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

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.

Keywords: Assisted Therapy with Animals; Pain Management; Systematic Review.

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
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 atten-
tive 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(4).

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 Health-
care 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 potentiazing behaviors
adopted by health professionals, which can be
used synergistically with traditional forms of
treatment(3).

One resource that has proved to be very pro-
mising 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 re-
ported in the literature, in which the reduction of
insomnia and chronic pain is observed in the eld-
erly (5); improvement of living conditions and the
general state of inactivity(5); reduction of symp-
toms 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 modula-
tion of respiratory and cardiac frequencies, blood
pressure and oxygen saturation in children(2). Mo-

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 in-
ternational 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 gen-
eral objective will be to evaluate the randomized
clinical trials existing in the literature on the ef-
ects 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 the-
rapy; 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 repor-
ted 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 com-
bination with other methods, and implemented
exclusively by health professionals. The control
group should include conventional routine treat-
ment 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, pro-
vided that there are therapeutic purposes.

Exclusion criteria: Theses, dissertations, edito-
rials, 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) (Table 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 Headings (MeSH) will be used, as well as keywords and free text search terms. All terms will be combined through BOOLEAN and OR operators. Table 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.

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

<table>
<thead>
<tr>
<th>PICO</th>
<th>Componentes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
<td>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)?</td>
</tr>
<tr>
<td>Population</td>
<td>People with pain clinical signs of any age, gender, and ethnicity treated at any level of health care (primary, secondary, tertiary)</td>
</tr>
<tr>
<td>Intervention</td>
<td>Therapy with Animals (dogs, cats, horses, snakes, turtles, rodents, guinea pigs, and birds)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Conventional routine treatment or other non-pharmacological interventions for pain management</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Pain management</td>
</tr>
</tbody>
</table>

Source: Elaborated by the authors, 2022.
Table 2 - Search 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'

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]
34. Randomized controlled trial [Mesh] 38. Ensaio Controlado Aleatório

C. OR/31-38

A AND B AND C

Source: Elaborated by the authors, 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\(^{(10,11)}\) (Table 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.
Table 3 - Information to be extracted from the selected articles. Viçosa, MG, Brazil, 2022

<table>
<thead>
<tr>
<th>Study identification</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year of publication of the study</td>
</tr>
<tr>
<td></td>
<td>Country of study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>Eligibility Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinical condition (time and type of pain)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Level of health care where the study was conducted</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Design and allocation of the group</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Duration of study</td>
</tr>
<tr>
<td></td>
<td>Follow-up groups (experimental group x control group/placebo)</td>
</tr>
<tr>
<td></td>
<td>Randomization</td>
</tr>
<tr>
<td></td>
<td>Masking of allocation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Professional who carried out the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Animal used, with justification for the choice</td>
</tr>
<tr>
<td></td>
<td>Frequency of the sessions</td>
</tr>
<tr>
<td></td>
<td>Duration time of each session</td>
</tr>
<tr>
<td></td>
<td>Duration time of complete treatment</td>
</tr>
<tr>
<td></td>
<td>Authorizations for the use of the animal in the health service</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AT intervention</th>
<th>Type of control (no treatment, standard treatment, placebo)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Description of intervention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
<th>Instrument used for evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moments of measurement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Name and definition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Instrument used for evaluation</td>
</tr>
<tr>
<td></td>
<td>Moments of measurement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other outcomes</th>
<th>Number of participants randomized/allocated per group/analyzed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Details of any missing participants</td>
</tr>
<tr>
<td></td>
<td>Basic demographic data for each group</td>
</tr>
<tr>
<td></td>
<td>Summary data for each group in each evaluation time</td>
</tr>
<tr>
<td></td>
<td>Adverse events</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th>Interpretation of results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Extension of generalization</td>
</tr>
<tr>
<td></td>
<td>Limitations of the study</td>
</tr>
<tr>
<td></td>
<td>Suggestions for new studies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discussion</th>
<th>Main conclusions</th>
</tr>
</thead>
</table>

Source: Elaborated by the authors, 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 Q statistics and Higgins Method (Statistics I^2). Values of 25%, 50%, and 75% for I^2 represent low, medium, and high heterogeneity. 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)\textsuperscript{(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.

**REFERENCES**

1. Ferrari MFM, Daher DV, Antunes JM, Amim EF, Jesus CM, Geraldo MA. Pain as the fifth vital sign, challenges for its incorporation in health training. REME (Online). 2019;23(e-1233):1-5. https://doi.org/10.5935/1415-2762.20190081


**AUTHORSHIP CONTRIBUTIONS**

<table>
<thead>
<tr>
<th>Project design:</th>
<th>Sant' Anna AV, Toledo LV, Salgado PO, Moura CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data collection:</td>
<td>Sant’ Anna AV, Toledo LV, Salgado PO, Moura CC</td>
</tr>
<tr>
<td>Data analysis and interpretation:</td>
<td>Sant’ Anna AV, Toledo LV, Salgado PO, Azevedo C, Nogueira DA, Moura CC</td>
</tr>
<tr>
<td>Writing and/or critical review of the intellectual content:</td>
<td>Sant’ Anna AV, Toledo LV, Salgado PO, Azevedo C, Nogueira DA, Moura CC</td>
</tr>
<tr>
<td>Final approval of the version to be published:</td>
<td>Sant’ Anna AV, Toledo LV, Salgado PO, Azevedo C, Nogueira DA, Moura CC</td>
</tr>
<tr>
<td>Responsibility for the text in ensuring the accuracy and completeness of any part of the paper:</td>
<td>Sant’ Anna AV, Toledo LV, Salgado PO, Azevedo C, Nogueira DA, Moura CC</td>
</tr>
</tbody>
</table>

Copyright © 2023 Online Brazilian Journal of Nursing

This is an Open Access article distributed under the terms of the Creative Commons Attribution License CC-BY, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.