care[3,4,8]. This can trigger feelings and behaviors that include disengagement, apathy, anger, sadness, and a decline in the ability to perform work-related tasks, increasing absenteeism[3,4,8,9] and, consequently, reducing the quality of care provided[3,8,9]. Therefore, it is essential to adopt measures to reduce CF among nursing professionals[3,9], which should preferably be developed in the workplace to enhance adherence and acceptability among professionals[8,10].

It is noteworthy that auricular acupuncture (AA) has proven to be beneficial in reducing CF among nursing professionals[11,12] because it is a non-pharmacological resource, accessible and easy to apply in hospital settings[13]. This is a therapeutic approach of traditional Chinese medicine (TCM), based on the concept that the ear is formed by the three embryonic layers and, therefore, contains reflex areas corresponding to the entire human body structure[14,15].

Contemporary studies indicate that the neural action of AA is related to the rich innervation of the auricular pavilion and, therefore, stimuli in the regions of the conchae and auricular tragus activate the afferent vagosympathetic pathway through the auricular branch of the vagus nerve (ABVN), triggering organic effects such as vasodilation, sensation of relaxation and analgesia[14–16]. Thus, AA can be used to manage physical and emotional disorders by stimulating acupoints located on the auricular surface[15].

Experimental studies that evaluated the action of AA on CF using randomized groups composed of nursing professionals working in a hospital setting[11,12], despite showing promising and significant results, did not include groups with placebo-type interventions for data comparison, which can weaken and limit the inference of outcomes. Moreover, the lack of studies that present detailed comparison groups has been a significant methodological gap in AA research[13,17]. This is because placebo controls are considered the gold standard for evaluating the benefits and/or risks of active interventions[18] and should be used alongside non-intervention control groups to allow specific placebo-related outcome comparisons[19].

Conducting research with well-designed randomized groups, with adequate statistical power and post-intervention follow-up is essential to produce robust evidence demonstrating the efficacy of AA in reducing levels of compassion fatigue[8,10,17]. However, for this to occur, it is essential to develop rigorous protocols that describe in detail the eligibility criteria, the randomization process, the definition and comparison of groups, and the methods of statistical analysis, aiming to ensure replicability, and the dissemination of robust evidence.

Therefore, the study is justified by the considerable prevalence of moderate to high levels of CF among nursing professionals, a condition that affects both individuals and the organizations of which they are part, especially due to the risk of a decrease in the quality of care provided[3,6,7,9]. Additionally, the study is innovative because it explores the efficacy of a non-pharmacological intervention, such as AA, by proposing a protocol with specific auricular points, including randomization and comparison among three groups.

In view of this, the question that this study seeks to answer is: Is AA effective in reducing CF levels in nursing professionals when compared to the placebo group and control group? The hypothesis is that the group exposed to the intervention, with the points selected for CF, will have a more pronounced decrease in CF scores compared to the placebo and control groups.

To answer this question, this manuscript aims to present a study protocol to evaluate the efficacy of auricular acupuncture on compassion fatigue scores in nursing professionals, compared to the placebo group and control group.

METHOD

This protocol complies with the guidelines of the Standard Protocol Items for Interventional Trials (SPIRIT) [20], of the Consolidated Standards of Reporting Trials: extension to randomized pilot and feasibility trials (CONSORT)[21]. It also complies with its extension for use in acupuncture studies, called Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [22], and the Template for Intervention Description and Replication (TIDIeR-PLACEBO)[18].

Study design

This clinical trial protocol is characterized as a randomized, controlled, double-blind, three-arm parallel stud. The protocol will evaluate the efficacy of AA (intervention group) on CF scores in nursing professionals when compared to the placebo group and the control group (without intervention). The study is called double-blind because only the main researcher, responsible for applying the intervention, will be aware of the allocation of each volunteer in the groups, while the participants and the evaluators of results and statistics will be blinded to the assignments of group members[18].

Therefore, an intervention using AA in three comparative groups is proposed: intervention group (IG), placebo group (PG) and control group (CG). This division aims to better evaluate the efficacy of AA in reducing CF levels among nursing professionals at a university hospital. Volunteers will be assessed at three different time points: before the intervention (baseline), at the end of the intervention, and fifteen days after follow-up.

Study participants

Nursing professionals from a medium-sized general public hospital located in the Central-West region of Brazil and affiliated with the *Universidade Federal de Mato Grosso* (UFMT), which is part of the healthcare network of the *Empresa Brasileira de Serviços Hospitalares* (EBSERH).

Eligibility criteria

The study will include: nursing professionals from the aforementioned hospital with at least six months of work experience and who work at the healthcare level (clinical and/or outpatient) in the provision of direct care to patients[3,11]; who have fully responded to all items on the scale that assesses CF - Professional Quality of Life Scale adapted to Brazil (ProQoL-BR) -, as well as to the questionnaires on sociodemographic, work, and physical and mental health variables; and who are interested and have time available to participate in all stages of the research.

In the recruitment phase, participants who present a low level (percentile < 25%) of CF according to the ProQoL-BR scale[4] and diagnoses of severe mental disorders will be excluded. In the intervention application phase, during the first consultation, participants will be excluded if: based on the applicator's assessment or report: the presence of dermatological lesions, infection, inflammation, wound, and/or excessive oiliness in the auricular pavilion; allergy to adhesive tape (bandage and micropore); use anticoagulants or hearing aids; or if pregnant[23,24]. The exclusion of these participants was based on the need to maintain sample homogeneity and control potential biases.

Sample size estimation and randomization

The sample size was estimated using the GPower software, version 3.1.9.7[25], for the Analysis of Variance test for repeated measures. For this, the following parameters were considered: sample power 80%, significance level of 0.05%, small effect size (0.25), number of groups (3), number of assessments (3), moderate interaction between and within subjects (0.5), and non-sphericity correction $\varepsilon = 1$. Thus, the minimum sample size for the study was estimated at 36 participants. Anticipating the possibility of participant dropout, a minimum percentage of 35% will be added to the final value of the sample calculation, totaling 48 participants. The allocation will be 1:1:1, resulting in 16 participants in each group.

The sample power of 80% was chosen because it is a widely accepted standard in the literature, balancing the ability to detect real effects with the practical feasibility of the study. Any values different from 80%

increase the risk of Type II error or require excessively large sample sizes. Furthermore, a small effect size was adopted due to the lack of previous data on the magnitude of effect for the variables used in this study, maintaining a conservative approach to minimize the risk of Type II errors[26] and ensure a larger sample size, regardless of the magnitude of the effect to be found in the study.

After applying the eligibility criteria, volunteers will be allocated to one of three groups: IG, who will receive AA with action points for CF; PG, who will receive AA with neutral points for CF; and CG, who will not receive intervention and will only be monitored. Participants will be allocated through a simple randomization conducted through the website http://random.org. Everyone will have an equal chance of being assigned to any of the three groups, thus reducing the chances of confounding bias.

Study protocol

In the first phase of the study, nursing professionals will be recruited through visits to hospital sectors conducted by a previously trained assistant researcher. After accepting the informed consent form (ICF), professionals interested in participating in the study will have access to self-administered research instruments that will be applied through the Google® Forms tool, which include:

1) Sociodemographic, health and work questionnaire, containing 57 questions to characterize the sample (sex, age, race, sexual orientation, marital status, number of children, income, education, religion, lifestyle habits [diet/sleep/exercise], medication use, pre-existing conditions, psychological monitoring, use of complementary therapies, occupation, sector of activity, type of patient care, work shift, time since graduation, weekly workload, type of employment bond, whether worked on Covid-19, days off work in the past year and perception of working conditions).

2) Professional Quality of Life Scale (ProQoL)[4] adapted to Brazil[5], called ProQoL-BR. It consists of 28 items divided into two subscales that measure Compassion Satisfaction (15 items) and CF (13 items), three of which refer to Burnout and 10 to Secondary Traumatic Stress (STS). Responses follow a 5-point Likert scale, ranging from 0 (Never) to 5 (Always), with option 0 considered null in the final score set. The final score (continuous) for both domains is obtained by summing their respective items, with scores ranging from 0 to 75 points, where higher scores indicate a greater occurrence of the phenomenon. Cut-off points will be set around the 25th and 75th percentiles based on the database, where percentiles below 25% indicate a low level of the variable, and above 75% indicate high levels of CF[4].

3) Depression, Anxiety and Stress Scale (DASS-21)[27] adapted to Brazil[28], consisting of 21 questions divided into three subscales: Depression, Anxiety and Stress, scored on a Likert scale from 0 to 3 points, ranging from "totally disagree" to "totally agree". Higher scores indicate greater severity of symptoms[27]. In this study, the reliability of the scales will be tested using McDonald's Omega.

The second phase of the study involves the application of the interventions and will involve nursing professionals who meet the eligibility criteria and who were randomized into the groups of interest in this study. After randomization, contact will be made via the WhatsApp® application to schedule and begin AA care, according to the time and availability of participants.

At the end of phase two, after the completion of the AA services for the IG and PG groups, the research instruments (2 and 3) will be applied to all participants in the experiment. Also in this stage, the IG and PG groups must complete the fourth data collection instrument:

4) Evaluation form of the participants' experience in the AA services, containing 11 questions, applied to assess the expectations regarding the services, the perceived benefits, degree of blinding perception and adverse reactions to AA, and trust in AA and in the intervention provider[18,22] by the groups that underwent the intervention (IG and PG).

The research instruments of this protocol were pre-tested by a group of nurses with experience in hospital clinical practice and in scientific research involving topics such as mental health, occupational health of healthcare professionals and intervention studies. The testing was conducted to assess the comprehensibility and coherence of the statements in the sociodemographic, health and work questionnaire, as well as the time required to complete the applied scales.

The third phase will occur 15 days after the end of the intervention with the reapplication of the scales (ProQoL-BR and DASS-21) to the three groups (IG, PG and CG). The steps of this study protocol are described in Figure 1.

Interventions

Participants in the IG and PG will receive AA sessions administered by the main researcher, who is a nurse with a postgraduate degree in acupuncture and six years of experience. Eight AA sessions will be performed, one every five to seven days, depending on the nurse's shift schedule. In the first session, the application of AA will be standardized on the right ear, alternating the auricles in the other sessions, and the order in which the adhesives are applied will start from the point closest to the auricle and continue to the lowest point (lobular region). The applicator will maintain neutral communication with the participants throughout the process.

The services will be conducted at the volunteers' workplace, in the area designated for rest in each sector, where they will be invited to sit. The auricular pavilion will be sanitized and then the ear points will be palpated using a rigid angled palpator, specific for the technique. After the points have been identified, mustard seeds attached to light brown hypoallergenic tape, prepared in a disposable plastic card for application, will be fixed using a 12 cm serrated straight tweezer. The name and location of the predetermined auricular points will follow the guidelines of the World Federation of Acupuncture and Moxibustion Societies (WFAS), which is the international standard for mapping auricular points[15,29].

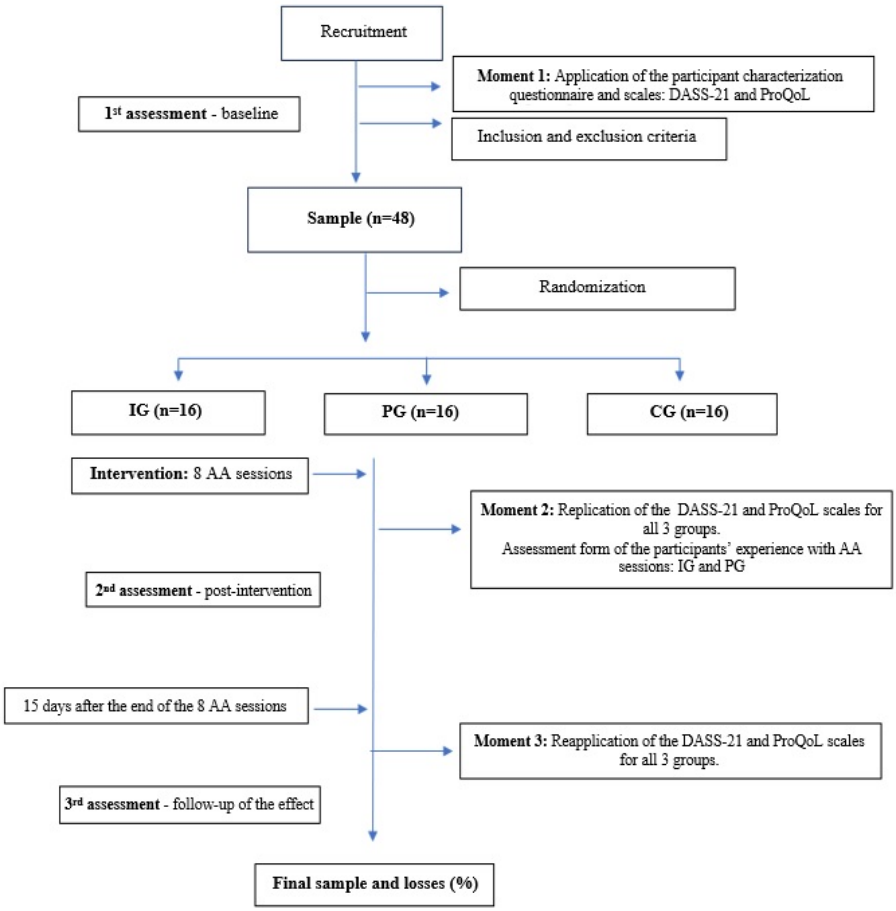

Figure 1 – Flowchart of study interventions. Cuiabá, Mato Grosso, Brazil, 2023.
Source: Authors

The protocol for the IG was constructed based on a literature review and considered the auricular points frequently used for CF and occupational stress[11,12,13,30], due to their direct relationship with the construct[3,4,9]. The IG volunteers will receive AA at the shenmen, brainstem/cerebral, kidney, sympathetic, upper lung and liver points.

On the other hand, the PG point protocol was constructed to replicate neutral points used in similar studies[30,31,32], in addition to safeguarding the auricular concha, considering the stimulation of the ABVN[15,16]. The PG volunteers will receive AA at the following points: ear/external ear point; wrist point and cheek point. The participants included in the CG will not receive interventions.

Volunteers will be instructed on hygiene and conservation of the material attached to the auricular pavilion during intervals between sessions and will also be instructed to apply manual pressure to the auricular points three times a day for 10 seconds, until they feel pressure/pain. In addition, they will be instructed not to remove the seeds from the auricular points until the next session[13,23,31,32], and will be advised to contact the applicator if they experience any discomfort.

Moreover, participants will be monitored for complaints, discomfort and frequency of participation. Thus, participants will be discontinued from the sample if there is an gap of more than 10 days between AA sessions; if they are absent without returning on the days scheduled for the evaluations; if they have significant reactions, such as intolerable pain, lesions in the ear or allergy to the AA materials[13,23,31,32]; or if they wish to withdraw from the study. Losses and withdrawals and their respective reasons will be carefully recorded[18,22]. In cases of reactions to AA, participants will receive support from the research team.

Furthermore, after data evaluation, participants who complete the follow-up and do not show improvement in their CF scores will be referred to the occupational health sector of the study site, for monitoring regarding their quality of life at work.

Data Management and Analysis

Data related to the research instruments will be collected from the Google® form and stored in online Excel spreadsheets on Google Drive®. Two copies of these forms, protected by passwords, will be kept, with one as a backup, accessible only to the principal researcher and the intervention practitioner. The information will be categorized according to the collection stage and participant groups, and the variable naming will be guided by a data dictionary.

For the analysis stage, data access will be granted to the researchers involved through shared folders with their respective emails. There will be external sharing only of the analyzed data, alongside the publication of the manuscripts, to ensure the confidentiality of the participants and the originality of the results. The information collected in the study will be retained for a period of five years and will not be reused in other studies.

The data will be tabulated using Microsoft Office Excel 2017® software and analyzed using the Statistical Package for Social Sciences (SPSS)® version 27. In descriptive statistical analysis, categorical variables will be analyzed using absolute and relative frequency measures; continuous quantitative variables will be evaluated using measures of central tendency and dispersion.

Sequentially, for inferential analyses, Generalized Estimating Equations (GEE) will be employed to verify the effect of group (IG, PG and CG), time (pre, post and follow-up) and interaction (group x time) on the participants' CF score, as well as on the scores of the secondary outcome variables (SC and DAS). For pairwise comparisons, the Bonferroni post hoc test will be used. Effect size measures will be estimated using standardized Beta (β) coefficients, and a significance level of 5% will be adopted for the inferential analyses.

The use of GEE presents a series of advantages over traditional analyses, especially in contexts in which there are small samples that do not meet all the assumptions necessary for traditional analyses, such as ANOVA. In addition, GEE allows the application of different probability distributions and makes use of all available information from the sample subjects, minimizing losses throughout the study[33].

DISCUSSION

This protocol involves a randomized, double-blind, three-arm parallel study aimed at evaluating the effectiveness of AA on the CF scores of nursing professionals at a university hospital. Furthermore, the protocol

advances by comparing the outcomes found with the groups, PG and CG, to minimize the risk of confounding bias.

The primary outcome of the study will be assessed through the CF score (ProQoL-BR), and the secondary outcome will be assessed using the compassion satisfaction (CS) score, as it is considered the moderating factor of CF[4,34], and is also measured by ProQoL-BR.

CF is associated to adverse mental health outcomes, high levels of occupational stress, and reduced overall well-being among healthcare professionals[3,4,7,9]. Thus, depression, anxiety, and stress (DAS) scores will be investigated using the DASS-21 scale as secondary outcomes of the intervention, to verify whether these parameters will also be influenced by auricular acupuncture. The decrease in CF and DAS scores provides significant benefits to the worker's mental health and, when associated with an increase in CS, promote an overall improvement in the professional quality of life[3,4,8,9,34].

Regarding therapy, AA is considered a method of treating physical and psychosomatic dysfunctions through the stimulation of specific points on the ear[13,14,15], and is widely used to treat the conditions that this study seeks to address, such as depression[32], stress, anxiety, burnout[13,24,35], insomnia[36] and compassion fatigue[11,12]. AA treatment shows evidence of positive impacts on nursing professionals when applied in the workplace[13,30].

It is noteworthy that during the development of this protocol, the evidence on the factors that could affect the effectiveness of AA in the study population was carefully analyzed, such as the number of sessions, therapeutic insertion points and placebos, duration and laterality of stimulation. Research suggests positive results with the application of eight[13] to eleven AA sessions[24]. However, they also indicate that a higher number of sessions resulted in considerable dropout rate by participants during treatment[13,24,31]. Regarding the time the material should remain applied, systematic reviews recommend maintaining the stimulus in the ear for three[37] to seven days[13]. However, evidence suggests that after the fifth day of application, there is a decrease in the pain perception of the points and, consequently, in the therapeutic effect[15].

Moreover, removing the stimulus at the end of the fifth day prevents point saturation and reduces the risk of pressure-related injury at the site, thus making it ideal to alternate the stimulated auricle in each session[15,23]. Regarding the points used, these were constructed based on previous research that showed significant results in the evaluated outcomes and in the study population[11,12,13,30,31,32], associated with research that evaluated the action of stimuli on ABVN[15,16] and knowledge of TCM. Furthermore, AA is considered a safe therapy[23,32,37] and is rarely associated with severe complications, especially when using non-invasive devices such as seeds and spheres[15,23].

Furthermore, it is important to emphasize that the proposed protocol involves the application of a nursing specialty care intervention[38] and its proposal complies with the provisions of resolution no. 739 of 2024 of the Federal Nursing Council (*Conselho Federal de Enfermagem* - COFEN)[39], which recommends that nurses establish care protocols in integrative and complementary practices (PICS) in healthcare services.

In view of the above, it is expected that the methodological structure adopted in this study will provide a robust comparative analysis and strengthen the validity of the effectiveness of AA to mitigate CF, for the incorporation of this therapy as an effective mental health care strategy for the nursing team in the workplace.

ETHICAL CONSIDERATIONS

This study is part of an academic doctorate in Nursing at UFMT and complies with Resolution 466/2012 and was approved by the Research Ethics Committee (REC) of the *Hospital Universitário Júlio Muller* (HUJM), CAAE number: 71245823.2.0000.5541. The study is also registered in the Brazilian Clinical Trials Registry (REBEC), in its first version, under the identifier RBR-28xttdt, and under the universal test number (UTN), number U1111-1294-5827.

Volunteers interested in participating in the study will provide written consent before any stage of the research takes place. At the end of the study, participants in the PG and CG will be offered the same treatment provided to the IG. Allocation will only be revealed at the end of the study if requested by the volunteer.

It is noteworthy that the study is in the eligibility phase, scheduled to be completed in December 2025, and is being conducted with self-funding. The research results will be published in scientific journals and included in open access repositories.

FINAL CONSIDERATIONS

This study presented a randomized, double-blind clinical protocol involving three distinct groups (intervention, placebo, and control) and three comparison moments (baseline, post-intervention, and follow-up). This methodology was adopted to evaluate the effects of AA on the CF levels in nursing professionals working in a hospital setting, aiming at generating evidence about the effectiveness of this therapy.

It is expected that this protocol will contribute to disseminating the phenomenon of CF in nursing professionals and to expand research that provides reliable results of the effects of AA. Finally, this protocol was developed to support hospital managers in improving the QoL of nursing professionals, as well as expanding the application of this form of care recognized as a nursing specialty.

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Data and material availability

Access to the dataset can be obtained upon request to the corresponding author.

Authorship contribution

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