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REVIEW PROTOCOL

Effects of assisted therapy with animals for pain management: systematic review protocol

Efeitos da terapia assistida com animais no manejo da dor: protocolo de revisão sistemática

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ABSTRACT

Objective: To evaluate the existing randomized clinical trials in the literature on the effects of Animal Assisted Therapy on pain management in people with pain when compared to conventional treatment or other non-pharmacological interventions. **Method:** Systematic Review, reported according to Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P). The protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO). The search will be carried out in various sources of information, combining the descriptors 'Animal Assisted Therapy', 'Pain Management', and 'Controlled Clinical Trial' and their variations. Only randomized clinical trials will be included, and results will be managed in EndNote and Rayyan software. The assessment of bias risk will be carried out by the Cochrane Collaboration Risk of Bias 2 tool, and the assessment of the certainty of evidence by the Grading of Recommendations, Assessment, Development, and Evaluation. If possible, a meta-analysis will be performed to determine the effect of Assisted Therapy with Animals on pain intensity.
Descriptors: Assisted Therapy with Animals; Pain Management; Systematic Review.

RESUMO

Objetivo: Avaliar os ensaios clínicos randomizados existentes na literatura sobre os efeitos da terapia assistida com animais no manejo da dor, em pessoas com quadros álgicos, comparando-a ao tratamento convencional ou a outras intervenções não farmacológicas. **Método:** Trata-se de um protocolo de revisão sistemática reportado segundo o *Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols* (PRISMA-P). O protocolo foi registrado na *International Prospective Register of Systematic Reviews* (PROSPERO). A busca será realizada em bases de dados variadas, combinando os descritores 'Animal Assisted Therapy', 'Pain Management' e 'Controlled Clinical Trial' e suas variações. Serão incluídos apenas ensaios clínicos randomizados e o gerenciamento dos resultados se dará nos softwares EndNote e Rayyan. A ferramenta *Cochrane Collaboration Risk of Bias* 2 será utilizada para avaliação do risco de viés, e a ferramenta *Grading of Recommendations, Assessment, Development and Evaluation* (GRADE) será utilizada para avaliação da certeza de evidência. Se possível, a metanálise será realizada para determinar o efeito da terapia assistida com animais sobre a intensidade da dor.
Descritores: Terapia Assistida com Animais; Manejo da Dor; Revisão Sistemática.

INTRODUCTION

Pain is one of the main stressors present in people who seek or are in a health unit. It interferes with the respiratory, hemodynamic, physical and metabolic systems; and can cause damage to sleep, physical wear and fatigue. This substantially compromises the quality of life of people and may promote less motivation in cooperation with treatment[1].

Pharmacological treatment is one of the main pillars of pain management[2], based on analgesics. However, despite being a relatively effective solution, it may also present unwanted side effects[1], such as nausea, vomiting, respiratory depression, and hallucinations[2]. In addition, pain is considered a

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multidimensional condition, not restricted only to the physiological part; it also involves affective, emotional, spiritual, psychological, and social variables[1].

Therefore, health professionals must be attentive to the multidimensionality of pain in their clinical practice, adopting systematic evaluation techniques that allow the understanding of the whole and not only of the parts. It leads to the construction of a more accurate diagnosis, brings greater specificity to the interventions adopted, and reveals the professional's accountability to the patient with pain, which can provide better assistance and a more humanized approach[1].

Nowadays, seeking a better offer of the services provided, health managers and professionals have increasingly been concerned with the theme of pain and its variables. Above all, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes pain relief as an item to be evaluated in the hospital accreditation process[1]. Thus, there is a greater demand for effective strategies and potentializing behaviors adopted by health professionals, which can be used synergistically with traditional forms of treatment[3].

One resource that has proved to be very promising and whose practice has already been regulated in several countries is Animal Assisted Therapy (AAT). It is defined as a structured, non-pharmacological therapeutic approach involving trained professionals who use the animal as part of the work process to intervene in the social, physical, emotional, and cognitive aspects of the people involved[4].

The application of AAT has been positively reported in the literature, in which the reduction of insomnia and chronic pain is observed in the elderly [5]; improvement of living conditions and the general state of inactivity[5]; reduction of symptoms of depression and improvement of cognition and mood in those with Alzheimer's disease [4]. The literature also brings that it reduces anxiety in adults and students, helps in the recovery of surveillance after anesthesia, improves the feeling of well-being in children and adolescents with cancer, and motivates physical activity in overweight children[4]; it also provides modulation of respiratory and cardiac frequencies, blood pressure and oxygen saturation in children[2]. Moreover, it can be configured as a complementary intervention to conventional treatment to control pain in children[6,7] and adolescents[6]. However, through prior investigation in national and international sources of information, systematic reviews on the subject were not found with the general population, detailing, for example, the type of disease and the nature of pain in which AAT is most effective, as well as the effects, risks, benefits and their implications in patient care. In addition, among the existing studies, a few have high methodological rigor, making the applicability of therapy controversial[2]. Thus, it is necessary to carry out this review, whose general objective will be to evaluate the randomized clinical trials existing in the literature on the effects of AAT on pain management in people with pain when compared to conventional treatment or other non-pharmacological interventions; In addition to identifying in which types of pain the AAT is applied; the instruments used for pain assessment and measurement; the levels of health care in which therapy is performed; the professionals involved in the conduction of therapy; the types of animals used; The risks and benefits of AAT; and the overall effect of AAT on pain intensity.

METHOD

Protocol and registration

This systematic literature review will be reported according to Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)[8].

The protocol was entered on the International Prospective Register of Systematic Reviews (PROSPERO) basis under the registration CRD42021269685.

Eligibility criteria

Randomized clinical trials will be included in the systematic review, available in full at reading, of any year or language, which employ the AAT performed with any animal, used alone or in combination with other methods, and implemented exclusively by health professionals. The control group should include conventional routine treatment or other non-pharmacological interventions for pain management.

No limits will be established on gender, age group, or ethnic origin. Studies involving the application of AAT at different levels of health care (primary, secondary, and tertiary) and in other environments will also be considered, provided that there are therapeutic purposes.

Exclusion criteria: Theses, dissertations, editorials, and studies with incomplete data will be

considered. Observational studies and reviews will not be included but will be read to identify possible eligible studies.

Sources of information

The search for the studies will be carried out in the following sources of information: Medical Literature Analysis and Retrieval System Online (MEDLINE) via PubMed, *PubMed* Central (PMC), EMBASE (via Embase.com), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials (CENTRAL), World Health Organization International Clinical Trials Registry Platform (ICTRP), ClinicalTrials.gov (CT. gov), *Biblioteca Virtual de Saúde* (BVS), *Medicina Tradicional*, *Complementar e Integrativa* (MTCI Américas), Web of Science, Scopus, Physiotherapy Evidence Database (PEDro).

For each selected article, abstracts and full texts will be obtained. Reference lists of included studies and systematic reviews will be examined during the review. Even if not published and/or indexed, studies identified by Google Scholar, ClinicalTrials.gov, Brazilian Registry of Clinical Tests (ReBEC), and Brazilian Library of Theses and Dissertations will also be evaluated.

Development of the research question

The research question was developed based on the acronym PICO (P– population; I– intervention; C– comparison; O– Outcomes)[9] (Figure 1).

Search strategy

The search strategy will be developed by two authors with the contribution of a librarian with experience in the health area. The bibliographical research will be repeated immediately after the final analysis to enable the review of new studies and inclusion in this review. The descriptors in Health Sciences (DeCS) /Medical Subject Heading (MeSH) will be used, as well as keywords and free text search terms. All terms will be combined through BOOLEAN and OR operators. Figure 2 describes the terms that will be used for the search strategy.

After completing the Medline research, the research strategy will be adapted to the other databases.

Data management

The search will be carried out in the information sources and uploaded to EndNote, reference management software. All results will be inserted into a single folder in this software, and duplicate studies will be identified and removed. After removing duplicates, the search results will be loaded into Rayyan, software that allows selecting articles by titles and abstracts in blind cooperation between reviewers.

Process of articles selection

The selection of articles will be done in two stages. The first step will involve reading the titles and abstracts of articles found in each database based on eligibility criteria. In the second stage, the pre-selected articles will be read in full to confirm whether or not they meet the eligibility criteria. In both stages, each article will be independently evaluated by two reviewers. Furthermore, in case of disagreements, a third reviewer will perform a new analysis, and the divergences will be resolved by mutual discussion among all researchers.

PICO	**Componentes**
Question	What is the effect of AAT (intervention) on pain management (results) in people with pain (population) when compared to conventional treatment or other non-pharmacological interventions (comparison)?
Population	People with pain clinical signs of any age, gender, and ethnicity treated at any level of health care (primary, secondary, tertiary)
Intervention	Therapy with Animals (dogs, cats, horses, snakes, turtles, rodents, guinea pigs, and birds)
Comparator	Conventional routine treatment or other non-pharmacological interventions for pain management
Outcomes	Pain management

Figure 1 – Development of the research question according to the PICO strategy. Viçosa, MG, Brazil, 2022

A. Search strategy to locate 'Assisted Therapy with Animals'	
1. Animal assisted therapy [Mesh]	10. Terapia assistida com animais [DeCS]
2. Animal assisted therapies	11. Terapia com Animais
3. Animal assisted activity	12. Atividade assistida com animais
4. Animal assisted activities	13. Atividades assistidas com animais
5. Animal Facilitated Therapy	14. Terapia facilitada com animais
6. Animal Facilitated Therapies	15. Terapias facilitadas com animais
7. Therapy animals	16. Animais de terapia
8. Animal assisted intervention	17. Intervenção assistida por animais
9. Animal assisted interventions	18. Intervenções assistidas por animais
A. *OR/1-18*	
B. Search strategy to locate 'pain'	
19. Pain [Mesh]	25. Ache
20. Pain management [Mesh]	26. Aches
21. Pain control	27. Dor [Decs]
22. Pain relief	28. Manejo da dor [DeCs]
23. Acute pain [Mesh]	29. Dor aguda [DeCs]
24. Chronic pain [Mesh]	30. Dor crônica [DeCs]
B. OR/19-30	
C. Search strategy to locate 'Randomized Clinical Trial'	
31. Clinical trial	35. Ensaio Clínico Controlado [DeCS]
32. Controlled clinical trial [Mesh]	36. Ensaio Clínico Controlado Aleatório [DeCS]
33. Clinical Study [Mesh]	37. Ensaio Clínico Controlado Randomizado
34. Randomized controlled trial [Mesh]	38. Ensaio Controlado Aleatório
C. OR/31-38	
A AND B AND C	

Figure 2 - Search strategy. Viçosa, MG, Brazil, 2022

Data extraction process

Data from the included studies will be extracted independently by two researchers, using a data extraction form, with the following information[10,11] (Figure 3):

The authors of the studies may be contacted by e-mail to obtain the missing data.

Evaluation of the outcome

The main outcome of the study is pain management. It will be measured by objective methods (physiological parameters – respiratory rate, heart rate, blood pressure, pain threshold measured by an algometer) and subjective (validated uni or multidimensional instruments). The outcome will be evaluated from the results presented by the studies in two moments: immediately before and immediately after the intervention.

Assessment of risk of bias

In this study, the bias risk assessment will be performed using the *Cochrane Collaboration Risk of Bias* – ROB 2.0tool, encompassing three types of randomized clinical trials: parallel controlled, cluster and *cross-over*[12]. Two researchers will independently evaluate the risk of bias, and a third researcher will discuss and resolve the divergences.

Data synthesis and analysis

The data can be analyzed quantitatively, through meta-analysis and/or qualitative, through narrative synthesis.

Study identification		Author Year of publication of the study Country of study
Method	**Participants**	Eligibility Criteria Clinical condition (time and type of pain)
	Scenario	Level of health care where the study was conducted
	Design and allocation of the group	Study design Duration of study Follow-up groups (experimental group x control group/placebo) Randomization Masking of allocation
	AT intervention	Professional who carried out the intervention Animal used, with justification for the choice Frequency of the sessions Duration time of each session Duration time of complete treatment Authorizations for the use of the animal in the health service
	Control group	Type of control (no treatment, standard treatment, placebo) Description of intervention
	Primary outcome	Instrument used for evaluation Moments of measurement
	Other outcomes	Name and definition Instrument used for evaluation Moments of measurement
	Results	Number of participants randomized/allocated per group/analyzed Details of any missing participants Basic demographic data for each group Summary data for each group in each evaluation time Adverse events
	Discussion	Interpretation of results Extension of generalization Limitations of the study Suggestions for new studies
	Conclusion	Main conclusions

Figure 3 - Information to be extracted from the selected articles. Viçosa, MG, Brazil, 2022

If meta-analysis can be conducted, Stata statistical software will be used for data analysis. The risk odd will be used to estimate dichotomous variables, and the mean difference will be used for continuous variables, with a 95% confidence interval. 5% of significance will be adopted for the hypothesis tests.

The potential heterogeneity between the studies will be examined using of Cochran's Qstatistics[13] and Higgins Method (Statistics I^2)[14]. Values of 25%, 50%, and 75% for I^2 represent low, medium, and high heterogeneity[14]. The result will be displayed using a forest graph. If necessary, subgroup analysis will be performed, based on possible factors that can lead to heterogeneity, such as intervention, control, age, treatment duration, and study quality.

Evaluation of the quality of evidence

Grading of Recommendations, Assessment,

Development and Evaluation (GRADE)[15] will be used to assess the certainty of evidence. This evaluation will be carried out independently by two researchers. A meeting will be held in case of disagreement according to a third researcher.

CONFLICT OF INTERESTS

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

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