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Fu's Subcutaneous Needling for Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2025 and was last updated on 22 May 2025.

INTRODUCTION

Review question / Objective Is Fu's Subcutaneous Needling (FSN) effective and safe compared to sham interventions, standard care, or other needling therapies in reducing pain intensity and improving functional outcomes among adults with acute or chronic pain?

Condition being studied Pain, a leading cause of global disability, impairs physical and mental health. Acute pain triggers metabolic, endocrine, and immune dysfunction, while chronic pain (affecting 20–30% of adults) is linked to depression, anxiety, and reduced quality of life. Current treatments (e.g., NSAIDs, physical therapy) face limitations such as partial efficacy, medication side effects, and accessibility challenges. Fu's Subcutaneous Needling (FSN), a novel technique derived from Chinese medicine, shows promise in pain management. Unlike traditional acupuncture, FSN employs subcutaneous "floating" needles to modulate neuromuscular activity and local microcirculation. Preliminary studies suggest its application in conditions such as musculoskeletal pain, osteoarthritis, and tension-type headaches. However, current evidence remains fragmented, with a lack of high-quality synthesis to confirm its efficacy, safety, and comparative advantages over existing therapies. This systematic rev iew addresses a critical gap by evaluating FSN's role as a standalone or adjunctive intervention for painrelief.

METHODS

Search strategy The following electronic bibliographic databases will be searched to identify relevant studies: PubMed, Embase, Scopus, Cochrane Library, and Web of Science. In addition, clinical trial registries, such as ClinicalTrials.gov, will also be searched for ongoing trials with unpublished data. The search period will be recorded for each database. A combination of subject words and free text words will be applied in the searches. In addition, a manual search will also be carried out to supplement the electronic

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searches, and the references of relevant studies will be investigated for any further material for inclusion. Search Terms (PubMed Example):“Fu's Subcutaneous Needling” [Title/Abstract] OR “Fu's Acupuncture” [Title/Abstract] OR “Floating Needle” [Title/Abstract] OR “Fu Needling” [Title/Abstract] OR “Floating-Acupuncture” [Title/Abstract] OR “FSN” [Title/Abstract].

Participant or population The participants in this review will include Adults (≥18 years) with clinically diagnosed acute/chronic pain (musculoskeletal, neuropathic, postoperative, etc.).

Intervention FSN as a standalone or primary intervention.

Comparator All comparator/control groups are eligible. Sham FSN, standard care, other needling therapies (e.g., acupuncture, dry needling, electroacupuncture).

Study designs to be included Only randomized controlled trials (RCTs) were considered eligible.

Eligibility criteria
Eligibility criteria were detailed using the Participants, Interventions, Controls, Outcomes, and Studies (PICOS) framework.
Inclusion criteria:
(1)Studies involving adults (≥18 years) with clinically diagnosed pain.
(2)Studies must have examined FSN as a a standalone or primary intervention.
(3) Studies with a control group receiving Sham FSN, standard care, or other therapy.
(4) Studies reporting on quantitative pain assessment or related functional outcomes.
(5) The study design was a randomized controlled trial (RCT).

Exclusion criteria:
(1) Studies in which FSN combined with other interventions, such that the individual effects of FSN cannot be assessed.
(2) Incomplete or missing outcome indicators.
(3) Non-RCTs, case reports, case series, review articles, and qualitative studies.

Information sources The following electronic bibliographic databases will be searched to identify relevant studies: PubMed, Embase, Scopus, Cochrane Library, and Web of Science. In addition, clinical trial registries, such as ClinicalTrials.gov, will also be searched for ongoing trials with unpublished data.

Main outcome(s) The primary outcomes include Pain intensity (VAS, NRS, or equivalent scales).

Additional outcome(s) Functional improvement, quality of life, safety measurements and adverse events.

Data management Two reviewers will assess the eligibility of the studies retrieved during the searches independently against the inclusion and exclusion criteria, and those studies meeting the criteria will be selected for use in the review. The following data will then be extracted from the studies selected for inclusion using a data collection form, and recorded in an Excel file. The results will be cross-checked by the two reviewers, and any disagreements will be resolved by consensus, with any ongoing differences in opinion being arbitrated by a third reviewer.

Quality assessment / Risk of bias analysis Two reviewers independently assessed the quality of each trial according to the Cochrane risk of bias tool, which contained 7 domains: random sequence generation, allocation concealment, blinding of participants and investigators, blindness of outcome assessments, incomplete outcome data, selective outcome reporting, and other biases. We will judge the each of the domains as ’low risk of bias’, ’high risk of bias’, or ’unclear risk of bias’ according to Higgins (2011).Disagreements were rechecked by discussion with a third reviewer. We will illustrate the potential biases within each of the included studies by presenting a ’risk of bias’ table or graph and summary.

Strategy of data synthesis RevMan 5.4 software from the Cochrane Collaboration (Higgins, 2011) was used to conduct the meta-analysis. To examine the effect of Baduanjin exercise on cognitive impairment in older adults, we performed separate qualitative analyses of various cognitive outcomes. The effect sizes for these outcomes were summarized using the inverse variance method, weighting individual studies accordingly. Depending on the measurement tools used for specific outcomes, we reported either the mean difference (MD) or the standardized mean difference (SMD) along with their 95% confidence intervals (CIs). The statistical heterogeneity among the included studies was assessed using the I^2 statistic. I^2 values between 25% and 50%, 50% and 75%, and >75% indicated low, moderate, and high heterogeneity, respectively. A fixed-effects model was employed if the I^2 value was 0.1. Otherwise, we applied a random-effects model.

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Subgroup analysis Where possible, the analysis of sub-groups will explore the difference in the effectiveness of FSN for varying population groups, intervention duration or type of control intervention.

Sensitivity analysis Sensitivity analysis may be performed by removing low quality studies, or trials with a short-term follow-up.

Language restriction English.

Country(ies) involved China.

Keywords Fu's Subcutaneous Needling; Pain relief; meta-analysis; Complementary and Alternative Medicine.

Contributions of each author

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