INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Efficacy and safety of acupuncture in Gastric Cancer-related Pain: A protocol for systematic review and meta analysis

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Review question / Objective: **Efficacy and safety of acupuncture in Gastric Cancer-related Pain.**
Condition being studied: **The review will include randomised controlled trials (RCTs) that were reported in English or Chinese without any regional restrictions. The first period of randomised cross- over trials will be included.**
Information sources: **Seven databases will be searched, including Cochrane Library, MEDLINE, Embase, Chinese National Knowledge Infrastructure (CNKI), Wanfang Database, the Chongqing VIP Chinese Science and Technology Periodical Database and Chinese Biomedical Literature Database (CBM) from their inception to November 2020. Simultaneously, other resources are manually retrieved which include reference lists of identified publications, conference articles, and grey literature. We also included the clinical randomized controlled trials of acupuncture treatment for Gastric Cancer-related Pain in the study. The search language is limited to Chinese and English.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 January 2021 and was last updated on 4 January 2021 (registration number INPLASY202110013).

INTRODUCTION

Review question / Objective: **Efficacy and safety of acupuncture in Gastric Cancer-related Pain.**

Rationale: **The systematic review of this study will summarize the current published evidence of acupuncture and moxibustion for the treatment of Gastric Cancer-related Pain, which will be more convincing and thus better guide the acupuncture**

treatment of pain in patients with gastric cancer.

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METHODS

Search strategy: "gastric cancer", "stomach cancer", "gastric carcinoma", "carcinoma of stomach", "pain", "analgesia", "acupuncture", "electro acupuncture", "auriculotherapy", "acupoint", "needle", "acupoint catgut embedding", "wrist- ankle acupuncture", "moxibustion", "scalp acupuncture", "transcutaneous electrical acupoint stimulation"," acupoint injection", "randomized controlled trial"," randomised controlled", "randomised, controlled" and "clinical trial". Chinese translations of these search terms will be used for the Chinese databases.

Participant or population: We will include patients with Gastric cancer- related pain, which includes the pain caused by surgical trauma and the cancer pain caused by tumor itself, without limitation of age, race, sex, economic level, and severity.We will define Gastric cancer- related pain as pain directly linked to the development of cancer confirmed by pathology or radiology.

Intervention: We will define acupuncture in this review as acupoint- based therapy, regardless of needling techniques and stimulation method, including manual acupuncture, electro- acupuncture, auricular (ear) acupuncture, acupressure, acupoint application, moxibustion, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection and others. We will rule out interventions without stimulating the acupoint.

Comparator: Treatments in the comparison groups can be sham- acupuncture, placebo, pharmacotherapy or no additional intervention to usual care. Studies that compared different types of acupoint-based therapy will be included.

Study designs to be included: The review will include randomised controlled trials (RCTs) that were reported in English or Chinese without any regional restrictions. The first period of randomised cross- over trials will be included. Non- RCT reviews, case report, animal experimental studies, expert experience, conference article and duplicated publications will be excluded.

Eligibility criteria: We will include patients with Gastric cancer- related pain, which includes the pain caused by surgical trauma and the cancer pain caused by tumor itself, without limitation of age, race, sex, economic level, and severity.We will define Gastric cancer- related pain as pain directly linked to the development of cancer confirmed by pathology or radiology.

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Main outcome(s): The change of pain intensity will be measured by a visual analogue scale (VAS),McGill Pain Questionnaire (MPQ),Brief Pain Inventory (BPI)or other vali-dated outcome measures.

Additional outcome(s): 1. Quality of life measured by validated scales including the

European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC- QLQC30), the General Version of the Functional Assessment of Cancer Therapy (FACT- G), the Edmonton Symptom Assessment System (ESAS) or other validated scales. 2. Consumption of analgesics, including opioids and non- opioids. 3. Frequency of breakthrough pain and rescue medication use or dosage. 4. Side effects of analgesic regimen, such as nausea and vomiting, constipation and cognitive deficits. 5. Safety of the acupoint- based therapies, including adverse events and withdrawals for any reason.

Data management: RevMan (V.5.3) software was used to perform data statistical analysis and Grading of Recommendations Assessment, Development, and Evaluation (GRADE) was used to evaluate the quality of evidence.

Quality assessment / Risk of bias analysis: The Grading of Recommendations Assessment, Development and Evaluation System (GRADE) system will be used to grade the quality of the evidence for main outcomes.Two reviewers will use the GRADE system to independently assess the quality of evidence for each outcome. Evidence quality will be rated 'high', 'moderate', 'low' or 'very low' according to the GRADE rating standards. The quality of evidence of a specific study will be assessed according to the risk of bias, inconsistency, indirectness, imprecision and publication bias.

Strategy of data synthesis: Two independent reviewers will extract information using a pre- designed form including: (1) identification information (publication year, first author); (2) general information (country, study type, number of centres, sample size and study design); (3) participants (type and/or stage of cancer, age, sex and pain intensity before treatment); (4) interventions (type of acupuncture, acupuncture points selection and treatment frequency/session/duration); (5) comparator (if there is any, details of the treatment including name, dosage, frequency and course); and (6) outcomes (data and time points for each measurement, and safety). We will try to contact corresponding authors for missing data or clarification for unclear information. Any disagreements will be arbitrated by a third reviewer . Cross- check of all data will be done by two independent reviewers before transfering into RevMan software (V.5.3).

Subgroup analysis: If sufficient evidence is available, we will conduct subgroup analyses based on cancer types and degree of pain.

Sensibility analysis: In order to obtain a stable conclusion, a sensitivity analysis will be conducted to remove effects of trials with small sample size and remove studies rated as high risk of bias based on accounting of methodological quality.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Acupuncture;Gastric Cancer-related Pain;systematic review;protocol.

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