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Acupuncture for Chemotherapy-induced Peripheral Neuropathy in Patients with Gastrointestinal Cancer: Protocol for a Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

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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 14 February 2025 and was last updated on 14 February 2025.

INTRODUCTION

Review question / Objective Does acupuncture reduce the severity of CIPN (chemotherapy-induced peripheral neuropathy) symptoms (e.g., pain, numbness, tingling, motor dysfunction and weakness) in gastrointestinal cancer patients?
What is the effect of acupuncture on improving the quality of life in gastrointestinal cancer patients with CIPN?
How is the safety of acupuncture in this patient population, including adverse events and complications?

Condition being studied Chemotherapy-induced peripheral neuropathy (CIPN) is a common adverse event of chemotherapy. It is particularly prevalent in patients receiving chemotherapy for gastrointestinal cancers, such as gastric cancer or colorectal cancer. CIPN is an injury of the somatosensory nervous system leading to sensory abnormalities. It typically presents as symptoms including pain, numbness, tingling, motor dysfunction and weakness. In most cases, the sensation occurs in the hands and feet, often referred to “gloves and stocking” distribution. CIPN can significantly affect a patient’s quality of life, causing difficulty in performing daily activities, and, in severe cases, discontinuation or dose reduction of chemotherapy. Despite the high prevalence of CIPN, effective treatments for it remain limited. Acupuncture, a traditional Chinese medical practice, has been a potential treatment for CIPN. It is considered that acupuncture may reduce pain and modulate nerve function.

METHODS

Participant or population Enrolled patients are diagnosed as gastrointestinal cancer (e.g., esophageal cancer, gastric cancer, small intestine

cancer, or colorectal cancer), receiving chemotherapy and suffering from symptoms of CIPN. The inclusion of patients is regardless of age, gender, race, nationality, or medical facilities.

Intervention The treatment group receives acupuncture (e.g., manual acupuncture or electroacupuncture) in addition to chemotherapy. Studies with both the control group and treatment group receiving acupuncture will be excluded.

Comparator The control group undergoes chemotherapy without acupuncture or any other non-pharmacological interventions. The chemotherapeutic prescription can be administered alone, or along with a placebo or standard care. Studies with both the control group and treatment group receiving acupuncture will be excluded.

Study designs to be included Randomized controlled trials (RCTs), observational studies, cohort studies, and other relevant clinical studies.

Eligibility criteria Animal studies, case reports, case series, commentaries, reviews, non-controlled trials and duplicate publications will be excluded. Studies where the full text cannot be accessed or data cannot be extracted will be excluded. For studies that are published multiple times, the one with the most comprehensive data and information will be selected.

Information sources Following databases will be searched: PubMed, Web of Science, EMBASE, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang data, and China Science and Technology Journal Database.

Main outcome(s) Peripheral neurotoxicity grade, total effective rate of treatment of peripheral neurotoxicity, quality of life (KPS scores or FACT/GOG-Ntx scores), and adverse events.

Quality assessment / Risk of bias analysis The risk of bias will be assessed on the Cochrane tool of risk of bias (V.5.1.0). The following items will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding (performance bias and detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other bias. The assessments of the evaluated domains will be categorized as high, low, or unclear.

Strategy of data synthesis The Review Manager 5.4 (RevMan) software will be used to perform the meta-analysis. For dichotomous variables, the risk ratio (RR) will be used, while for continuous variables, the mean difference (MD) and standard mean difference (SMD) will be used to calculate the combined effect size, along with a 95% confidence interval (95% CI) and P-value (p). A χ^2 test will be conducted to assess heterogeneity among the studies (significance level $\alpha = 0.05$), and the degree of heterogeneity will be determined based on the I^2 value. If $P < 0.05$ or $I^2 > 50\%$, indicating statistical heterogeneity among the studies, a random effects model will be used, and subgroup analysis will be conducted to explore the sources of heterogeneity. If $P > 0.05$ or $I^2 < 50\%$, a fixed effects model will be used for the combined analysis. If there are enough studies (≥10) included, a funnel plot will be drawn to assess publication bias.

Subgroup analysis There will be no subgroup.

Sensitivity analysis Sensitivity analysis will be conducted to evaluate the quality of the research in the sampled documents. The stability of the conclusions can be tested by re-analyzing the results, incorporating missing data, and varying the types of studies. When the number of all included trials is≥10, the funnel plots will be used to assess the potential bias in the included studies. If the left and right sides in the funnel plots are symmetric, the publication bias will be low.

Country(ies) involved China.

Keywords Acupuncture, Gastrointestinal Cancer, Chemotherapy, Chemotherapy-induced Peripheral Neuropathy.

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