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Control groups in clinical trials of non-pharmacological interventions for cancer pain: a meta-research study

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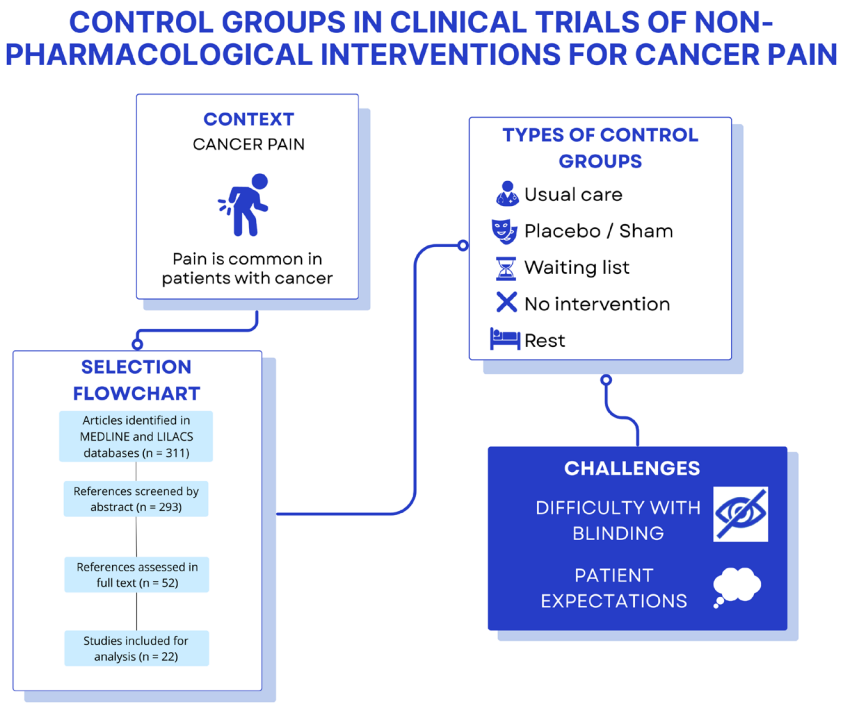
Highlights

- *Discussion of blinding strategies and performance bias was limited in most randomized controlled trials (RCTs) of non-pharmacological interventions (NPIs) for cancer pain.*
- *Of the 311 articles identified, only 52 met the inclusion criteria, and 22 had full text available.*
- *Most studies employed single-blind or open-label designs; only one study reported being double-blind.*
- *Acupuncture, music, and massage were the most frequently investigated NPIs.*
- *Usual care was the most commonly used control group intervention; however, different interventions may be identified as "usual care" by the primary study.*
- *The absence or limitation of blinding tends to overestimate the effects of the interventions evaluated.*

Graphical Abstract



Abstract

Cancer pain is a common challenge in patients with cancer, arising from tumor progression or adverse effects of treatment. For its management, non-pharmacological interventions have been investigated through randomized controlled trials (RCTs), which require appropriate comparative strategies (placebo or sham) to isolate the effects of the intervention. However, limitations in blinding inherent to this type of intervention may influence the interpretation of results. The objective of this study was to identify the strategies used in the control groups of randomized controlled trials evaluating non-pharmacological interventions for cancer pain. This is a meta-research study (research on how science is produced) conducted in the MEDLINE and LILACS databases, using MeSH/DeCS descriptors and free-text terms related to "Cancer pain" and "Complementary therapies," with no restrictions on language or year of publication. Non-randomized studies and those involving surgical interventions were excluded. Study selection and data extraction were performed in duplicate. Information on the type of blinding and the strategies used in the control groups was extracted. The search retrieved 311 articles; 52 were included after screening, of which 22 had full-text availability. Of these, 15 were single-blind, 6 were open-label, 1 was described as double-blind, and 12 discussed the impact of performance bias. The most frequently evaluated interventions included acupuncture, therapeutic massage, and music therapy. Control groups varied between usual care, placebo, no intervention, and sham procedures. It is concluded that there is substantial variability in control strategies and that the absence of discussion regarding performance bias may compromise the interpretation of results and clinical decision-making.

Keywords: Cancer Pain. Complementary Therapeutic Methods. Holistic Health.

#Study awarded 10th place in the poster category at the *Congresso Médico Universitário São Camilo* 2025.

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INTRODUCTION

Pain management in patients with cancer remains one of the main challenges in clinical practice, given its significant impact on the physical and emotional well-being of these individuals[1]. To systematize pain control, the World Health Organization (WHO) developed the Analgesic Ladder, a model that guides the progressive use of analgesics according to pain intensity[2]. Although this strategy represented an important advance in oncological care, evidence indicates that it is not effective in approximately 50% of cases[3,4]. Apparently, the use of analgesics, including opioids, does not always provide adequate control of cancer pain, and therefore non-pharmacological interventions (NPIs) have emerged as promising strategies for the management of this symptom[1,4].

The most well-known techniques include massage therapy, music therapy, reiki, and yoga[1,5,6]. Acupuncture is another method used in the treatment of pain in individuals with cancer and has shown positive results in pain relief across different studies[3,4].

However, clinical trials evaluating such interventions face challenges in implementing blinding strategies[7]. NPIs, such as those used for pain control, are mostly and by their nature non-blindable, as participants and staff are aware of whether they are delivering or receiving the intervention or the control[7]. Blinding is important in randomized controlled trials (RCTs) because it prevents observed outcomes from being related to changes in participants' behavior rather than to the true effect of the intervention. Thus, variability in the application of simulated procedures, placebo, or sham interventions may influence study results, particularly when outcomes are subjective[3].

A recent review indicated that only 4% of studies on pain interventions used sham procedures in the control group, highlighting the scarcity and inconsistency of such designs[8]. Johnson and Goebel[8] indicated that the main source of bias in studies assessing subjective outcomes is precisely the loss of blinding, resulting from perceptible differences between active and simulated conditions.

In this context, it becomes essential to map and understand which strategies are being used in control groups in clinical trials for cancer pain and how study authors have addressed the issue of the lack of blinding inherent to the intervention and its potential impact on results, discussions, and conclusions. Therefore, the objective of this study was to identify the strategies used in the control groups of clinical trials on non-pharmacological interventions for cancer pain.

METHODOLOGY

This study is a meta-research investigation, a scientific field dedicated to examining how science is produced, communicated, evaluated, and used[9], with a focus on identifying randomized controlled trials (RCTs) that investigated non-pharmacological interventions (NPIs) for individuals with cancer pain. Accordingly, the following research question was formulated: which strategies were used in the control groups of RCTs (placebo, usual care, or another intervention) that investigated non-pharmacological interventions for adults with cancer pain? Was the lack of blinding discussed by the studies?

A sensitive search strategy (the use of multiple terms conveying the same conceptual group, including both controlled descriptors and free-text terms) was conducted to maximize the identification of potentially relevant studies[10] in the MEDLINE (via PubMed) and LILACS (via BVS) databases, using the descriptors "Cancer Pain" AND "Complementary Therapies," along with their respective synonyms (Cancer-Related Pain, Neoplasm-Related Pain, Alternative Medicine, Complementary Medicine).

The terms were combined with specific filters for RCTs available in the PubMed and BVS databases in order to refine the results to this specific study design. The complete search strategies are presented in full in Box 1.

Box 1 - Search strategy in the databases. (Centro Universitário São Camilo-SP. May 2025).

Database	Search strategy
MEDLINE via Pubmed	#1 "Cancer Pain"[Mesh] OR "Cancer Pain" OR "Cancer Pains" OR "Cancer-Related Pain" OR "Cancer Related Pain" OR "Cancer-Related Pains" OR "Cancer-Associated Pain" OR "Cancer Associated Pain" OR "Cancer-Associated Pains" OR "Neoplasm-Related Pain" OR "Neoplasm Related Pain" OR "Oncological Pain" OR "Oncological Pains" OR "Tumor-Related Pain" OR "Tumor Related Pain" OR "Tumor-Associated Pain" OR "Tumor Associated Pain" OR "Oncology Pain" #2 "Complementary Therapies"[Mesh] OR "Complementary Therapies" OR "Complementary Therapy" OR "Alternative Medicine" OR "Complementary Medicine" OR "Alternative Therapies" #3 ((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]) #4 #1 AND #2 AND #3 109
LILACS / BDENF / IBECS / Index Psicologia via BVS	#1 MH:"Dor do Câncer" OR MH:"Dolor en Cáncer" OR MH:"Cancer Pain" OR "Dor do Câncer" OR "Dolor en Cáncer" OR "Cancer Pain" OR "Dor Associada a Câncer" OR "Dor Associada a Neoplasia" OR "Dor Associada a Tumor" OR "Dor Oncológica" OR "Dor Relacionada a Câncer" OR "Dor Relacionada a Neoplasia" OR "Dor Relacionada a Tumor" OR "Dor em Oncologia" OR "Cancer Pains" OR "Cancer-Associated Pain" OR "Cancer Associated Pain" OR "Cancer-Associated Pains" OR "Neoplasm--Related Pain" OR "Neoplasm Related Pain" OR "Neoplasm-Related Pains" OR "Oncological Pain" OR "Oncological Pains" OR "Tumor-Related Pain" OR "Tumor Related Pain" OR "Tumor-Related Pains" OR "Tumor-Associated Pain" OR "Tumor Associated Pain" OR "Tumor-Associated Pains" OR "Oncology Pain" OR "Oncology Pains" OR "Cancer-Related Pain" OR "Cancer Related Pain" OR "Cancer-Related Pains" OR "Neoplasm-Associated Pain" OR "Neoplasm Associated Pain" OR "Neoplasm--Associated Pains" OR "Dolor Asociado a las Neoplasias" OR "Dolor Asociado a los Tumores" OR "Dolor Asociado al Cáncer" OR "Dolor Asociado al Tumor" OR "Dolor Asociado con Neoplasia" OR "Dolor Canceroso" OR "Dolor Oncológico" OR "Dolor Relacionado al Cáncer" OR "Dolor Relacionado con Neoplasia" OR "Dolor Relacionado con el Cáncer" OR "Dolor Relacionado con el Tumor" OR "Dolor Relacionado con las Neoplasias" OR "Dolor Relacionado con los Tumores" OR "Dolor en Oncología" #2 MH:"Terapias Complementares" OR MH:"Terapias Complementarias" OR MH:"Complementary Therapies" OR "Terapias Complementares" OR "Terapias Complementarias" OR "Complementary Therapies" OR "Práticas Complementares e Integrativas" OR "Práticas Integrativas e Complementares" OR "Práticas de Saúde Complementares e Integrativas" OR "Práticas de Saúde Integrativas e Complementares" OR "Terapias Complementares e Integrativas" OR "Tratamentos Complementares" OR "Medicina Complementar" OR "Medicina Complementar e Integrativa" OR "Medicina Integrativa e Complementar" OR "Medicina Alternativa" OR "Terapias Alternativas" OR "Terapia Alternativa" OR "Complementary Medicine" OR "Alternative Medicine" OR "Alternative Therapies" OR "Prácticas Complementarias e Integradoras" OR "Prácticas Integradoras y Complementarias" OR "Prácticas de Salud Complementarias e Integradoras" OR "Prácticas de Salud Integradoras y Complementarias" OR "Tratamientos Complementarios" OR "Medicina Complementaria" OR "Medicina Complementaria e Integradora" OR "Medicina Integradora y Complementaria" OR "Medicina Alternativa" OR "Terapias Alternativas"

Source: Authors' own elaboration, 2025.

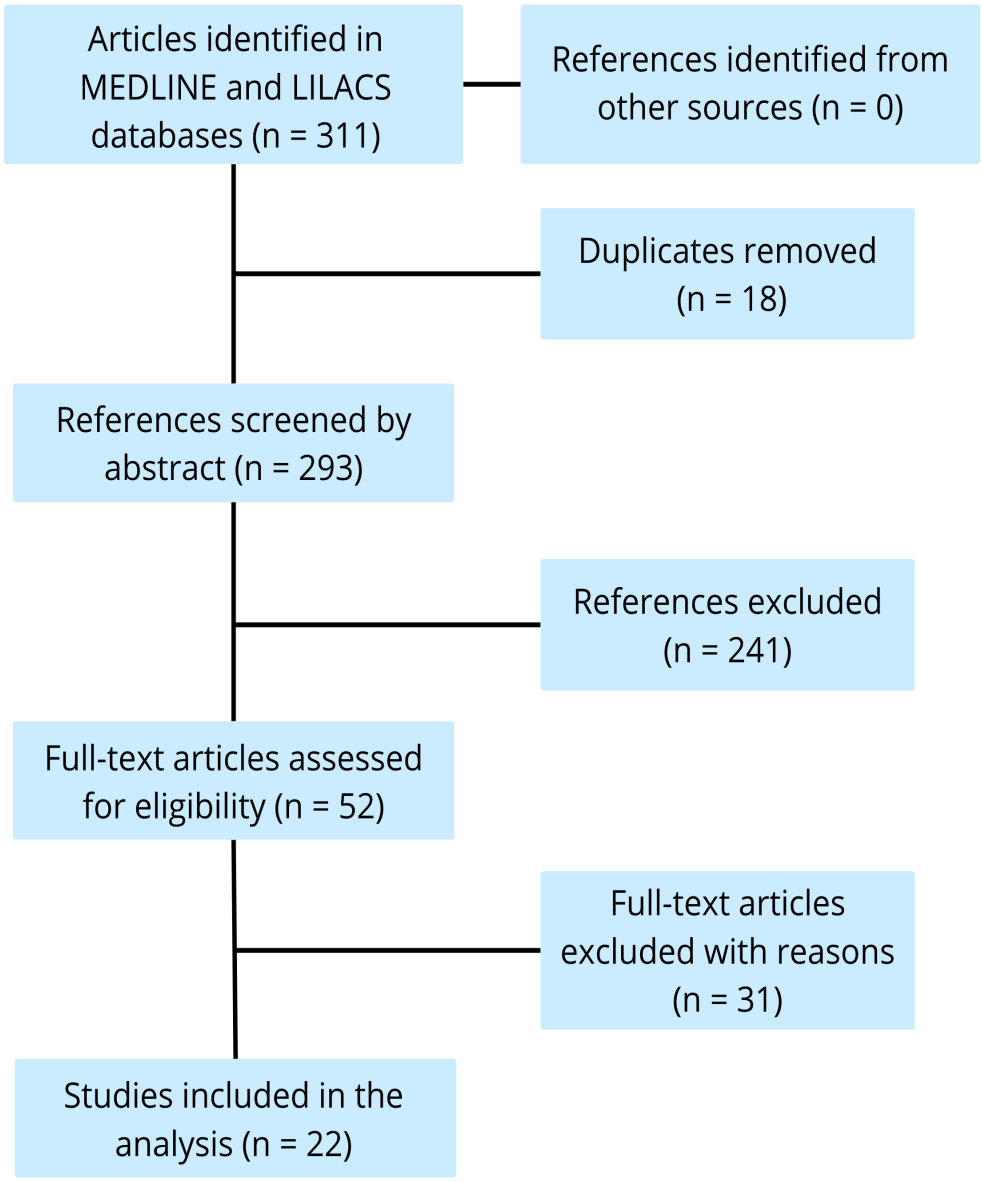
The inclusion criteria considered were randomized controlled trials (RCTs) that compared any type of non-pharmacological intervention (such as complementary and integrative therapies) with any other form of intervention, placebo, sham procedure, waiting list, or no intervention in adults with cancer-related pain. Studies involving surgical procedures, although they could be considered non-pharmacological interventions, were excluded due to the potential bias introduced by postoperative pain management.

Study selection and data extraction were performed independently by two reviewers, and disagreements were resolved by consensus. The Rayyan platform [Ouzzani 2016][11] was used for study selection, and a standardized spreadsheet in Microsoft Excel was used for data extraction. The following information was extracted from the included studies: first author and year of publication, country, number of participants, population characteristics, intervention and control, whether the study was classified as open-label, single-blind, or double-blind, declaration of conflicts of interest, and source of funding.

RESULTS

The searches of the electronic databases retrieved 311 articles. After the selection process, 53 were assessed in full text and, of these, only 22 had the full text available, were included, and had their data extracted.

Figure 1 - Flowchart of articles selected through database searching (Centro Universitário São Camilo-SP. May 2025).



Source: Authors' own elaboration, 2025.

The included studies were published between 1992 and 2024. The countries with the highest number of studies were China (7 studies), the United States (4 studies), Germany (2 studies), Spain (2 studies), and South Korea (2 studies). The total number of participants across the 22 studies was 1,908 individuals, with a mean of approximately 86 participants per study. The most frequently addressed cancer types included breast cancer (13.63%), pancreatic cancer (9.09%), liver cancer (4.55%), prostate cancer (4.55%), and hematological malignancies (4.55%), in addition to studies involving individuals with different cancer diagnoses (63.64%).

All included RCTs employed a parallel-group design. Most RCTs (86.3%) allocated participants into two groups (intervention and control), whereas three studies allocated participants into three groups. Declarations of conflicts of interest were identified in 9.09% of the studies, and sources of funding were reported in 68.18%.

Table 1 presents a detailed description of the main characteristics of the included studies.

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Table 1 - General characteristics of the included studies. (Centro Universitário São Camilo-SP. May 2025).

Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Syrjala, KL, 1992[12]	United States	67 participants; hematological cancer and bone marrow transplantation	Group 1: hypnosis; Group 2: cognitive-behavioral skills training and therapist contact; two sessions before transplantation and 10 sessions during hospitalization	Usual care	Not mentioned	Not mentioned	Not mentioned
Ferrel-Torry AT, 1993[13]	United States	9 participants; any cancer	Group 1: therapeutic massage and trigger-point therapy (30 minutes)	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Sryrjala KL, 1995[14]	United States	94 participants; hematological cancer and bone marrow transplantation	Group 1: therapist support, relaxation training, and guided imagery; Group 2: cognitive-behavioral skills training and therapist contact without specific intervention; two sessions before transplantation, twice weekly, and during the first five weeks of treatment	Usual care	Not mentioned	Not mentioned	Not mentioned
Reinhardt U, 1999[15]	Germany	28 participants; any cancer	Group 1: music therapy (30 minutes) for 14 days	No intervention	Not mentioned	Not mentioned	Not mentioned
Wilkie DJ, 2000[16]	United States	29 participants; any cancer	Group 1: therapeutic massage; four sessions twice weekly	Morphine	Not specified	Not mentioned	Not mentioned
Olson K, 2003[17]	Canada	24 participants; any cancer	Group 1: Reiki + standard treatment	Rest + standard treatment	Open-label	Not mentioned	Not mentioned
Alimi D, 2003[18]	United States	90 participants; any cancer	Group 1: music therapy (standard music and participant-preferred music)	No intervention	Not specified	Not mentioned	Not mentioned
Siedliecki SL, 2006[19]	United States	60 participants; non-malignant cancer-related pain	Group 1: music therapy	No intervention	Not specified	Not mentioned	Not mentioned
Zhang T, 2006[20]	China	84 participants; any cancer	Group 1: nutritive yin and meridian-unblocking prescription (NUR) + opioid analgesics	Opioids	Not specified	Not mentioned	Not mentioned
Stephenson NL, 2007[21]	United States	86 participants and their partners (172 participants); any cancer	Group 1: foot reflexology (30 minutes) with partners	30 minutes of reading with partners	Not specified	Not mentioned	R21 CA 105432 / NCI / NIH / HHS (USA)
Tsai PS, 2007[22]	Twain	24 participants; advanced cancer	Group 1: electromyography biofeedback-assisted relaxation (4 weeks)	Usual care	Not specified	Not mentioned	Not mentioned

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Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Chen ZJ, 2008[23]	China	66 participants; advanced cancer	Group 1: acupuncture	Usual care	Not specified	Not mentioned	Not mentioned
Kwekkeboom KL, 2008[24]	United States	40 participants; any cancer	Group 1: progressive muscle relaxation (PMR) and analgesic imagery	No intervention	Open-label	No	National Institute of Nursing Research (NINR), HHS (USA)
Butler LD, 2009[25]	United States	124 participants; metastatic cancer	Group 1: group hypnosis therapy and disease education (1 year)	Disease education	Not specified	Not mentioned	5R01MH047226 / NIMH / NIH / HHS (USA)
Huang ST, 2010[26]	Taiwan	126 participants; hospitalized patients with cancer	Group 1: music therapy (30 minutes)	Bed rest	Single-blind	Not mentioned	No external funding
Jane SW, 2011[27]	Taiwan	72 participants; cancer with bone metastases	Group 1: massage therapy	Not mentioned	Not specified	Not mentioned	2T32NR007106 / NINR / NIH / HHS (USA)
Chen H, 2013[28]	China	60 participants; pancreatic cancer	Group 1: electroacupuncture	Placebo	Single-blind	No	Not mentioned
Lee J, 2014[29]	South Korea	16 participants; metastatic cancer	Group 1: direct moxibustion	*Sham moxibustion*	Single-blind	No	Clinical Research Institute, Kyung Hee University Hospital at Gangdong
Warth M, 2015[30]	Germany	84 participants; cancer patients in palliative care	Group 1: monochord music therapy	Guided relaxation	Single-blind	No	Not mentioned
Sharif Nia H, 2015[31]	Iran	100 participants; hospitalized leukemia patients	Group 1: acupressure + usual care	Usual care	Not specified	Not mentioned	Not mentioned
Uysal N, 2016[32]	Turkey	60 participants; colorectal cancer	Group 1: classical foot massage; Group 2: reflexology; twice weekly for five weeks	Usual care	Not specified	Not mentioned	Not mentioned
Lam TY, 2017[33]	China	42 participants; any cancer	Group 1: Si Guan acupuncture	Placebo-point acupuncture	Single-blind	No	No external funding
Mendoza ME, 2017[34]	Spain	44 participants; any cancer	Group 1: hypnosis + cognitive-behavioral therapy	Symptom education	Single-blind	No	Spanish Foundation of Science and Technology
Ruela LO, 2018[4]	Brazil	31 participants; any cancer	Group 1: auriculotherapy at energy balance points	Sham auriculotherapy	Double-blind	No	CAPES (Brazil)
Xu L, 2018[35]	China	65 participants; advanced hepatocellular carcinoma	Group 1: electroacupuncture at multiple points	Transdermal fentanyl patch	Single-blind	No	No external funding

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Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Eyigor S, 2018[36]	Turkey	42 participants; breast cancer	Group 1: hatha yoga (10 weeks, twice weekly)	Usual care	Single-blind	Not mentioned	Not mentioned
Kim K, 2018[37]	South Korea	30 participants; advanced cancer	Group 1: intradermal acupuncture	Sham acupuncture	Single-blind	No	Bio-Synergy Research Project (Ministry of Science, ICT and Future Planning, South Korea) and Comprehensive and Integrative Medicine Institute
Liang Y, 2019[38]	China	160 participants; any cancer	Group 1: transcutaneous electrical acupoint stimulation (TEAS) + opioids	Sham TEAS + opioids	Single-blind	No	National Natural Science Foundation of China
De Paolis G, 2019[39]	Italy	91 participants; terminal cancer	Group 1: progressive muscle relaxation and interactive guided imagery	Usual care	Not specified	Not mentioned	Not mentioned
Hsieh FC, 2019[40]	Twaian	60 participants; breast cancer	Group 1: home-based music therapy (30 min/week for 24 weeks)	Not mentioned	Not specified	Not mentioned	Not mentioned
He Y, 2019[41]	China	30 participants; any cancer	Group 1: acupuncture	Usual care	Open-label	No	Guangdong Provincial Academy of Chinese Medical Sciences (China) and RMIT University (China–Australia International Research Centre for Chinese Medicine); PhD scholarship, School of Health and Biomedical Sciences, RMIT University; Specific Research Fund for TCM Science and Technology of Guangdong Provincial Hospital of Chinese Medicine; Research Project of the Traditional Chinese Medicine Bureau of Guangdong Province
Wu QL, 2019[42]	China	60 participants; any cancer	Group 1: acupuncture (once daily for 10 days)	Usual care	Not mentioned	Not mentioned	Not mentioned
Rambod M, 2019[43]	Iran	72 participants; lymphoma	Group 1: foot reflexology (5 consecutive days)	Usual care	Not mentioned	Not mentioned	Not mentioned
Li D, 2020[44]	China	60 participants; advanced cancer	Group 1: acupuncture	Opioids	Not mentioned	Not mentioned	Not mentioned
Lei Y, 2020[45]	China	120 participants; prostate cancer	Group 1: acupuncture + usual care	Placebo + usual care	Single-blind	No	Current Graduate Program 2019, Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine

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Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Xu LP, 2020[46]	China	160 participants; any cancer	Group 1: wrist–ankle acupuncture and auricular acupuncture	Opioids	Not mentioned	Not mentioned	Fujian University of Traditional Chinese Medicine and the Education Department of Fujian Province
Han XC, 2020[47]	China	140 participants; any cancer	Group 1: electroacupuncture (once daily for two days)	Analgesics	Not mentioned	Not mentioned	Not mentioned
Siemens W, 2020[48]	Germany	25 participants; advanced cancer in palliative care	Group 1: intensity-modulated transcutaneous electrical nerve stimulation (TENS)	Placebo TENS	Open-label	No	Open Access funding by Projekt DEAL; internal funding from the Clinic for Palliative Care, University Medical Center Freiburg
Lu DR, 2021[49]	China	60 participants; any cancer	Group 1: thermal electroacupuncture at specific points (30 min/day for 5 days) + opioids	Opioids	Not mentioned	Not mentioned	Not mentioned
Saraswati W, 2021[50]	Indonesia	28 participants; cervical cancer	Group 1: electroacupuncture + analgesics	Analgesics	Not mentioned	Not mentioned	Not mentioned
Mao JJ, 2021[51]	United States	360 participants; cancer survivors with musculoskeletal pain	Group 1: electroacupuncture or auriculotherapy	Usual care	Single-blind	Declared (multiple authors; no influence reported)	National Cancer Institute (USA)
Carson JW, 2021[52]	United States	48 participants; metastatic breast cancer	Group 1: mindful yoga	Support sessions	Single-blind	No	Not mentioned
Ji JF, 2021[53]	China	60 participants; any cancer	Group 1: intradermal acupuncture + thermosensitive moxibustion at specific points + opioids	Opioids	Not mentioned	Not mentioned	Not mentioned
Miladinia M, 2021[54]	Iran	104 participants; leukemia	Group 1: gentle massage (SSBM)	Music therapy or usual care	Single-blind	No	Ahvaz Jundishapur University of Medical Sciences (Iran)
He Y, 2022[55]	China	30 participants; any cancer	Group 1: acupuncture	Usual care	Not mentioned	Not mentioned	Not mentioned

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Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Amini K, 2022[56]	Iran	145 participants; cancer patients undergoing chemotherapy	Group 1: spiritual care (3 days)	No intervention	Not mentioned	Not mentioned	Not mentioned
Wang H, 2022[57]	Australia	72 participants; breast cancer survivors	Group 1: breathing exercises	Usual care + pain information booklet	Open-label	No	Australian Government Research Training Program (RTP), Charles Darwin University
Utli H, 2023[58]	Turkey	156 participants; advanced cancer	Group 1: acupressure or reiki	Usual care	Not mentioned	Not mentioned	Not mentioned
Chen H, 2023[59]	China	60 participants; lung cancer	Group 1: acupuncture	Opioids	Not mentioned	Not mentioned	Not mentioned
Epstein AS, 2023[60]	United States	298 participants; advanced cancer	Group 1: acupuncture	Massage	Single-blind	E: received royalties from UpToDate; B: received a grant from the Patient-Centered Outcomes Research Institute (PCORI); D: received a grant from PCORI; F: received grants from PCORI and from the National Institutes of Health (NIH) National Center for Advancing Translational Sciences, the NIH National Institute of Diabetes and Digestive and Kidney Diseases, and the NIH National Institute of Neurological Disorders and Stroke; a contract from the US Food and Drug Administration; personal fees from Vertx Pharma and EicOsis Pharma outside the submitted work; and serves as the unpaid president of the US Association for the Study of Pain; M: received a grant from Tibet CheeZheng Tibetan Medicine Co Ltd for Memorial Sloan Kettering Cancer Center and from Zhongke Health International LLC for Memorial Sloan Kettering Cancer Center; co-chair of the Society for Acupuncture Research.	PCORI Award SMPAI-2018C2-12883; NIH/NCI Cancer Center Support Grant (Memorial Sloan Kettering Cancer Center)

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Author, year	Country	Population characteristics / number of participants	Intervention	Control	Author's self-reported classification (single-blind, double-blind, open-label)	Conflict of interest	Funding source
Lyu Z, 2023[61]	China	59 participants; any cancer	Group 1: transcutaneous electrical acupoint stimulation (TEAS) (3 weeks)	Sham stimulation	Not mentioned	Not mentioned	National Health Commission and Zhejiang Province Health Science Program; Zhejiang Province Chinese Medicine Research Program; Zhejiang Chinese Medicine University Graduate Student Research Fund
Tian W, 2024[3]	China	80 participants; advanced pancreatic cancer	Group 1: transcutaneous electrical acupoint stimulation (TEAS) + analgesics	Analgesics	Open-label	No	College Foundation of Fudan University Shanghai Cancer Center
Bradt J, 2024[1]	United States	92 participants; advanced cancer	Group 1: music therapy or social attention control	Not mentioned	Not mentioned	Not mentioned	National Institute of Nursing Research, NIH (R01NR016681)
Martínez-Miranda P, 2024[62]	Spain	49 participants; breast cancer survivors	Group 1: online pain neuroscience education program + therapeutic yoga	Usual care	Single-blind	No	Universidad de Sevilla / CBUA and Professional College of Physiotherapists of Andalusia

Explanatory notes: 1. Classification refers to the type of blinding reported by the study authors (single-blind, double-blind, or open-label); 2. When the study did not report an item (e.g., conflict of interest, funding), it was recorded as "Not mentioned".
Source: Authors' own elaboration, 2025.

The most frequently evaluated non-pharmacological interventions identified in the RCTs were acupuncture (54.55%), including electroacupuncture (22.73%), music therapy (9.09%), and massage (9.09%). It was not clear whether these interventions were the most frequently evaluated because they are the ones most commonly offered by health services or because there is, in fact, a greater need for evidence regarding their effectiveness.

In most studies, participants in the control group received usual care for cancer pain management, which may include analgesics such as aspirin, oxycodone, and morphine. However, each service adopts a "usual care" strategy based on what is available within its health system; therefore, these characteristics may vary across studies. In addition, participants in control groups also received sham stimulation, such as transcutaneous electrical stimulation and electroacupuncture, massage, support sessions, and educational strategies such as informational booklets.

Regarding blinding, 15 studies self-identified as single-blind, six as open-label, and one as double-blind. Among all included studies, 11 explicitly discussed the impact of the lack of blinding of participants and staff, mainly because many interventions were easily distinguishable from those applied to the control group or involved specific techniques delivered differently across groups. An example is the study by Lam *et al.* (2017)[33], which compared a combination of commonly used acupuncture points defined as specific points versus common points. Considering that blinding of participants and staff is assessed jointly and that professionals responsible for delivering the intervention are expected to know the procedure being performed, blinding tended to be systematically compromised.

Despite these limitations, some studies devel-

oped strategies to simulate the intervention in the control group. In Kim (2018)[37], which investigated intradermal acupuncture in patients with advanced cancer, the sham group received the same intervention as the experimental group, but with the needle tip bent, producing a pricking sensation without skin penetration. The sham intervention was carefully designed to maximize participant blinding.

A similar strategy was adopted by Siemens *et al.* (2020)[48], who evaluated transcutaneous electrical nerve stimulation (TENS) in a sham-controlled trial. The control group used a placebo-based TENS mode, with continuous stimulation at 100 Hz and intensity below the sensory threshold, perceptible only for a few seconds at the beginning, while the device remained visually identical to the active one.

Conversely, some studies used less structured control conditions. In He *et al.* (2019)[55], Lei *et al.* (2020)[45], and Mao (2021)[51], the control group consisted of usual pain care, but with limited details regarding its composition, allowing for substantial variability among participants under the same designation. Moreover, none of these studies — which evaluated acupuncture or electroacupuncture versus usual care — discussed the impact of the lack of blinding on the observed effects. Other studies also reported controls based on usual medical care without sufficient detail, such as Miladinia *et al.* (2021)[54].

In contrast, other studies employed more active and structured control conditions or simple interventions, such as rest in Huang *et al.* (2010)[26] or verbal relaxation exercises in Warth *et al.* (2015)[30]. In Ruela *et al.* (2018)[4], the placebo group received needles applied to the auricle at non-specific points, allowing a direct comparison to assess the effectiveness of auriculotherapy.

Mendoza *et al.* (2017)[34] provided the control group with a standardized educational intervention composed of didactic sessions and discussions about symptoms, as well as reading materials and home activities, but without training in therapeutic techniques such as cognitive restructuring or self-hypnosis. Similarly, in Wang *et al.* (2022)[5], participants in the control group received usual care and the same informational booklet on pain provided to the intervention group.

Regarding yoga-based interventions, Carson *et al.* (2021)[52] offered the control group a structured emotional support intervention without body – mind components. Additionally, in Martínez-Miranda *et al.* (2024)[62], the control group did not receive any additional educational or movement-based intervention during the study period.

DISCUSSION

The results of the 22 RCTs included in this meta-research highlight the diversity of non-pharmacological interventions used for the management of cancer pain, as well as the substantial variability in the control conditions employed in the analyzed clinical trials. The impossibility of conducting double-blind studies and the predominance of single-blind or open-label designs illustrate the challenges inherent to blinding in interventions involving physical contact, direct human interaction, or sensory procedures. In this context, the absence of effective blinding, even in studies that attempted to include objective measures such as blood pressure and heart rate, limits the exclusion of placebo effects, particularly for subjective outcomes such as pain.

Two key issues may be raised: either there is a chronic problem in the teaching of randomized controlled trial design, and research groups conducting these studies are unaware of performance bias and the extent to which lack of blinding may overestimate the observed effects of their interventions; or the impact of the lack of blinding is being disregarded. In either case, results continue to be overestimated, as all included studies reported at least one outcome favoring the intervention, and only 12 discussed the lack of blinding.

It is also important to consider that the lack of blinding arises from the nature of the intervention rather than from a methodological failure to blind participants and staff. It is expected that teams delivering interventions such as yoga, acupuncture, music therapy, or others analyzed in this meta-research are aware of what they are administering, and when they know they are participating in a study evaluating the effectiveness of an intervention they believe in, they may unconsciously treat participants differently.

Thus, even when experienced participants are excluded — as in the acupuncture study that removed individuals who had previously received the technique to avoid recognition of differences — the problem of non-blinding of staff remains[37]. Similarly, in the study by Huang (2010)[26], music selection based on participant preference may have contributed to an overestimation of results. Olson *et al.* (2003)[17] also noted that the mere presence of the therapist in the experimental group (Reiki) may have influenced the observed effects, reinforcing the role of human interaction in outcome assessment.

These aspects suggest that participants receiving the intervention tend to feel more cared for, whereas those who know they are in the control group — particularly when usual care, a waiting list, or no intervention is offered — may become discouraged, potentially leading to higher dropout rates and imbalances in participant characteristics between groups. Intervention group participants may feel motivated, while control group participants may feel demotivated, resulting in unequal conditions for outcome assessment.

Studies evaluating subjective outcomes are particularly affected by the lack of participant blinding. One approach to minimizing the impact of performance bias is to keep outcome assessors blinded, thereby reducing the risk of detection bias, which occurs when outcome assessors are aware of group allocation. Even so, subjective outcomes such as pain remain vulnerable to the lack of blinding, and results should be interpreted with caution.

This meta-research has limitations primarily related to the lack of full-text availability for all eligible studies. In addition, the clinical superiority of one type of control group over another was not assessed, making it impossible to recommend a single control strategy for all non-pharmacological interventions. Nevertheless, the processes of search, selection, and data extraction were robust and conducted independently in duplicate.

CONCLUSION

The strategies used in control groups of clinical trials evaluating non-pharmacological interventions for cancer pain highlight the methodological complexity of this field. The absence or limitation of adequate blinding strategies poses significant challenges to result validity, particularly when outcomes are subjective, such as pain, underscoring the importance of discussing performance bias in trials involving non-pharmacological interventions.

In conclusion, the heterogeneity of control methods—ranging from usual care and placebos to supervised rest and sham procedures—reflects the need for greater standardization and methodological rigor in the analysis and discussion of results, taking into account biases related to participant expectations. Although many studies report promising findings, the data should be interpreted with caution due to the identified limitations, particularly those related to performance bias.

By highlighting these challenges, this meta-research fulfills its purpose of elucidating relevant methodological weaknesses and contributing to improvements in the quality of future research in the field, suggesting that, given the nature of these interventions and the frequent impossibility of double-blinding, greater detail should be provided regarding control group interventions and performance bias should be explicitly addressed in result interpretation.

CRediT author statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the workreported in this paper.

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