INPLASY PROTOCOL

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Conflicts of interest:
None.

The pretreatment of moxibustion or moxibustion with related therapies for preventing chemotherapy-induced nausea and vomiting: a protocol for systematic review and meta-analysis

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Review question / Objective: The objective of this systematic review and meta analysis is to evaluate the effectiveness of moxibustion or moxibustion combined with other conventional therapies' pretreatment for patients with chemotherapy-induced nausea and vomiting. At the same time, it can promote a more rational approach to patient care.

Condition being studied: Tumors have become a serious threat to people's health and life, the current tumor treatment methods are mainly surgery, radiotherapy, chemotherapy, biological therapy, among which the number of people receiving chemotherapy is the largest. Chemotherapy, as a systemic treatment, can cause some unavoidable side effects such as nausea and vomiting. Moxibustion, as a key component of traditional Chinese medicine(TCM), has become more and more popular in many countries. However, there are few summative literatures on moxibustion pretreatment of chemotherapy-induced nausea and vomiting. Therefore, we will conduct the systematic review and meta-analysis to analyse moxibustion or moxibustion combined with other conventional therapies for preventing chemotherapy-induced nausea and vomiting.

INTRODUCTION

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METHODS

Search strategy: We will search the following electronic databases without restrictions for language or publication status:PubMed, EMBASE, The Cochrane Library, Web of Science, Chinese National Knowledge Infrastructure(CNKI), Wanfang database, Chinese Science and Technology Periodical Database (VIP) and China Biology Medicine Database (CBM) from inception to November 2020. We will apply a combination of Medical Subject Heading (MeSH) and free-text terms incorporating database-specific controlled vocabularies and text words to implement search strategies.The key words are moxibustion, acupuncture, warm acupuncture, electroacupuncture, auricular point compress, acupoint catgut embedding, acupoint injection, acupressure and chemotherapy-induced nausea and vomiting.And the searches will be re-run just before the final analyses to retrieve the most recent studies eligible for inclusion.

Participant or population: Inclusion: (1)All the included patients were diagnosed as tumor after pathological examination, age, gender, race, educational or economic status , types of tumors and chemo-therapeutics are not restricted. (2)All the included patients will receive chemothera-py. Exclusion: (1)The patients had symptoms of nausea and vomiting before

chemotherapy. (2)People with additional severe diseases. (3)Participants who are not appropriate to receive moxibustion and other related therapies, such as pregnant or lactating.

Intervention: The pretreatment of moxibustion and other related therapies including but not limited to: moxibustion, acupuncture, electroacupuncture, warm acupuncture, acupoint injection, auricular point compress, acupoint catgut embedding, acupressure. The pretreatment method can only be moxibustion, or it can be a combination of moxibustion and the above therapies. Moxibustion pretreatment should be performed before the chemotherapy or on the day of the chemotherapy. Only clinical trials involving moxibustion were included. The trials comparison of different forms of moxibustion would be excluded. Differences in the material and origin of moxa sticks will be ignored. Moxibustion therapy or moxibustion combined with other conventional treatments will be compared to placebo control, conventional treatment or no treatment.

Comparator: The interventions are compared with a placebo, with conventional treatment, with the standard of care or blank control.

Study designs to be included: The review will include randomised controlled trials (RCTs) that were reported in English or Chinese. Non RCTs reviews, animal experimental studies, case report, expert experience and conference article will be excluded.

Eligibility criteria: (1)Only clinical trials involving moxibustion were included. (2)The pretreatment method can only be moxibustion, or it can be a combination of moxibustion and related therapies. (3)Moxibustion pretreatment should be performed before the chemotherapy or on the day of the chemotherapy. (4)All the included patients were diagnosed as tumor after pathological examination, age, gender, race, educational or economic status , types of tumors and

chemotherapeutics are not restricted. (5)All the included patients will adopt the chemotherapy.

Information sources: (1)We can search the electronic databases. (2)We will try to contact with authors to get some details that their literatures did not express. (3)We will try our best to find relevant trial registers or grey literatures.

Main outcome(s): (1)The effective rate of preventing chemotherapy-induced nausea and vomiting; (2)Improvement of nausea and vomiting symptoms: frequency and positive influence on the patients' life.

Additional outcome(s): (1)Health-related quality of life (HRQL) assessed using validated instruments. (2)incidence of nausea and vomiting. (3)incidence of adverse reactions.

Data management: Two reviewers(Qiqi YANG and Fangyuan XU) will screen literatures independently. Firstly, duplicates publications will be excluded.Secondly, reviewers will read the title and abstract for preliminary exclusion. The remaining literatures need to be further screened by reading the full text. Two reviewers will independently extract data about the general information, study population characteristics, methodological description, intervention characteristics, outcome measures, and note and fill in a data extractiontable. Any discrepancies will be resolved by consulting a senior review through discussion. The following data will be extracted mainly: research topic, author, year of publication, specific information of the treatment groups and control groups and outcome index. The data will be extracted and validated by two reviewers independently. The third reviewer will solve the difference by discussion.

Quality assessment / Risk of bias analysis: The methodological quality for each included literature will be evaluated using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials, which comprises random sequence generation, allocation concealment,

blinding, data incompleteness, selective reporting and other biases. According to the above indicators, the results are expressed as low risk, unclear and high risk. Any discrepancies will be discussed with the third reviewer to reach an agreement.

Strategy of data synthesis: RevMan V.5.3 will be used for data analysis of the included studies.The I^2 test was used to test the heterogeneity of the included literatures: when $I^2 \geq 50\%$, it means that the heterogeneity between the studies is significant, and a random-effect model will be used to synthesize the data. We should look for sources of heterogeneity actively. And the obvious clinical heterogeneity will be treated by the method of subgroup analysis or sensitivity analysis or just descriptive analysis. When $I^2 \leq 50\%$, use a fixed effect model. Dichotomous variables are expressed by relative risk (RR) with 95% confidence intervals (CIs); continuous variables are expressed by mean difference(MD) or standardized mean difference (SMD) with 95% CIs.

Subgroup analysis: If the data are available, we will consider to conduct subgroup analyses based on the following three aspects: (1)different methods of moxibustion pretreatment; (2)types and stage of cancer; (3)different types of chemotherapy drugs.

Sensibility analysis: After conducting a quality assessment of the included studies, we will conduct a sensitivity analysis if there are studies of low quality. Sensitivity analysis will also be performed when there exists unacceptable heterogeneity between studies ($I^2 > 50\%$). Then we will acquire a more stable result of our study.

Language: There is an English language summary and language limits will not be imposed on the search.

Country(ies) involved: China.

Keywords: chemotherapy-induced nausea and vomiting; moxibustion pretreatment; systematic review and meta-analysis.

Contributions of each author / Email:

Author 1 - Fangyuan XU did preliminary searches.
Email: 949599987@qq.com
Author 2 - Qiqi YANG provided statistical expertise.
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Author 3 - Wei HUANG contributed to the development of the selection criteria and the risk of bias assessment strateg.
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