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Mini Review

# Current Clinical Research on Incremental Benefits and Potential Synergy of Acupuncture Combined with Chinese Herbal Medicine: A Mini-Review from a Methodological Perspective

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## Abstract

Acupuncture combined with Chinese herbal medicine (CHM) has been widely used for various diseases, with a growing body of clinical research. However, previous reviews have mainly focused on specific diseases or conventionally evaluated the efficacy and safety of acupuncture combined with CHM. Limited attention has been paid to the methodological question of whether the combination itself provides incremental or synergistic effects. This mini review examines the current clinical research on acupuncture combined with CHM from a methodological perspective, focusing on whether existing studies can adequately distinguish incremental benefit and potential synergy of combination therapy, while identifying current limitations and future directions. Current evidence suggests that acupuncture combined with CHM has shown potential incremental benefits in selected conditions; however, evidence supporting true synergistic effects remains insufficient. The few factorial studies that have specifically assessed interaction effects have important limitations, including inadequate prespecification of interaction analyses, sample-size calculations not specifically powered for interaction effects, and reliance on significance testing without reporting interaction estimates and confidence intervals. As a conclusion, existing studies do not yet adequately distinguish such incremental benefits from true synergistic effects because interaction-focused designs and analyses remain methodologically insufficient. Future studies should adopt appropriate multi-arm or 2 × 2 factorial designs according to the research question, with prespecified hypotheses, interaction-specific sample-size calculations, and reporting of interaction estimates with confidence intervals, to more accurately evaluate interaction effects and potential synergy between acupuncture and CHM.

## Introduction

Acupuncture and Chinese herbal medicine (CHM) are major therapies in traditional Chinese medicine (TCM), and their combination is widely used in clinical practice, with a substantial body of clinical research.[1,2] The combination is generally expected to integrate the benefits of both therapies and produce synergistic effects, thereby addressing multiple symptoms and functional impairments.[3] Thus, the key question is not simply whether acupuncture combined with CHM is effective, but whether the combination provides clinically meaningful benefits beyond acupuncture or CHM alone. However, previous reviews have mainly focused on specific diseases or used conventional evidence synthesis to assess the efficacy and safety of the combined treatment.[4,5] Such approaches can determine whether the combination improves disease-related outcomes, but provide limited insight into whether the combination itself produces incremental benefit or synergy. Therefore, this review examines the current evidence from a methodological perspective, focusing on whether existing studies can adequately distinguish incremental benefit and potential synergy of combination therapy, while identifying current limitations and future directions.

**Keywords:** Acupuncture; Chinese herbal medicine; Combination therapy; Incremental benefit; Synergy; Factorial design.
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To define the scope of this review, we conducted a structured literature search of China National Knowledge Infrastructure (CNKI), Wanfang Data, PubMed, Embase, and Web of Science to identify representative studies published between January 2022 and September 2026, with the last search conducted on September 18, 2026. The search was organized around two core concepts: acupuncture and CHM. In the context of clinical research, acupuncture may be conceptualized as a broader category of interventions involving the stimulation of specific acupuncture points using different techniques, such as manual acupuncture, electroacupuncture, press needles (a type of acupuncture needle designed for superficial insertion into the skin at specific acupoints and secured with adhesive tape to provide sustained stimulation over an extended period), and other acupoint stimulation techniques. CHM interventions include oral preparations such as decoctions (liquid preparations made by boiling or simmering herbal ingredients in water) and granules, as well as external therapies, including fumigation and washing (external treatments using herbal steam or herbal solutions for washing or soaking), herbal hot packs (heated herbal preparations applied externally), external application, and iontophoresis. The full search strategy is provided in Supplementary File 1. Records were deduplicated and reviewed on the basis of titles and abstracts, with full texts consulted where available or necessary. Studies were considered eligible if they involved clinical participants, evaluated the combined use of acupuncture-related interventions and CHM, and reported relevant clinical outcomes. Studies that did not evaluate both interventions in combination or did not provide relevant clinical outcome data were excluded from the narrative selection. Priority was given to studies with distinct designs that allowed the assessment of incremental benefit or potential interactions between acupuncture and CHM. Earlier studies that exemplified key designs or helped clarify methodological issues related to incremental benefit and potential synergy were additionally identified through reference tracking.

## Current landscape of clinical studies

Existing literature indicates that acupuncture combined with CHM has been investigated across a broad range of clinical conditions, with continued research activity in recent years in neurological,[6,7] cardiovascular,[8] respiratory,[9,10] musculoskeletal,[11,12] digestive,[13,14] genitourinary,[15,16] endocrine,[17,18] and immune diseases.[19,20] Randomized controlled trials (RCTs) are commonly used, particularly two-arm parallel designs. Other approaches, including multi-arm RCTs, sham-acupuncture and CHM-placebo controls, factorial designs,[21] and real-world studies,[22] have also been reported. Research objectives have expanded beyond evaluating the overall treatment effect and safety of acupuncture combined with CHM to assessing incremental benefits and potential interactions between acupuncture and CHM.

Intervention patterns vary considerably. A commonly used approach is an add-on in which both acupuncture and CHM are added to conventional treatment and compared with conventional treatment alone. Other designs include comparisons between combination therapy and acupuncture or CHM alone, as well as multi-arm comparisons among acupuncture, CHM, and their combination.[23,24] CHM interventions include oral preparations such as decoctions and granules, as well as external therapies, including fumigation and washing, herbal hot packs, external application, and iontophoresis.[25-28] The specific procedures and protocols of these external therapies vary substantially.

Common outcome measures include overall clinical response rates, disease-specific symptom or functional scales, TCM syndrome scores (composite scores used to quantify the severity of symptoms and signs defined within TCM diagnostic patterns), and laboratory indicators. In contrast, patient-important outcomes such as quality of life, sustained functional recovery, recurrence, and other long-term outcomes are reported less frequently.

## Clinical evidence across major disease areas

Among the disease areas discussed in this review, cerebrovascular diseases and musculoskeletal disorders are represented by multiple studies.[6,7,11,12] Although findings across studies are generally consistent, many cerebrovascular studies add both acupuncture and CHM to the control treatment, meaning that the observed effects reflect the added value of the overall combined treatment rather than the specific interaction between acupuncture and CHM.[1] In musculoskeletal disorders, current evidence mainly focuses on symptom improvement and scale changes at the end of treatment,[29,30] while data on long-term functional maintenance, disease progression, and the need for surgery remain limited.

In gynecological and reproductive disorders, research has mainly focused on polycystic ovary syndrome (PCOS) and infertility. Studies of acupuncture-related therapies in PCOS have reported improvements in insulin resistance, reproductive endocrine outcomes, and ovarian morphology. A network meta-analysis of combined TCM therapies further suggested that acupuncture-plus-herbal medicine regimens may improve ovulation and clinical pregnancy rates in women with PCOS-related infertility.[31,32] Notably, a PCOS infertility trial comparing real and sham acupuncture under the same CHM background found that real acupuncture further increased pregnancy rates, suggesting an independent additional effect of acupuncture.[33] However, another three-arm study found that both the acupuncture-plus-CHM group and the CHM group had better ovulation outcomes than the control group, while the combined group showed no incremental effect over CHM alone.[34] Improvements in hormone levels, follicular development, or ovulation indicators cannot be directly equated with final fertility outcomes, and long-term maternal and infant outcomes are rarely reported.

Studies on allergic rhinitis provide further methodological insights. Some studies have reported that acupuncture combined with CHM improves nasal symptoms, quality of life, and certain immune indicators.[35] However, an early randomized double-blind trial found that adding CHM to the same acupuncture treatment did not provide incremental effects in symptoms or quality of life,[36] whereas another randomized study supported the efficacy of acupuncture combined with syndrome-based CHM treatment (herbal treatment individualized according to the patient's TCM diagnostic pattern).[37] These differences suggest that conclusions from such studies depend not only on the disease itself but also on the choice of control groups and the specific research question being addressed.

### Does acupuncture combined with CHM provide incremental effects?

When evaluating the clinical value of acupuncture combined with CHM, three different levels of effects should be distinguished. The first is the overall treatment effect, referring to whether the combination is superior to conventional treatment or conventional pharmacotherapy. The second is the incremental benefit, referring to whether adding CHM to acupuncture, or adding acupuncture to CHM, provides additional clinical benefits beyond either therapy alone. The third is the interaction effect, which provides the statistical basis for assessing potential synergy, that is, whether the combined effect exceeds that expected under additivity on a prespecified scale. These three effects differ in both clinical implications and statistical interpretation.

The clearest evidence supports the overall treatment effect of acupuncture combined with CHM compared with conventional treatments. For example, a two-arm randomized controlled trial in optic atrophy showed that acupuncture combined with CHM was superior to oral mecobalamin in improving visual function, reducing whole blood viscosity, and increasing peak systolic velocity of retrobulbar blood flow (all $P < 0.05$).[38] A randomized controlled trial in episodic migraine without aura found that preventive treatment with a traditional Chinese medicine regimen (comprising acupuncture and CHM) significantly reduced monthly migraine days compared with flunarizine ($P = 0.004$).[39] A study in children with obstructive sleep apnea syndrome reported that acupuncture combined with CHM was superior to conventional pharmacotherapy such as montelukast and mometasone furoate.[40] Most such studies compare acupuncture plus CHM (or acupuncture plus CHM plus conventional treatment) with conventional treatment alone. Therefore, they mainly demonstrate the overall treatment effect of the combined approach rather than the incremental effect of combination therapy compared with acupuncture or CHM alone.

To determine whether acupuncture combined with CHM provides additional benefit beyond either therapy alone, the combination should be directly compared with its individual components. Several studies using two-arm parallel designs have provided evidence of incremental benefits. For example, a randomized controlled trial in patients with multiple plantar warts compared acupuncture plus CHM with CHM alone and found that the combination was superior in improving symptoms, quality of life, and reducing recurrence, supporting an incremental benefit from adding acupuncture to CHM.[41] Another two-arm trial in patients with vascular dementia used acupuncture alone as the control and provided evidence of an incremental benefit from adding CHM to acupuncture.[42] In addition, several three-arm studies comparing acupuncture plus CHM, acupuncture alone, and CHM alone have shown incremental benefits of the combination over both single therapies. For example, a study in patients with acute exacerbation of chronic obstructive pulmonary disease directly compared the three approaches and found greater improvements in pulmonary function, blood gas parameters, and immune function in the combination group than in either single treatment group.[9] A study in perimenopausal women with chronic tension-type headache and nonalcoholic fatty liver disease showed that acupuncture combined with CHM was superior to either acupuncture or CHM alone in improving pain scores, body mass index, controlled attenuation parameter, and Patient Health Questionnaire-9 scores.[43] Similar findings have also been reported in benign essential blepharospasm.[44] A trial in knee osteoarthritis also compared combination therapy with acupuncture alone.[45] These designs provide stronger evidence for incremental benefit than comparisons of combination therapy with conventional treatment alone; however, because they do not formally estimate an acupuncture × CHM interaction, they cannot by themselves establish synergy between the two interventions.

A rigorous evaluation of potential synergy requires study designs that can estimate interaction effects, but such studies remain limited. A master's thesis by Zhou Bingying used a 2 × 2 factorial design with active/sham acupuncture and active/placebo CHM to evaluate women with mixed urinary incontinence. Participants were randomized into four groups: acupuncture plus CHM, sham acupuncture plus CHM, acupuncture plus placebo CHM, and sham acupuncture plus placebo CHM. The study used a two-way factorial analysis of variance for continuous outcomes and assessed interactions between interventions using interaction plots. Results showed statistically significant interaction effects between acupuncture and CHM for daily urine leakage ($P < 0.05$), International Consultation on Incontinence Questionnaire–Short Form symptom scores ($P < 0.001$), urinary incontinence frequency ($P = 0.005$), and Incontinence Quality of Life scores ($P < 0.001$).[46] However, the study did not report interaction effect estimates or 95% confidence intervals, making it difficult to quantify the magnitude and precision of the interaction effect. In contrast, a 2025 multicenter, triple-blind, four-arm 2 × 2 factorial trial involving 480 patients with abdominal obesity compared CHM plus press needles, CHM plus sham press needles, press needles plus CHM placebo, and placebo plus sham press needles. CHM plus press needles significantly reduced waist circumference compared with CHM placebo plus press needles (between-group difference, −1.59 cm; 95% confidence interval (CI), −3.03 to −0.16; $P = 0.030$), but not compared with CHM plus sham press needles (between-group difference, −1.20 cm; 95% CI, −2.62 to 0.21; $P = 0.095$). No statistically significant acupuncture and CHM interaction was detected ($P > 0.05$).[21] Importantly, the sample size calculation was based on the expected main effects of press needles and CHM under an assumption of no interaction and therefore was not specifically powered to detect interaction effects. Because interaction effects are often smaller than main effects, detecting them may require larger sample sizes. Thus, failure to detect a statistically significant interaction should not be interpreted as evidence that synergy is absent, particularly when the study was not designed or adequately powered for interaction testing.[47] Li *et al.*[48] used a four-arm design in older adults with mild cognitive impairment, comprising acupuncture plus CHM, acupuncture plus CHM placebo, sham acupuncture plus CHM, and sham acupuncture plus CHM placebo. Although this design allowed the main effects of acupuncture and CHM to be estimated separately, the study was not statistically planned to evaluate their interaction.[48] Therefore, assessing potential synergy between acupuncture and CHM requires not only a 2 × 2 factorial design, but also prespecification of the interaction hypothesis, sample-size planning for the interaction effect, and reporting of the interaction estimate with its confidence interval.

In addition, factorial designs used to test interactions between

acupuncture and CHM are not limited to sham acupuncture and placebo designs. An add-on 2 × 2 factorial design, in which two additional interventions are evaluated on a common background treatment, can also estimate the main effects of acupuncture and CHM and assess whether their combination produces an interaction effect beyond their individual effects. For example, a study in patients with post-stroke dysphagia assigned patients to four groups: standard swallowing rehabilitation plus CHM plus electroacupuncture, CHM plus standard rehabilitation, electroacupuncture plus standard rehabilitation, and standard rehabilitation alone (20 patients per group). This design allowed estimation of the main effects of CHM and electroacupuncture and their interaction. Significant time-by-group interactions were observed for the Standardized Swallowing Assessment and Swallowing Quality of Life Questionnaire scores (both $P < 0.01$), indicating differences in the trajectories of these outcomes among treatment groups. For the Videofluoroscopic Dysphagia Scale, both CHM and electroacupuncture showed significant main effects (both $P < 0.01$), but no statistically significant treatment-by-treatment interaction was detected ($P = 0.717$).[49] However, this study reported only $P$ values for the interaction tests and did not provide numerical interaction estimates or confidence intervals.

Regardless of the factorial framework used, reliable assessment of potential synergy depends on whether the interaction hypothesis is prespecified, whether the sample size provides sufficient statistical power for detecting interactions, and whether interaction effect estimates with confidence intervals are reported. Overall, current evidence suggests that acupuncture combined with CHM provides additional clinical benefits over single therapies for some diseases and outcomes. However, whether acupuncture and CHM produce clinically meaningful synergistic effects remains uncertain.

## Safety considerations in acupuncture combined with Chinese herbal medicine

Beyond efficacy, the clinical value of acupuncture combined with CHM also depends on its safety. In a trial of atopic dermatitis, both groups received Xiao-Feng-San (a Chinese herbal formula used for atopic dermatitis); adverse events occurred in 19.1% of patients in the auricular acupuncture (a type of traditional Chinese medicine acupuncture therapy that involves stimulation of acupoints on the ear) combined with CHM group, mainly including transient acupuncture-related pain and bruising, compared with 11.5% of patients in the sham acupuncture combined with CHM group, in whom events were mainly related to skin irritation from the sham procedure. All reported events were mild and resolved without sequelae.[19] A 2 × 2 factorial trial in patients with post-stroke dysphagia further showed that CHM-related events mainly included nausea and abdominal distension, whereas electroacupuncture-related events included needling pain, minor bleeding, and hematoma. The incidence of adverse events per intervention was 19.3% in the combination group, higher than 0% in the rehabilitation-only group, suggesting that although combination therapy did not cause serious safety concerns, it may increase minor treatment-related adverse events.[49] In contrast, a study of menopausal insomnia found no significant difference in adverse event rates between acupuncture combined with Ningshen mixture (a Chinese herbal preparation used in the cited trial for menopausal insomnia) and conventional medication (19.5% *vs.* 24.4%, $P = 0.594$), with no serious adverse events reported.[50] A study of lumbar disc herniation comparing CHM with loxoprofen on the basis of acupuncture treatment showed similar overall adverse event numbers between groups. Treatment-related heartburn occurred more frequently in the loxoprofen group, and liver and kidney function remained normal in both groups.[51]

However, current safety assessments and reporting remain insufficient to fully exclude potential risks. Some studies only provide general statements such as "no adverse events occurred" or "no significant abnormalities in safety indicators." For example, a study of mild-to-moderate COVID-19 reported no adverse events,[10] while a study of menopausal mood disorders mainly reported laboratory safety indicators without systematic descriptions of acupuncture-related events, CHM-related events, severity, causality, or treatment discontinuation.[52] In addition, potential interactions between CHM and concomitant medications represent an additional safety consideration, particularly in patients receiving cardiovascular medications.[53] However, as these interactions were not systematically evaluated in the included studies, their clinical implications in the context of acupuncture combined with CHM remain uncertain and warrant further investigation.

The incremental clinical value of acupuncture combined with CHM should therefore be judged by considering both additional benefits and additional risks. Incremental effects are clinically meaningful only when the additional efficacy is achieved without an unacceptable increase in treatment-related harm. The characteristics of the representative clinical trials discussed above are summarized in Table 1.[19,21,39,45,46,49]

## Methodological limitations of current studies

Although a substantial body of clinical studies on acupuncture combined with CHM has been published, individual studies remain limited in scale, and single-center, small-sample, and short-duration trials are still frequently encountered. RCTs are commonly reported, but methodological reporting is often incomplete. Random sequence generation is more frequently described than allocation concealment, blinding, and prospective trial registration. A bibliometric analysis and reporting-quality evaluation of Chinese RCTs on acupuncture combined with CHM for low back pain similarly found incomplete reporting of randomization, allocation concealment, and blinding.[54]

The most critical methodological issue lies in the control group structure. Many studies compare "acupuncture + CHM + conventional treatment" with "conventional treatment alone." Because both acupuncture and CHM differ between groups, the independent contributions of acupuncture and CHM cannot be determined. Two-arm designs comparing acupuncture combined with CHM versus acupuncture alone or CHM alone can estimate only an unidirectional incremental effect. A three-arm design comparing the combination with acupuncture alone and CHM alone can assess incremental effects relative to both individual components. However, unlike a complete factorial design, it cannot estimate the two main effects and their interaction within a factorial framework. Existing factorial studies provide an important methodological basis for evaluating potential synergy between acupuncture and CHM, but important limitations remain,

**Table 1. Characteristics of the representative clinical trials**

| Author (year) | Study design | Sample size | Intervention group | Control group | Duration | Outcomes | Adverse events | Main limitations |
|---|---|---|---|---|---|---|---|---|
| Liu *et al.* (2026)[39] | Multicenter, two-arm parallel-group randomized, active-controlled trial | 212 randomized (106 per group) 204 completed (103/101) | CHM + Acupuncture | Flunarizine | 4 weeks | MMDs | Intervention group: 3, control group: 7 No serious AEs (participants with ≥ 1 AE) | Cannot isolate the independent contributions of acupuncture and CHM |
| Tran *et al.* (2026)[19] | Multicenter, two-arm parallel-group randomized, sham-controlled trial | 156 randomized (78 per group) 156 completed | Xiao-Feng-San + AA | Xiao-Feng-San + sham AA | 4 weeks | SCORAD; DLQI | Intervention group: 15, control group: 9 No serious AEs (participants with ≥ 1 AE) | Evaluates the added effect of acupuncture on a common CHM background; does not formally assess a CHM × acupuncture interaction |
| Ye *et al.* (2025)[21] | Multicenter, four-arm triple-blind, 2 × 2 factorial, randomized trial | 480 randomized (120 per group) 429 completed (111/110/106/102) | A: CHM + PN | B: CHM + SPN; C: Placebo CHM + PN; D: placebo CHM + SPN | 12 weeks | Waist circumference, body weight, BMI, BDI, BAI, PSQI | No serious AEs recorded | Sample-size calculation was not specifically designed to detect interaction effects |
| Venuti *et al.* (2023)[45] | Single-center, three-armed randomized controlled trial | 45 randomized (15 per group) 42 completed (14/14/14) | A: Acupuncture + normal-dose herbal fumigation | B: Acupuncture alone; C: acupuncture + low-dose herbal fumigation | 4 weeks | VAS, ROM, WOMAC, HRQoL; TCMSQ | A: 2, B: 0, C: 1 No serious AEs (participants with ≥ 1 AE) | Small pilot sample; numerical between-group effect estimates unavailable |
| Zhou (2022)[46] | Single-center, four-arm 2 × 2 factorial, randomized controlled trial | 144 randomized (36 per group) 133 completed (34/34/33/32) | A: Acupuncture + CHM | B: acupuncture + CHM placebo; C: sham acupuncture + CHM; D: sham acupuncture + | 8 weeks | 24-h pad test, ICIQ-SF, incontinence episodes, I-QOL | A: 2, B: 3, C: 1, D: 1 No serious AEs (participants with ≥ 1 AE) | Master's thesis; numerical interaction estimates and confidence intervals not reported |

**Table 1. Characteristics of the representative clinical trials (*continued*)**

| Author (year) | Study design | Sample size | Intervention group | Control group | Duration | Outcomes | Adverse events | Main limitations |
|---|---|---|---|---|---|---|---|---|
| | | | | CHM placebo | | | | |
| Shao *et al.* (2022)[49] | Pilot, single-center, four-arm, add-on 2 × 2 factorial design, randomized controlled trial | 80 randomized (20 per group) 76 completed (19/19/20/18) | A: CHM + EA + SRT | B: CHM + SRT; C: EA + SRT; D: SRT alone | 4 weeks | SSA, SWAL-QOL, VFSS, VDS, Effective Rate Assessment, new aspiration pneumonia | A: 11, B: 3, C: 10, D: 0 No serious AEs (number of AE occurrences) | Small pilot sample;interaction estimates and confidence intervals not reported |

AA, auricular acupuncture; AE, adverse event; BAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; BMI, body mass index; CHM, Chinese herbal medicine; DLQI, Dermatology Life Quality Index; EA, electroacupuncture; HRQoL, health-related quality of life (measured by WHOQOL-BREF and MOS SF-12); ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; I-QOL, Incontinence Quality of Life; MMDs, monthly migraine days; MOS SF-12, Medical Outcomes Study 12-item Short Form Health Survey; PN, press needles; PSQI, Pittsburgh Sleep Quality Index; ROM, range of motion; SCORAD, Scoring Atopic Dermatitis; SPN, simulated (sham) press needles; SRT, swallowing rehabilitation training; SSA, Standardized Swallowing Assessment; SWAL-QOL, Swallowing-Related Quality of Life; TCMSQ, Traditional Chinese Medicine Syndrome Questionnaire; VAS, visual analog scale; VDS, videofluoroscopic dysphagia scale; VFSS, Video Fluoroscopic Swallowing Study; WHOQOL-BREF, World Health Organization Quality of Life brief version; WOMAC, Western Ontario and McMaster Osteoarthritis Index.

including inadequate prespecification of interaction analyses, sample-size calculations not specifically powered for interaction effects, and insufficient reporting of interaction estimates and confidence intervals. Consequently, whether acupuncture and CHM produce true synergistic effects cannot yet be established reliably.

Outcome assessment also shows considerable imbalance. Overall clinical response rates are still widely used and are often accompanied by multiple symptom scales, TCM syndrome scores, and inflammatory, immune, hormonal, or hemorheological indicators. Although these secondary and mechanistic outcomes may provide useful insights, they also increase the risk of multiple comparisons and selective reporting. More importantly, improvements in surrogate outcomes may not translate into patient-important benefits. For example, changes in hormones or anti-Müllerian hormone levels in PCOS are not substitutes for live birth; reductions in inflammatory biomarkers in osteoarthritis do not necessarily reflect sustained long-term functional improvement; and short-term improvements in stroke-related scales may not fully capture long-term disability or functional independence. Long-term follow-up, quality of life, recurrence, and sustained clinical benefit remain insufficiently evaluated in many studies, while systematic safety reporting is also limited.

## Clinical and methodological challenges

Acupuncture combined with CHM also faces specific challenges due to its complex intervention characteristics. First, both acupuncture and CHM have substantial heterogeneity in their treatment protocols. The effects of acupuncture may be influenced by acupoint selection, needle depth, stimulation methods, treatment frequency, and practitioner experience. CHM interventions vary in formula composition, dosage, preparation forms, modification principles, and quality control. Clinical practice emphasizes syndrome differentiation (a TCM diagnostic process that identifies patterns of symptoms and signs to guide individualized treatment) and individualized treatment, whereas clinical trials require sufficient standardization and reproducibility, creating an inherent tension between the two.[55] Therefore, even when studies are classified as acupuncture combined with CHM, the actual interventions evaluated may differ substantially.

Second, implementing dual placebo controls is more challenging than controlling a single intervention. Acupuncture trials require credible sham acupuncture methods that minimize physiological activity,[56] while CHM trials need to address placebo simulation of color, smell, and taste.[57] When both interventions are included in factorial trials, control of blinding, adherence, and treatment expectations becomes even more complex. In addition, evaluation of synergistic effects depends on the choice of statistical scale.[47] If the research aim is to test interaction effects, sample size calculations should be based on the expected interaction effect rather than the main effects of individual interventions. Many existing small-sample studies may show numerical advantages for the combination group but lack sufficient statistical power to determine whether true interactions exist.

Third, a balance is needed between explanatory research and real-world clinical practice. Strictly standardized four-arm factorial trials provide high internal validity but may not fully reflect the individualized and syndrome-based characteristics of CHM practice. Real-world studies better represent clinical settings but are more vulnerable to confounding by indication and treatment selection bias.[58,59] Existing real-world studies of acupuncture combined with CHM have used methods such as propensity score matching to reduce measurable confounding, providing valuable complementary evidence. However, observational findings cannot replace randomization for identifying causal effects.

## Limitations

This review has several limitations. It is a descriptive review rather than a systematic review; therefore, it did not follow a preregistered systematic review protocol, nor did it involve standardized dual-reviewer full-text screening or risk-of-bias assessment for all identified records. The reported numbers are intended to describe the current literature landscape rather than provide an exhaustive synthesis of evidence. In addition, acupuncture protocols and CHM prescriptions vary substantially across studies, with considerable differences in disease areas, intervention formats, and outcome measures. Selective study inclusion and potential language and publication bias should also be considered. The findings from the master's thesis included in this review could not be fully evaluated because interaction effect estimates and their corresponding 95% confidence intervals were not reported, limiting assessment of the magnitude and precision of the reported interactions. Although the thesis described randomization, allocation concealment, and adverse events, the absence of these quantitative interaction estimates restricts independent appraisal of the evidence for potential synergistic effects. These limitations may affect the robustness and generalizability of the conclusions. Therefore, the research characteristics and methodological issues summarized in this review may not fully represent all clinical applications of acupuncture combined with CHM. The conclusions of this review are mainly intended to describe the current research status and provide methodological insights.

## Conclusions

Current evidence suggests that acupuncture combined with CHM may provide incremental benefits in selected conditions; however, evidence supporting true synergistic effects remains insufficient. Available two-arm trials using acupuncture or CHM alone as comparators further indicate that combination therapy may provide incremental benefits over single therapy alone in selected diseases and outcomes. However, multi-arm studies directly comparing acupuncture combined with CHM, acupuncture alone, and CHM alone, as well as factorial studies designed to test interaction effects, remain limited. Moreover, some factorial trials have limitations, including insufficient prespecification of interaction hypotheses or analyses, sample size calculations not specifically powered for interaction effects, and reporting only statistical significance testing without reporting interaction effect estimates and confidence intervals. Therefore, superiority of the combination group over either single-treatment group does not by itself establish synergy. Conversely, when statistical power to detect an interaction is insufficient, failure to detect a statistically significant interaction cannot exclude potential synergy.

Future clinical studies of acupuncture combined with CHM should select appropriate designs according to their research objectives. If the aim is to determine whether adding acupuncture or CHM provides incremental benefit, the other component should be held constant, with appropriate sham or placebo controls incorporated where feasible. If the aim is to evaluate potential synergy, 2 × 2 factorial designs should be preferred, with prespecified interaction hypotheses, sample size calculations specifically powered for the interaction effects, and reporting of interaction estimates with confidence intervals. Potential benefits should also be evaluated alongside treatment-related risks. Only when combination therapy provides additional benefit without an unacceptable increase in risks can its incremental benefit be considered clinically meaningful.

## Supporting information

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## Conflict of interest

The authors declare no conflicts of interest.

## Author contributions

Literature search (QZ), supervision (YL), and drafting and critical revision of the manuscript (YL, QZ). Both authors have approved the final version of the manuscript and agree to its publication.

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