# INPLASY PROTOCOL

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Conflicts of interest: None declared.

## INTRODUCTION

Review question / Objective: The aim of this overview is to comprehensive summary and critically evaluate the current evidence from systematic reviews (SR)/ Meta-analysis pertaining to risk of bias and quality of evidence and methodological quality of systematic reviews of TCM

# The Effects of TCM Combined with Chemotherapy in Patients with Nonsmall Cell Lung Cancer: An Overview of Systematic Review and Meta-analysis

Chen, CM<sup>1</sup>; Chen, YF<sup>2</sup>; Chen, L<sup>3</sup>.

**Review question / Objective:** The aim of this overview is to comprehensive summary and critically evaluate the current evidence from systematic reviews (SR)/Meta-analysis pertaining to risk of bias and quality of evidence and methodological quality of systematic reviews of TCM combined with chemotherapy in patients with non-small cell lung cancer (NSCLC).

**Information sources:** Five international electronic databases(Web of Science, The Cochrane Library, PubMed, MEDLINE, and EMBASE) and 4 Chinese electronic databases (China National Knowledge Infrastructure (CNKI), the Chinese Science and Technology Periodical Database (VIP), China Biology Medicine disc (CBM), and Wan Fang Digital Journals).

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 July 2022 and was last updated on 27 July 2022 (registration number INPLASY202270114).

combined with chemotherapy in patients with non-small cell lung cancer (NSCLC).

Condition being studied: Lung cancer is one of the most common malignant tumors in human beings, and its incidence and mortality rank first in the world. According to statistics, about a quarter of all cancer deaths are caused by lung cancer, and the

cancer only have the 19% five-year survival rate .Among them, Non-Small Cell Lung Cancer (NSCLC) accounts for about 80%-85% of all lung cancer cases, and because of its insidious onset, early clinical symptoms are not obvious, it is difficult to find by self-examination of patients. So, most patients are tested after feeling unwell, and most have developed advanced NSCLC. Therefore, chemotherapy has become the main treatment for patients with NSCLC. However, most of the chemotherapeutics are cytotoxic periodic drugs with weak selectivity, which not only kill tumor cells, but also damage normal cells to varying degrees, resulting in further impairment of patients' immune function, and the toxic side effects also greatly affect the quality of life of patients. Some studies have shown that the addition of traditional Chinese medicine therapy in the process of chemotherapy for patients with NSCLC can effectively reduce the side effects of chemotherapy, improve immune resistance, and thus improve the survival rate of patients.And there have been clinical trials and systematic reviews published. In order to summarize and evaluate the authenticity of the current systematic review (SR)/ Meta-analysis evidence on the risk of bias, evidence quality and methodological quality of traditional Chinese medicine combined with chemotherapy in the treatment of nonsmall cell lung cancer (NSCLC), this study was conducted.

### **METHODS**

Participant or population: Patients with non-small cell lung cancer according to any accepted diagnostic criteria will be included.The patients' age, race, and gender were not limited.

Intervention: TCM combined with chemotherapy.

**Comparator:** The intervention in the control groups is chemotherapy alone.

Study designs to be included: SR/Metaanalysis of randomized controlled trials(RCTs)/cross-controlled trials (CCTs)(if have).No language limitation was used.

Eligibility criteria: Patients with NSCLC diagnosed pathologically and age≥18 years old will be included, and there are no restrictions on gender and race.

Information sources: Five international electronic databases(Web of Science, The Cochrane Library, PubMed, MEDLINE, and EMBASE) and 4 Chinese electronic databases (China National Knowledge Infrastructure (CNKI), the Chinese Science and Technology Periodical Database (VIP), China Biology Medicine disc (CBM), and Wan Fang Digital Journals).

Main outcome(s): 1.Evaluation of immune function: Cell levels of relevant tumor markers 2.Quality of life assessment: Karnofsky score (Karnofsky performance status).

Additional outcome(s): Evaluation of toxic and side effects.

Quality assessment / Risk of bias analysis: Assessment of Multiple Systematic Reviews 2 (AMSTAR-2) measurement tool. **PRISMA statement: The PRISMA Statement** for reporting quality consists of a 27-item checklist and a four-phase flow diagram. The checklist included items deemed essential for transparent reporting of a systematic review. Each item of the PRISMA form was graded with a "complete report" score of 1, a "partial report" of 0.5, and an "unreported" score of 0, with a total score of 27. When the literature score is 21 to 27, the report is considered relatively complete; when the score is 15 to 21, the report is considered to have some defects; when the score is less than 15, it is considered that there are relatively serious information defects. GRADE approach: The evidence quality of the included SR/Metaanalysis was evaluated by the GRADE approach. Two authors (CCM and CL) independently assessed。 The evidence of the outcomes, and the downgraded or upgraded factors affecting the guality of evidence should be described in detail to

guarantee the reliability and transparency of results. The overall quality of evidence was judged as high, moderate, low, or very low.

Strategy of data synthesis: We will provide a narrative description of the findings of the included systematic reviews (SRs). Tables will be produced to detail the included studies and their outcomes. In addition, we will synthesis these reviews and provide pooled effects for all SRs which include the following outcomes: 1. Evaluation of immune function. 2. Quality of life assessment. If necessary, this study will use RevMan5.4 software (Cochrane Collaboration)for data integration and analysis. The measurement data will use the mean difference (MD) as the effect indicator, and the count data will use the odds ratio (OR) as the effect index. Each effect indicator will be given as a point estimate with 95% confidence interval.The heterogeneity and size of each study result will be judged using statistical methods. For studies with no statistical heterogeneity, the analysis will be performed using a fixed-effect model, whereas a randomized effects model will be applied if for studies with significant statistical heterogeneity.

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows: 1.Intervention:The types of traditional Chinese medicine combined in the treatments included in the study. 2.Differences in chemotherapeutic drugs.

Sensitivity analysis: Sensibility analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Language restriction: No.

Country(ies) involved: China.

Keywords: Non-small Cell Lung Cancer; NSCLC; Chemotherapy; TCM.

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