


REVIEW OPEN ACCESS

Research Methodology in Acupuncture for Managing Interstitial Cystitis/Bladder Pain Syndrome: A Scoping Review

Miguel Ángel Infantes Rosales  | Ángeles Mesías Pesqueira | Astrid Castellanos Díaz | Esther Díaz Mohedo

University of Málaga, Málaga, Spain

Correspondence: Ángeles Mesías Pesqueira (mesiaspesqueira@gmail.com)

Received: 18 December 2024 | **Revised:** 5 March 2025 | **Accepted:** 24 March 2025

Funding: The authors received no specific funding for this work.

Keywords: acupuncture | acupuncture therapy | acupuncture treatment | bladder pain syndrome | IC/BPS | interstitial cystitis | painful bladder syndrome

ABSTRACT

Background: Acupuncture and moxibustion are being explored as complementary therapies with promising potential in managing interstitial cystitis/bladder pain syndrome (IC/BPS). While some studies indicate possible benefits, their scientific basis and clinical efficacy remain subjects of debate, partly due to methodological flaws in study designs involving acupuncture and related modalities, which warrant further attention and discussion. The main objective is to analyze and evaluate the research methodologies used in existing literature on acupuncture for managing IC/BPS, providing insight into the methodological challenges and opportunities in this field.

Materials and Methods: National Library of Medicine (PubMed), Allied and Complementary Medicine Database (AMED), Cochrane Library, Excerpta Medica database (EMBASE), Web of Sciences (WOS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulated Index in Nursing and Allied Health Literature (CINAHL), Scopus, SPORTDiscus, Epistemonikos, and Physiotherapy Evidence Database (PEDro) were searched from their inception to August 2024. Data were extracted based on the study designs, primary outcome measures, adverse events (AEs), and participants' subjective views.

Results: All the experimental studies (27.3%, 6 of 22) were randomized controlled trials (RCTs), but only 2 full texts were accessible. Of the 4 RCTs, 3 involved rats. Observational research (50%) included case reports (27.3%), cohort studies (9.1%), and theoretical studies (4.5%). Additionally, reviews (22.7%) were included. The main languages were English (77.3%), Chinese (13.6%), Japanese (4.5%), and Russian (4.5%). The most frequently reported outcome was pain, followed by quality-of-life impact (symptom burden), urinary frequency and urgency, nocturia, and bladder capacity. AEs were reported in only 5 articles, all of which concluded that these effects were not significant and that acupuncture could be considered a safe and relatively noninvasive technique. One review found a risk of 1 AE/76 000 patients, with the most common side effects being minor, such as bleeding or bruising.

Conclusion: Current evidence on acupuncture for interstitial cystitis is limited in quality, with studies often compromised by biases, small sample sizes, and lack of standardized protocols. Acupuncture is frequently part of multimodal treatments, aligning with Traditional Chinese Medicine's holistic approach to balance physical, mental, and emotional health. More high-quality experimental research is needed, focusing on standardized protocols and participant experiences to better evaluate its efficacy and safety.

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial](https://creativecommons.org/licenses/by-nc/4.0/) License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

© 2025 The Author(s). *Neurourology and Urodynamics* published by Wiley Periodicals LLC.

1 | Introduction

Guidelines from the *Canadian Urological Association* (CUA, 2016) [1], the *European Society for the Study of Interstitial Cystitis/Bladder Pain Syndrome* (ESSIC, 2021) [2], the *European Association of Urology* (EAU, 2023) [3], the *Asian 2020 Clinical Practice Guidelines* [4], and the *American Urological Association* guideline (AUA, 2022) [5] all define interstitial cystitis/bladder pain syndrome (IC/BPS) as a condition characterized by chronic pelvic pain (usually suprapubic) and bladder-related pressure or discomfort, accompanied by other urinary symptoms such as urgency and increased frequency. Additional signs described in the literature include nocturia, sleep disorders, sexual dysfunction, emotional or behavioral issues, and a higher prevalence in women [6–8].

Despite this general consensus, definitions vary across regions: North America favors “IC” with a bladder-centric focus [5, 9], Europe prefers “BPS” emphasizing pain and broader symptom-based criteria [2, 3], and some Asian countries use both terms but apply stricter diagnostic thresholds [4, 10]. These discrepancies pose challenges for global research collaboration, clinical trials, and patient management. Furthermore, some authors consider IC/BPS as synonymous [4, 5], while others define it as a syndrome [6], disorder [7], chronic pelvic pain syndrome [8, 11], or a symptom [4, 6, 7].

The unclear pathophysiology of IC/BPS complicates diagnosis and treatment, especially since IC and BPS often overlap but differ: IC involves chronic inflammation, while BPS typically does not [8, 11, 12]. Diagnostic practices vary globally, with North America emphasizing cystoscopy and biopsy for IC [1, 5], while other regions favor symptom-based diagnosis [1, 4, 5, 9] and highlight the need for biomarkers to improve early management [12].

Still, a comprehensive therapeutic solution is needed, so the current approach focuses primarily on symptom relief [6, 7, 13], starting with conservative treatments, followed by medication and more invasive treatments such as hydrodistension and surgery [1, 4, 5, 8]. Please see [Supporting Material](#) for more detailed treatment strategies (S1).

IC/BPS is a challenging condition to treat, with limited effective options, prompting many patients to explore complementary and alternative medicine (CAM). *Complementary medicine* is used alongside conventional treatments to enhance their effects, while *alternative medicine* replaces conventional treatments. Acupuncture and moxibustion, both practiced for over 3000 years, are among the most well-known CAM treatments [13]. The method is commonly practiced as a routine treatment in China, Japan, Korea, and Taiwan, but since the late 1970s, these therapies have gained popularity in the United States and other Western countries [14].

Acupuncture originated in China around 3000 years ago, where physicians stimulated specific body points using pain, touch, and temperature-based techniques. By 200 BC, it was well-documented in *The Yellow Emperor's Classic of Internal Medicine*, a foundational text of Traditional Chinese Medicine (TCM), which describes the meridian system, a

network of channels through which Qi (vital energy) flows [15]. This system connects internal organs with the body's surface, regulating physiological functions. Classical TCM theory holds that stimulating acupuncture points along the 12 primary and 8 extraordinary meridians restores balance and alleviates ailments. While modern science has not identified anatomical structures corresponding to meridians, some theories link them to neurovascular pathways or connective tissue networks [16]. An imbalance in Qi flow is believed to cause disease and pain [14]. In addition to acupuncture, TCM incorporated herbal medicine and lifestyle recommendations, including dietary and behavioral modifications [15].

Additionally, acupuncture includes various modalities, the most common of which are as follows [17]:

- *Classical Acupuncture*. Involves inserting fine, polished metallic needles at specific points, typically 10–12/session. The needles are manually manipulated through back-and-forth and rotational movements to elicit the “acupuncture sensation” (Deqi), which is believed to enhance therapeutic effects. Once this sensation is achieved, additional maneuvers may be applied, or the needles may be stimulated with heat (moxibustion) or electricity (electroacupuncture). Variants of this modality include *Auricular Acupuncture* and *Scalp Acupuncture*.
- *Moxibustion*. Applies heat to acupuncture points to improve circulation and Qi flow, often using burning mugwort (moxa, *Artemisia sinensis*) or herbal intermediaries.
- *Electroacupuncture*. Introduced in the 1940s, this method delivers low-frequency electrical currents (2–100 Hz) through needles, enhancing analgesic effects and providing a scientific basis for acupuncture-induced pain relief.
- *Laser Acupuncture*. Uses low-level laser light instead of needles for stimulation, making it suitable for needle-sensitive patients.
- *Trigger Point Acupuncture (Dry Needling)*. Involves inserting needles into muscular trigger points to relieve pain and tension.
- *Acupressure*. Applies pressure to acupuncture points instead of needles, commonly used in self-treatment or massage therapy.

Acupuncture has been extensively studied to understand its mechanisms of action from a modern scientific perspective. Several hypotheses have been proposed.

Sierpina and Frenkel [14] reviewed multiple theories, including the placebo effect and the endorphin hypothesis, which suggests that needle stimulation modulates endorphin and enkephalin levels in cerebrospinal fluid. Another hypothesis views the acupuncture needle as an electrode, altering the ionic environment of interstitial fluid and conducting signals through fascial planes. Additionally, the gate control theory of pain suggests that nociceptive stimulation from acupuncture may modulate pain perception, similar to transcutaneous electrical nerve stimulation.

Other proposed mechanisms include vascular and immune responses triggered by needle insertion, leading to local inflammatory mediator release. Acupuncture has also been associated with increased adrenocorticotrophic hormone (ACTH) levels, potentially stimulating adrenal glands and endogenous corticosteroid release. Some theories even explore physical concepts such as quantum mechanics, electromagnetic field changes, and wave phenomena to explain acupuncture's nonlocal effects [14].

Further research has identified additional mechanisms. Goldman et al. [18] found that acupuncture induces local adenosine release, which acts on A1 receptors to inhibit pain signals and produce analgesia. Dhond et al. [19], using functional neuroimaging, reported that acupuncture deactivates brain regions involved in pain perception and emotional regulation, such as the limbic system and default mode network. This deactivation has been linked to reduced pain perception and improved emotional well-being.

Despite the *World Health Organization* (WHO) recognizing acupuncture for over 100 conditions since 1996, skepticism remains regarding its scientific basis and biological mechanisms [20]. While accepted in some countries, it remains unapproved in many others [16]. The latest clinical guidelines do not recommend acupuncture for IC/BPS [5], and the 2020 guidelines [4] assign it a grade C due to the placebo effect and inconsistent results. However, the 2016 Canadian Urological Association guideline [1] supports its effectiveness for symptom relief. Modern adaptations incorporate evidence-based practices, integration with Western medicine, and techniques such as sterile needles, electroacupuncture, acupressure, and laser acupuncture. While TCM emphasizes holistic health—addressing the interconnectedness of mind, body, spirit, and emotions—contemporary acupuncture focuses more on symptom relief and pain management, particularly for chronic conditions [21].

Acupuncture and moxibustion studies are generally of moderate quality, but many have methodological flaws [22, 23]. Common issues include poor research design, lack of medium- and long-term follow-up, limited qualitative data, and inadequate reporting of adverse events (AEs) [24]. Despite this, recent meta-analyses have shown positive outcomes for acupuncture in conditions with symptoms similar to IC/BPS, such as endometriosis [25], overactive bladder [26], prostatitis, and chronic pelvic pain [27]. However, a dedicated review on IC/BPS is still lacking.

This review aims to analyze and evaluate the research methodologies used in acupuncture studies for IC/BPS, highlighting key challenges and potential improvements in the field.

2 | Materials and Methods

Following the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guideline and framework [28], the review questions have been established as follows:

- (a) What research designs were applied in studies using acupuncture to manage IC/BPS?
- (b) What are the characteristics of the research designs in studies that use acupuncture to manage IC/BPS?
- (c) What are the primary outcome measures in studies using acupuncture to manage IC/BPS?
- (d) What is the evidence of AEs when using acupuncture to manage IC/BPS?
- (e) What are participant attitudes, beliefs, and experiences when managing IC/BPS with acupuncture?
- (f) What are the gaps in the existing research on using acupuncture to treat IC/BPS, in order to support future decision-making in research?

2.1 | Eligibility Criteria

A peer review of the scientific literature was carried out until August 2024. We searched in 11 electronic databases in English: National Library of Medicine (PubMed), Allied and Complementary Medicine Database (AMED), Cochrane Library, Excerpta Medica database (EMBASE), Web of Sciences (WOS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulated Index in Nursing and Allied Health Literature (CINAHL), Scopus, SPORTDiscus, Epistemonikos, and Physiotherapy Evidence Database (PEDro). All searches were analyzed in English. Although we found some results in other languages, we were unable to access these papers despite contacting the authors. The original non-English studies were included nonetheless, as valid information was available in the English abstracts.

The following were the PICOs of this review.

2.1.1 | Participants

All individuals clinically diagnosed with IC/BPS, regardless of the presence or absence of Hunner lesions, were included in the study. The diagnostic criteria were not restricted to a specific guideline to ensure comprehensive coverage of the existing literature. Additionally, animal and theoretical studies were considered. IC/BPS is defined by *The Society for Urodynamics and Female Urology* (SUFU) and *The American Urological Association* (AUA) as a discomforting sensation (pain, pressure, discomfort) perceived/associated with the urinary bladder, and accompanied by at least one symptom of the lower urinary tract lasting for more than 6 weeks, in the absence of infection or other identifiable causes [1].

2.1.2 | Intervention(s)

All types of acupuncture (manual, electro, or laser) with or without moxibustion were included. Wrist-ankle needle,

auricular acupuncture, scalp acupuncture, acupoint catgut embedding, and acupoint injection were excluded.

2.1.3 | Comparator

Both observational and experimental studies were considered, including those with or without control groups, along with theoretical and animal studies.

2.1.4 | Outcomes

All types of outcomes related to IC/BPS and their used validated measurement tools.

2.1.5 | Study Type(s)

All types of original studies involving acupuncture with or without moxibustion as an intervention were included in this review, along with theoretical studies; however, theses and conference abstracts were excluded. Only completed studies were considered.

2.2 | Search Strategy

The search strategy was adapted to different database demands. The keywords in the search include “acupuncture,” “acupuncture therapy,” “acupuncture treatment,” “interstitial cystitis,” “bladder pain syndrome,” “painful bladder syndrome,” and “IC/BPS” in English. For example, the search strategy used on PubMed is shown in Table 1. No filters were applied due to the limited number of articles found and to ensure a broad scope.

2.3 | Study Selection

EndNote 21 software was employed to manage and screen the literature. PRISMA flowchart was used to present the process of study selection (Figure 1). After removing duplicates, two reviewers independently screened the titles and abstracts, excluding irrelevant articles. Next, they further screened the literature by reading the full text or abstract (if not access to full text) according to the inclusion and exclusion criteria. A third

TABLE 1 | Searching strategy example.

Search terms and combinations
PubMed
#1 MeSH
(“Cystitis, Interstitial”[Mesh]) AND “Accupuncture Therapy”[Mesh]
#2 Clinial queries
((cystitis interstitial) OR (bladder pain syndrome)) OR (IC/BPS) AND (acupuncture therapy))
#3 Advanced search
((cystitis interstitial) OR (bladder pain syndrome)) OR (IC/BPS) AND (acupuncture therapy))

reviewer was consulted throughout the process to resolve any conflicts and address uncertainties regarding study inclusion.

2.4 | Data Management

All data were entered into Excel spreadsheets (Microsoft Excel version 2016) by two entry personnel independently, after which the data manager cross-checked two data sets to ensure accuracy. The characteristics collected included the author, publication year, study design, interventions, primary outcome measures, and study-related AEs. A narrative synthesis approach was used to collate, summarize, and map the literature. Most data were analyzed descriptively by calculating frequencies and percentages, with the results presented in tables, column charts, and pie charts using Microsoft Excel 2016. Qualitative data were presented descriptively.

3 | Results

Across these searches, 458 records were retrieved. After deduplication and screening titles and abstracts for relevance, 299 and 64 records remained, respectively. Screening by full-text or abstract, 22 articles met the inclusion criteria. A flowchart of this review process is shown in Figure 1.

The type of publications was all journal articles, as thesis and conference papers were excluded. The main publication languages are English (77.3%), Chinese (13.6%), Japanese (4.5%), and Russian (4.5%) (Figure 2a). The studies were published between 1993 and 2024. There was a significant hike from 2019, reaching the highest in 2022 (Figure 2b).

3.1 | Research Design

There are two types of original studies: experimental and observational studies [29]. Among the experimental studies (27.3%), six were RCTs (100%), but we only had access to the full text of two. Notably, of the four RCTs for which only abstracts were available, three involved rats. Observational research (50%) included case reports (27.3%), cohort studies (9.1%), and theoretical studies (4.5%). Finally, to provide a broader view of the available research, we also considered reviews (secondary studies) [29] as part of our analysis (22.7%). The types of study designs are shown in Figure 2c.

The types of interventions identified are presented in Figure 2d. Six studies focused on electroacupuncture (27.27%), four on classical acupuncture (18.18%), two combined classical acupuncture with moxibustion (9.09%), one combined electroacupuncture with moxibustion (4.55%), nine articles included acupuncture as part of a multimodal treatment or within techniques used in CAM (40.91%), and one applied transdermal laser therapy in acupoints (4.55%).

Among the six RCTs, five focused on electroacupuncture (83.33%), while one used transdermal laser therapy (16.67%).

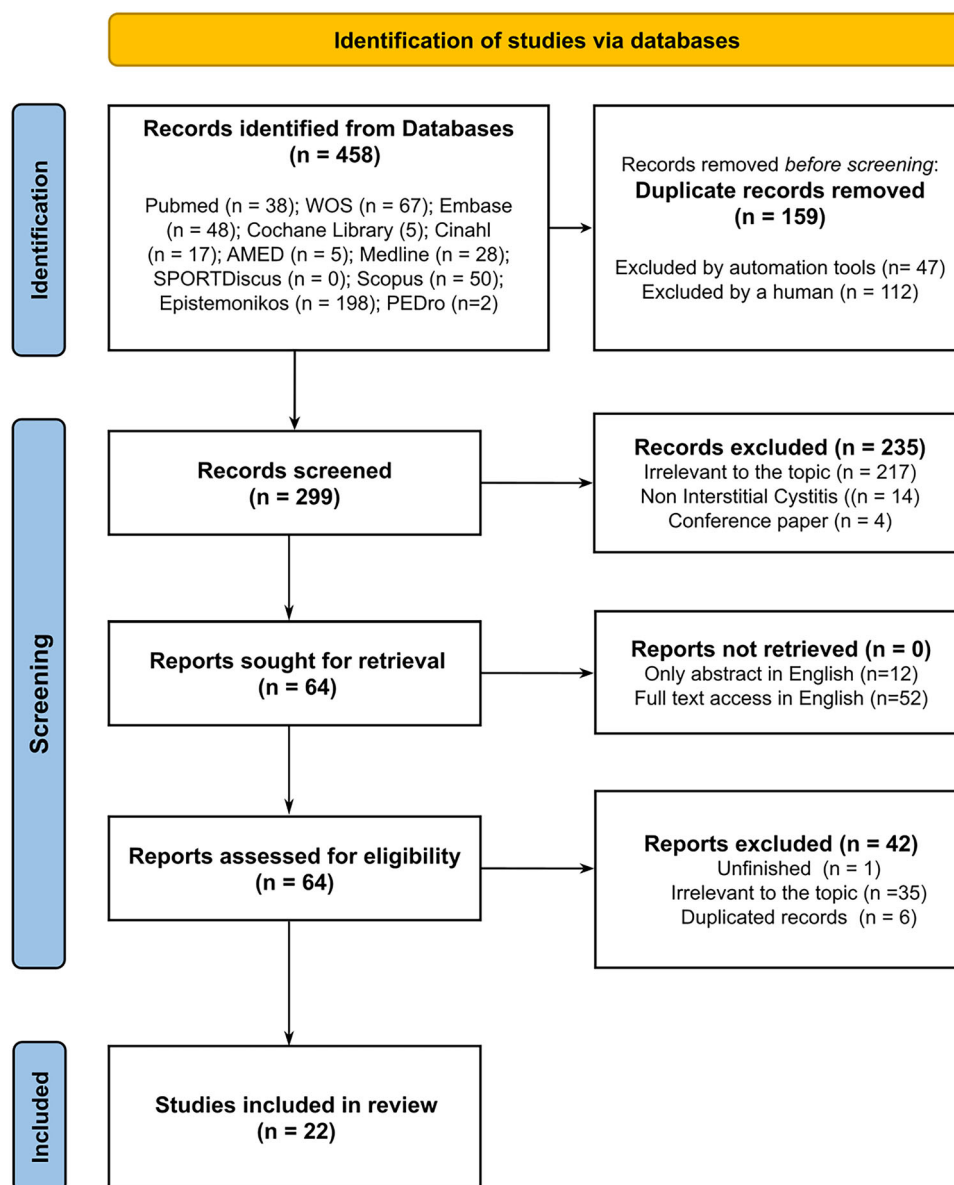


FIGURE 1 | Flowchart of the review process. National Library of Medicine (PubMed), Allied and Complementary Medicine Database (AMED), Excerpta Medica database (EMBASE), Web of Sciences (WOS), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulated Index in Nursing and Allied Health Literature (CINAHL), and Physiotherapy Evidence Database (PEDro).

Regarding their studied population, three studies were conducted in humans (50%) and three in rats (50%).

The control methods in these RCTs also differed: three of the rat studies used no intervention as a control, two applied a placebo, and one involved a combination infusion therapy with four medications. Among the two placebo-controlled studies, one implemented sham acupuncture, described as “minimal acupuncture,” where needles were superficially inserted away from acupoints and connected to inactive electrical cables. The other placebo-controlled study used transdermal laser therapy, with the same device turned off as a placebo, ensuring double-blinding for both patients and examiners.

Regarding intervention protocols, we endeavour to identify patterns. Only 13 articles provided detailed descriptions,

including the 6 RCTs, 6 case reports, and 1 cohort study. While the combination of acupuncture points varied, detailed intervention protocols were only explicitly detailed in 12 of the articles: 4 acupuncture points appeared frequently across 3 or more studies, ranked by frequency of occurrence (percentage based on these 12 articles), we observed:

- BL23 (Shenshu): 6 occurrences (50%)
- SP6 (Sanyinjiao): 5 occurrences (41.67%)
- BL35 (Huiyang): 4 occurrences (33.33%)
- SP9 (Yinlingquan): 3 occurrences (25%)

In the literature, clinical studies, reviews, and case reports specifically mentioning common acupuncture points used to

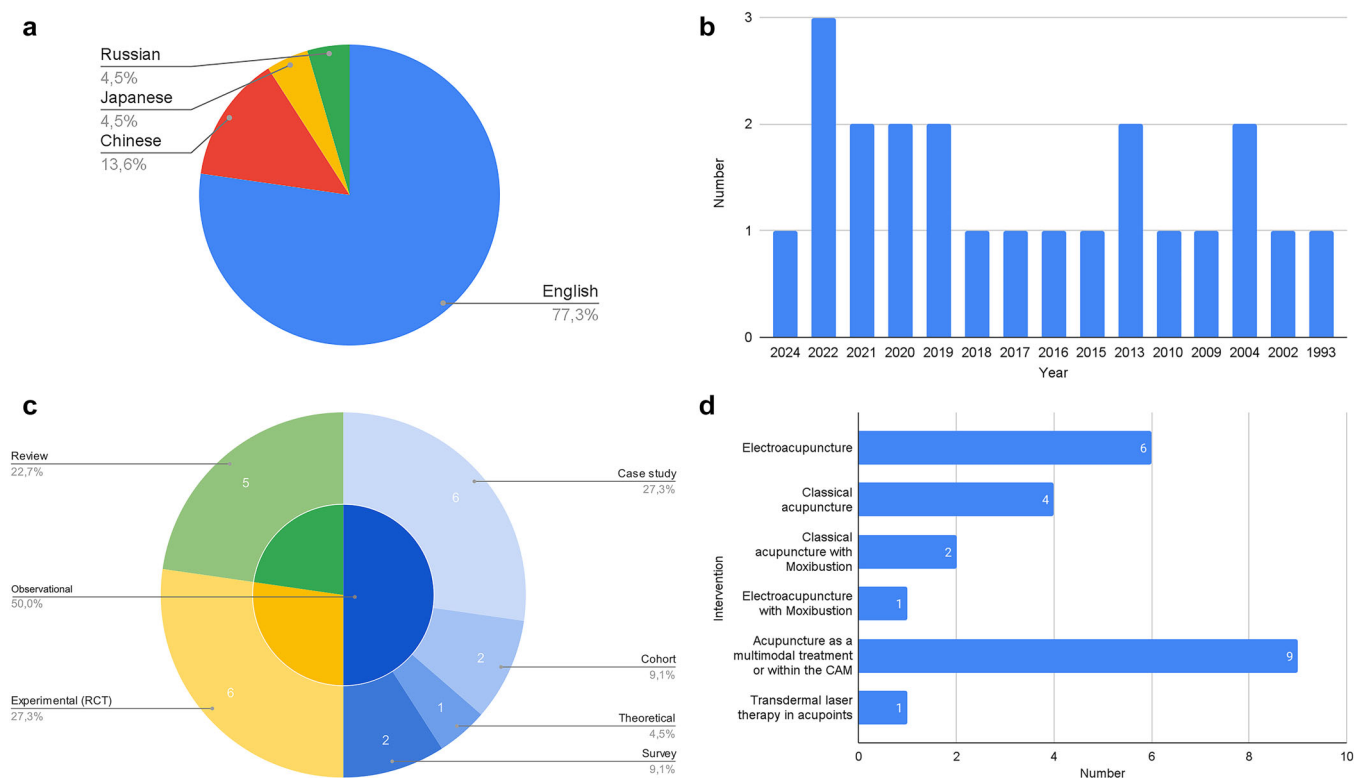


FIGURE 2 | Overview of included studies. (a) Languages of included studies. (b) Year of publications: 1993–2024. (c) Types of study designs: observational (case study, cohorts, theoretical, survey), experimental, and reviews. (d) Intervention of included studies: electroacupuncture, classical acupuncture, classical acupuncture with moxibustion, electroacupuncture with moxibustion, acupuncture as a multimodal treatment or within the CAM, transdermal laser therapy in acupoints. CAM, complementary and alternative medicine.

treat IC/BPS, the most frequently cited are CV3, BL23, and SP6, which largely align with our findings (for a more detailed explanation of each point, see Supporting Material S2).

3.2 | Main Outcome Measures and Measurement Tools

Different instruments were applied in these studies to measure the efficacy of acupuncture and moxibustion. Of the 22 articles analyzed, only 15 reported outcome variables. The most commonly measured variables were pain, quality-of-life impact (symptom burden), urinary frequency and urgency, nocturia, and bladder capacity. Based on these 15 articles, we observed the following.

Pain was the most frequently assessed outcome (73.33%), using tools like the VAS (40%), PUF questionnaire (13.33%), and bladder pain threshold tests (13.33%), including the Von Frey test (6.67%); other methods included the BPI-SF, Q-tip test, and myofascial exams. *Symptom burden and quality of life* were next (46.67%), primarily assessed with the ICSI/ICPI (33.33%) and OSS (26.67%), along with PCS, SF-36, and PHQ-9 (each 6.67%). *Bladder capacity* was evaluated in 40% of studies, mainly using maximum void volume (MVV) (26.67%), with some also measuring average void volume (AVV) (6.67%) or unspecified tools (13.33%). *Urinary frequency* was assessed in 33.33% of studies, urgency and nocturia in 20% each, using the PUF test (13.33%) and voiding diaries (26.67%).

3.3 | Adverse Events

AEs were reported in only five articles, all of which concluded that these effects were not significant and that acupuncture could be considered a safe and relatively noninvasive technique. The review by Verghese et al. [30] was the only one to perform a comprehensive analysis of this parameter, reporting data from 2.2 million treatment sessions. It found a risk of 1 AE/76 000 patients, with the most common side effects being minor, such as bleeding or bruising.

3.4 | Participant Attitudes, Beliefs, and Experiences

These variables could not be adequately analyzed as they are only addressed in two articles [31, 32], both of which are observational (surveys), thus limiting the validity of their outcomes. In general, the results are positive regarding patients' attitudes and beliefs, as well as greater effectiveness when acupuncture is administered in the early stages of the disease.

4 | Discussion

4.1 | Critical Evaluation and Comparison

The search revealed a *limited number of studies related to the topic*, with only 22 articles meeting the inclusion criteria. These criteria were designed with particular flexibility due to the low

number of articles found in the initial searches, in order to gather as much available information as possible. For this reason, our review included various study designs, articles in other languages, and also papers without full access (as long as the abstract provided sufficient information). Similarly, no filters were applied based on the age or gender of the study subjects, nor were studies involving animals excluded.

Of the total 22 articles, experimental studies such as RCTs accounted for only 27.3%. RCTs are the gold standard in clinical research because they minimize bias through randomization and the use of techniques such as *double blinding*. When well-designed, they provide the highest level of evidence for evaluating interventions [29, 33, 34]. However, they have limitations, particularly in acupuncture studies (Table 2), where double blinding is challenging due to the nature of the technique, making it difficult or impossible to blind the therapist [35]. To address this issue and minimize bias in acupuncture RCTs for IC/BPS, the most effective approaches include: Double-Blind Acupuncture Needles (specially designed needles that keep both practitioners and participants blinded), Sham/Minimal Acupuncture Controls (nonpenetrating needles or nontherapeutic acupuncture point to serve as a placebo) and Assessor-Blinded Designs (outcome assessors remain unaware of treatment allocation) [35–37].

Of the six RCTs analyzed, only one was double-blinded [38], which was achieved through transdermal laser therapy administered autonomously by patients. In this study, neither the therapist nor the patient knew which devices were functional, ensuring blinding.

TABLE 2 | Major barriers in acupuncture research in RCTs.

Identified barriers
1. Blinding and sham acupuncture: Creating an effective placebo acupuncture treatment that mimics real acupuncture is challenging.
2. Placebo effect: Distinguishing actual therapeutic effects from psychological responses is difficult.
3. Standardization: The highly individualized nature of acupuncture makes it hard to standardize treatment protocols.
4. Outcomes measurement: Measuring acupuncture's effectiveness in a consistent and objective manner is challenging.
5. Small sample sizes: Limited patient populations reduce statistical power and generalizability.
6. Bias and confounding factors: Bias in patient selection and outcome reporting can skew results.
7. Funding: Acupuncture research often struggles to secure sufficient funding due to skepticism.
8. Variability in acupuncturists' skills: Differences in practitioner expertise can affect outcomes.
9. Regulatory and ethical challenges: Ethical issues around informed consent and placebo controls complicate trial design.
10. Cultural and regional differences: Variation in acupuncture practices across cultures may affect consistency and outcomes.

As mentioned, RCTs establish causal relationships between interventions and outcomes, but the quality of the *placebo* is crucial to avoid bias and ensure valid conclusions [39]. Designing an appropriate placebo in acupuncture is particularly challenging, as *sham acupuncture* may still activate physiological pathways and produce therapeutic effects. This complicates the distinction between placebo effects and actual intervention, reducing the validity of the control [40]. Among the RCTs reviewed, improvements were observed in the control groups. Notably, the study by O'Reilly et al. [38] concluded that no significant differences were found between the intervention and control groups, as both showed improvements in physical and emotional symptoms. The study also highlighted the significant role of the placebo effect in treatments for overactive bladder and IC, underscoring the necessity of placebo-controlled RCTs.

Thus, we propose that the optimal sham acupuncture treatment should be nonpenetrating, ideally using a blunt-tip needle or keeping the needle within the guide tube to prevent skin insertion. If this method is used, a nontherapeutic acupuncture point may not be as necessary. Additionally, the sham procedures should exclude active interventions such as electrotherapy or moxibustion. This approach minimizes physiological effects while maintaining blinding, serving as a reliable control, though its superiority over other methods remains to be proven. However, its limitations include potential differences in patient perception and placebo effects compared to true acupuncture.

Regarding *randomization*, another key quality guarantee attributed to RCTs, all studies were described as randomized trials; however, we could not determine the randomization mechanism in four studies due to limited access to abstracts, and the two fully accessible studies did not specify their randomization method.

With respect to the *sample size*, it ranges from 68 to 18 participants. In one study (only abstract accessible), the number of participants could not be determined. As noted by Moher and colleagues in the PRISMA statement [35], an adequate sample size is essential to ensure sufficient statistical power to detect significant differences between experimental and control groups. Small samples are more prone to Type II errors (false negatives), and their results are more susceptible to random variability, which reduces the reliability and generalizability of the findings. Studies with small sample sizes may also exaggerate the effects of the intervention due to publication bias, as positive results are more likely to be published more. Altman [40] argues that in studies with fewer than 100 participants, the sample size is insufficient to draw meaningful conclusions. This is particularly critical in interventions such as acupuncture, where effects may be subtle and require larger sample sizes to demonstrate statistically significant differences.

The six RCTs analyzed report *positive results* in the treatment of IC/BPS with acupuncture. However, since three studies were conducted in rats and two were inaccessible, we are left with the study by Bresler et al. [41]. In this study, of the six measured variables, three were statistically significant while three were not. As noted, three of the RCTs included were conducted in *rats*. While animal studies are valuable for understanding basic biological mechanisms and exploring the initial effects, their

findings have limited applicability to human populations due to physiological and contextual differences between species, which can reduce the external validity of the results [42]. Animal acupuncture studies often overlook key human factors like treatment perception and placebo effects, which are crucial in this therapy [43].

Among the *observational studies*, 27.7% were low-evidence (Level V) [33, 34] case reports showing positive acupuncture effects. As they describe unique clinical events or specific treatments, they can be useful for hypothesis generation but not for testing them [44]. Cohort studies made up 9.1% (Level III) [33, 34], assessing associations but not causality [44]. Of the two cohort studies, one [13] examines the use of TCM for preventing mental disorders in individuals diagnosed with IC, while the other [45] compares combined acupuncture and TENS treatment for symptom relief. Both reported limited or ineffective results, noted study limitations, and called for higher-quality research, highlighting the treatments' safety and noninvasiveness.

This review includes two *theoretical studies*, but one was reclassified as a case report, leaving only one (4.5%). While not part of the Oxford Centre for Evidence-Based Medicine (OCEBM) evidence hierarchy [33], they are typically considered low level (Level V) due to their nonempirical nature. Despite this, they can serve as foundation for higher-level research if they generate testable hypotheses or clinical trials. Moreover, they can provide valuable insights from multidisciplinary perspectives, offering a more holistic view, particularly in integrative medicine [47]. In acupuncture, theoretical articles are common due to the historical and philosophical nature of the field. These works often explore concepts like “Qi” and meridians, forming a theoretical framework [48, 49]. A notable example is Tucker [46], which details the TCM approach to disease and its management, describing acupuncture points for IC/BPS symptoms and promoting a holistic approach to the condition.

Two surveys (9.1%) were included, both offering Level IV (low) evidence [33, 34]. One [31] explored perceptions of CAM therapies, linking acupuncture effectiveness to early-stage IC/BPS, while the other [32] reported symptom improvement and highlighted stress as a possible trigger. Though not suitable for establishing causality, these surveys provide useful insights into patient perceptions, cultural acceptance, and quality-of-life factors [50].

Finally, to offer a broader perspective on the available research, we included reviews in our analysis (22.7%). Systematic reviews, especially those with meta-analyses, are considered the highest level of evidence (Level I) [33, 34]. Of the five reviews included, only the abstracts were accessible, preventing an evaluation of their rigor. None of these reviews focused solely on acupuncture's role in managing IC/BPS, but rather included it as part of a multimodal approach. All reviews concluded that CAM can be a safe, noninvasive treatment for IC, with most studies reporting positive results. However, they emphasized the need for studies with stronger methodological quality and further investigation into the long-term effects of treatment.

4.2 | Limitations

The main limitation of this scoping review is its focus on summarizing existing research and conducting basic frequency analysis, rather than addressing specific clinical questions. This approach aimed to identify areas for further investigation, influenced by the low quality and variety of the studies. The need for more RCTs to support a comprehensive systematic review was emphasized. Additionally, we did not assess the risk of bias or perform detailed statistical analyses. These limitations highlight the need for systematic reviews or primary research to provide more robust evidence.

4.3 | Recommendations and Conclusion

Current evidence on acupuncture for IC/BPS is limited in both quality and quantity, with many studies compromised by bias risks. Challenges include small sample sizes, difficulties with double-blind designs, lack of appropriate placebo controls, and reliance on animal models. Future research should focus on standardized sham controls, unified diagnostic approaches, and a deeper understanding of IC/BPS's etiopathogenesis to improve study quality and simplify evidence evaluation.

This review highlights acupuncture's frequent use in multimodal treatments for IC/BPS. While this complicates isolating its specific effects, it aligns with TCM, which views acupuncture as part of a holistic system aimed at restoring balance between physical, mental, and emotional health, particularly relevant for the multifactorial nature of IC/BPS.

Further investigation is needed, as most studies report positive results in symptom relief and safety, with mild adverse effects. However, documentation of these effects is limited, and many studies acknowledge methodological weaknesses. To establish acupuncture's efficacy and safety, more high-quality experimental research with standardized protocols is required. Additionally, qualitative data on participants' beliefs and experiences should be prioritized, and exploring public perceptions could provide valuable insights into acupuncture's effectiveness, given the role of subjective experiences in treatment evaluation.

Acknowledgments

Acknowledgments to all authors who performed all eligible studies included in the present study.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data used to support the findings of this study are included within the article. Data sharing is not applicable to this article as no new data were created or analysed in this study.

References

1. A. Cox, N. Golda, G. Nadeau, et al., "CUA Guideline: Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome," *Canadian Urological Association Journal* 10, no. 5–6 (May 2016): 136, <https://doi.org/10.5489/cuaj.3786>.
2. European Society for the Study of Interstitial Cystitis/Bladder Pain Syndrome, *ESSIC Guidelines on Interstitial Cystitis/Bladder Pain Syndrome* (ESSIC, 2021), <https://www.essic.org>.
3. European Association of Urology, *EAU Guidelines on Chronic Pelvic Pain* (European Association of Urology, 2023), <https://uroweb.org/guidelines/chronic-pelvic-pain>.
4. Y. Homma, Y. Akiyama, H. Tomoe, et al., "Clinical Guidelines for Interstitial Cystitis/Bladder Pain Syndrome," *International Journal of Urology* 27, no. 7 (July 2020): 578–589, <https://doi.org/10.1111/iju.14234>.
5. J. Q. Clemens, D. R. Erickson, N. P. Varela, and H. H. Lai, "Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome," *Journal of Urology* 208, no. 1 (July 2022): 34–42, <https://doi.org/10.1097/JU.0000000000002756>.
6. M. G. Sönmez and B. Kozanhan, "Complete Response to Acupuncture Therapy in Female Patients With Refractory Interstitial Cystitis/Bladder Pain Syndrome," *Ginekologia Polska* 88, no. 2 (2017): 61–67, <https://doi.org/10.5603/GP.a2017.0013>.
7. N. Gao, X. Zeng, L. Wu, Z. Lin, X. Wang, and W. Wang, "Effects of Electroacupuncture on Refractory Interstitial Cystitis/Bladder Pain Syndrome: A One-Year Follow-Up Case Report," *Explore* 20, no. 4 (July/August 2024): 602–605, <https://doi.org/10.1016/j.explore.2023.12.001>.
8. S. Garzon, A. S. Laganà, J. Casarin, et al., "An Update on Treatment Options for Interstitial Cystitis," *Przegląd Menopauzalny = Menopause Review* 19, no. 1 (2020): 35–43, <https://doi.org/10.5114/pm.2020.95334>.
9. S. H. Berry, M. N. Elliott, M. Suttrop, et al., "Prevalence of Symptoms of Bladder Pain Syndrome/Interstitial Cystitis Among Adult Females in the United States," *Journal of Urology* 186, no. 2 (2011): 540–544, <https://doi.org/10.1016/j.juro.2011.03.132>.
10. Y. S. Lee and K. S. Lee, "Current Challenges in Interstitial Cystitis/Bladder Pain Syndrome in Korea," *International Neurourology Journal* 20, no. 3 (2016): 170–175, <https://doi.org/10.5213/inj.1632722.136>.
11. L. A. Birder, "Pathophysiology of Interstitial Cystitis," *International Journal of Urology* 26, no. S1 (June 2019): 12–15, <https://doi.org/10.1111/iju.13985>.
12. S. S. Patnaik, A. S. Laganà, S. G. Vitale, et al., "Etiology, Pathophysiology and Biomarkers of Interstitial Cystitis/Painful Bladder Syndrome," *Archives of Gynecology and Obstetrics* 295, no. 6 (June 2017): 1341–1359, <https://doi.org/10.1007/s00404-017-4364-2>.
13. H. H. Hung, W. C. Chen, Y. H. Chen, L. T. Chiu, and H. Y. Chen, "Evaluation of the Efficacy of Chinese Herbal Medicine and Acupuncture for the Prevention of Mental Disorders in Interstitial Cystitis Patients: A Nationwide Population-Based Study," *Medicine* 99, no. 30 (July 2020): e21422, <https://doi.org/10.1097/MD.00000000000021422>.
14. V. S. Sierpina and M. A. Frenkel, "Acupuncture: A Clinical Review," *Southern Medical Journal* 98, no. 3 (2005): 330–337, <https://doi.org/10.1097/01.SMJ.0000140834.30654.0F>.
15. G. A. Ulett, J. Han, and S. Han, "Traditional and Evidence-Based Acupuncture: History, Mechanisms, and Present Status," *Southern Medical Journal* 91, no. 12 (1998): 1115–1120, <https://doi.org/10.1097/00007611-199812000-00004>.
16. S. F. Elahee, H.-J. Mao, L. Zhao, and X.-Y. Shen, "Meridian System and Mechanism of Acupuncture Action: A Scientific Evaluation," *World Journal of Acupuncture - Moxibustion* 30, no. 2 (June 2020): 130–137, <https://doi.org/10.1016/j.wjam.2020.05.003>.
17. R. Cobos Romana, "Acupuntura, electroacupuntura, moxibustión y técnicas relacionadas en el tratamiento del dolor [Acupuncture, Electroacupuncture, Moxibustion, and Related Techniques in the Treatment of Pain,]," *Revista de la Sociedad Española del Dolor* 20, no. 5 (2013): 263–277, <https://doi.org/10.4321/S1134-80462013000500006>.
18. N. Goldman, M. Chen, T. Fujita, et al., "Adenosine A1 Receptors Mediate Local Anti-Nociceptive Effects of Acupuncture," *Nature Neuroscience* 13, no. 7 (2010): 883–888, <https://doi.org/10.1038/nn.2562>.
19. R. P. Dhond, N. Kettner, and V. Napadow, "Neuroimaging Acupuncture Effects in the Human Brain," *Journal of Alternative and Complementary Medicine* 13, no. 6 (2007): 603–616, <https://doi.org/10.1089/acm.2007.7040>.
20. World Health Organization, *A Proposed Standard International Acupuncture Nomenclature* Report of a WHO Scientific Group (World Health Organization, 1991), <https://apps.who.int/iris/handle/10665/40001>.
21. H. MacPherson, H. Tilbrook, S. H. Richards, T. M. Cummings, and A. J. Vickers, "A Critical Examination of the Main Premises of Traditional Chinese Medicine," *BMC Complementary Medicine and Therapies* 20, no. 1 (2020): 1–10, <https://doi.org/10.1186/s12906-020-03009-0>.
22. W. Liu, C. C. Wang, K. H. Lee, X. Ma, and T. L. Kang, "Research Methodology in Acupuncture and Moxibustion for Managing Primary Dysmenorrhea: A Scoping Review," *Complementary Therapies in Medicine* 71 (2022): 102874, <https://doi.org/10.1016/j.ctim.2022.102874>.
23. T. Yuan, J. Xiong, X. Wang, et al., "The Quality of Methodological and Reporting in Network Meta-Analysis of Acupuncture and Moxibustion: A Cross-Sectional Survey," *Evidence-Based Complementary and Alternative Medicine* 2021 (January 2021): 2672173, <https://doi.org/10.1155/2021/2672173>.
24. J. L. Tang, S. Y. Zhan, and E. Ernst, "Review of Randomised Controlled Trials of Traditional Chinese Medicine," *BMJ* 319, no. 7203 (1999): 160–161, <https://doi.org/10.1136/bmj.319.7203.160>.
25. N. Giese, K. K. Kwon, and M. Armour, "Acupuncture for Endometriosis: A Systematic Review and Meta-Analysis," *Integrative Medicine Research* 12, no. 4 (December 2023): 101003, <https://doi.org/10.1016/j.imr.2023.101003>.
26. J. J. Lee, J. W. Heo, T. Y. Choi, J. H. Jun, M. S. Lee, and J. I. Kim, "Acupuncture for the Treatment of Overactive Bladder: A Systematic Review and Meta-Analysis," *Frontiers in Neurology* 13 (January 2023): 985288, <https://doi.org/10.3389/fneur.2022.985288>.
27. J. Pan, S. Jin, Q. Xie, et al., "Acupuncture for Chronic Prostatitis or Chronic Pelvic Pain Syndrome: An Updated Systematic Review and Meta-Analysis," *Pain Research and Management* 2023 (March 2023): 7754876, <https://doi.org/10.1155/2023/7754876>.
28. A. C. Tricco, E. Lillie, W. Zarin, et al., "PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation," *Annals of Internal Medicine* 169, no. 7 (2018): 467–473, <https://doi.org/10.7326/M18-0850>.
29. F. Schulz Kenneth and A. Grimes David, *The Lancet Handbook of Essential Concepts in Clinical Research* (Elsevier, 2006).
30. T. S. Verghese, R. N. Riordain, R. Champaneria, and P. M. Latthe, "Complementary Therapies for Bladder Pain Syndrome: A Systematic Review," *International Urogynecology Journal* 27, no. 8 (2016): 1127–1136, <https://doi.org/10.1007/s00192-015-2886-3>.
31. P. G. O'Hare, III, A. R. Hoffmann, P. Allen, B. Gordon, L. Salin, and K. Whitmore, "Interstitial Cystitis Patients' Use and Rating of Complementary and Alternative Medicine Therapies," *International Urogynecology Journal* 24, no. 6 (2013): 977–982, <https://doi.org/10.1007/s00192-012-1966-x>.
32. E. Holford and T. Tucker, "An Investigation Into the Treatment of Interstitial Cystitis With Acupuncture," *Journal of Chinese Medicine* 94 (2010): 26–32.

33. P. B. Burns, R. J. Rohrich, and K. C. Chung, "The Levels of Evidence and Their Role in Evidence-Based Medicine," *Plastic and Reconstructive Surgery* 128, no. 1 (2011): 305–310, <https://doi.org/10.1097/PRS.0b013e318219c171>.
34. G. H. Guyatt, A. D. Oxman, G. E. Vist, et al., "GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations," *BMJ* 336, no. 7650 (2008): 924–926, <https://doi.org/10.1136/bmj.39489.470347.AD>.
35. D. Moher, A. Liberati, J. Tetzlaff, and D. G. Altman, "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," *Annals of Internal Medicine* 151, no. 4 (2009): 264–269, <https://doi.org/10.7326/0003-4819-151-4-200908180-00135>.
36. A. D. Steffen, L. A. Burke, H. A. Pauls, et al., "Double-Blinding of an Acupuncture Randomized Controlled Trial Optimized With Clinical Translational Science Award Resources," *Clinical Trials* 17, no. 5 (2020): 545–551, <https://doi.org/10.1177/1740774520934910>.
37. J. M. Schlaeger, N. Takakura, H. Yajima, et al., "Double-Blind Acupuncture Needles: A Multi-Needle, Multi-Session Randomized Feasibility Study," *Pilot and Feasibility Studies* 4 (2018): 72, <https://doi.org/10.1186/s40814-018-0265-9>.
38. B. A. O'reilly, P. L. Dwyer, G. Hawthorne, et al., "Transdermal Posterior Tibial Nerve Laser Therapy is not Effective in Women With Interstitial Cystitis," *Journal of Urology* 172, no. 5 Pt 1 (2004): 1880–1883, <https://doi.org/10.1097/01.ju.0000142846.47245.16>.
39. K. F. Schulz, D. G. Altman, and D. Moher, "CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials," *BMJ* 340 (2010): c332, <https://doi.org/10.1136/bmj.c332>.
40. D. G. Altman, "Statistics and Ethics in Medical Research," *British Medical Journal* 281, no. 6251 (1980): 1336–1338, <https://doi.org/10.1136/bmj.281.6251.1336>.
41. L. Bresler, L. C. Westbay, L. Hekman, C. Joyce, and C. M. Fitzgerald, "Acupuncture for Female Bladder Pain Syndrome: A Randomized Controlled Trial," *Canadian Journal of Urology* 29, no. 3 (June 2022): 11154–11161, <https://doi.org/10.1097/01.ju.0000142846.47245.16>.
42. J. P. A. Ioannidis, "Why Most Published Research Findings Are False," *PLoS Medicine* 2, no. 8 (2005): e124, <https://doi.org/10.1371/journal.pmed.0020124>.
43. P. Perel, I. Roberts, E. Sena, et al., "Comparison of Treatment Effects Between Animal Experiments and Clinical Trials: Systematic Review," *BMJ* 334, no. 7586 (2007): 197, <https://doi.org/10.1136/bmj.39048.407928.BE>.
44. J. W. Song and K. C. Chung, "Observational Studies: Cohort and Case-Control Studies," *Plastic and Reconstructive Surgery* 126, no. 6 (2010): 2234–2242, <https://doi.org/10.1097/PRS.0b013e3181f44abc>.
45. G. Geirsson, Y. H. Wang, S. Lindström, and M. Fall, "Traditional Acupuncture and Electrical Stimulation of the Posterior Tibial Nerve. A Trial in Chronic Interstitial Cystitis," *Scandinavian Journal of Urology and Nephrology* 27, no. 1 (1993): 67–70, <https://doi.org/10.3109/00365599309180416>.
46. T. Tucker, "The Treatment of Interstitial Cystitis by Acupuncture," *Journal of Chinese Medicine* 75 (2004): 38–44.
47. T. Greenhalgh, *How to Read a Paper: The Basics of Evidence-Based Medicine* (BMJ Publishing Group, 2014).
48. H. MacPherson, R. Hammerschlag, G. Lewith, and R. Schnyer, "Acupuncture Research Strategies for Establishing an Evidence Base," *Journal of Alternative and Complementary Medicine* 14, no. 7 (2008): 867–872, <https://doi.org/10.1089/acm.2008.0149>.
49. Y. Xu, C. S. Zhang, A. L. Zhang, et al, "Perceptions About and Attitudes Toward Traditional Chinese Medicine: A Systematic Review of Survey Studies," *Journal of Alternative and Complementary Medicine* 24, no. 10 (2018): 884–895, <https://doi.org/10.1089/acm.2018.0206>.
50. C. A. Smith, M. Armour, M. S. Lee, L. Q. Wang, and P. J. Hay, "Acupuncture for Depression," *Cochrane Database of Systematic Reviews* 3, no. 3 (2018): CD004046, <https://doi.org/10.1002/14651858.CD004046.pub4>.

Supporting Information

Additional supporting information can be found online in the Supporting Information section.