

INPLASY202560040  
doi: 10.37766/inplasy2025.6.0040  
Received: 9 June 2025  
Published: 9 June 2025

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**ADMINISTRATIVE INFORMATION**

**Support** - Government.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202560040

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 June 2025 and was last updated on 9 June 2025.

**INTRODUCTION**

**Review question / Objective** The efficacy and safety of Acupoint herbal patching in patients with Functional dyspepsia (FD) which compare with other treatment methods.

**Condition being studied** Functional dyspepsia (FD) refers to one or a group of symptoms located in the upper abdomen. It mainly includes upper abdominal pain, upper abdominal burning sensation, postprandial fullness and early fullness, as well as upper abdominal distension, belching, nausea and vomiting. It affects at least 20 % to 30 % of the global population. Acupoint herbal patching is a method guided by the theory of traditional Chinese medicine to treat diseases by stimulating specific parts of the skin and playing the role of traditional Chinese medicine and meridians. Through literature search, it is found that there are sufficient studies on treating FD by acupoint herbal patching in recent years. We will also provide evidence for subsequent clinical studies through this study.

**METHODS**

**Search strategy** #1 ("functional dyspepsia"[tw] OR "functional dyspeptic"[tw] OR "functional dyspep\*" [tw] OR "Dyspepsia / physiopathology"[mesh] OR "Postprandial distress"[tw] OR "postprandial discomfort"[tw] OR "Post prandial distress"[tw] OR "post prandial discomfort"[tw] OR "Epigastric pain syndrome"[tw]) #2 acupoint patching[tw] OR acupuncture point mounting[tw] OR acupoint sticking therapy[tw] OR acupoint application[tw] OR acupoint herbal patching[tw] #3 Randomized Controlled Trials as Topic [MeSH] #4 Clinical Trials, Randomized[Title/ Abstract ] OR Trials , Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/ Abstract] OR randomized controlled trial[Title/ Abstract] OR randomized[Title/Abstract] OR randomised controlled trial[Title/Abstract] OR randomised[Title/Abstract] OR randomly[Title/ Abstract] OR clinical trial[Title/Abstract] OR trial[Title/Abstract] #5 #3 OR #4

#6 #1 AND #2 AND #5.

**Participant or population** Patients with functional dyspepsia (as diagnosed using any recognised diagnostic criteria).

**Intervention** The experimental group was treated with Acupoint herbal patching or Acupoint herbal patching combined with other treatment methods.

**Comparator** The control group was treated with other treatment methods besides acupoint herbal patching alone.

**Study designs to be included** This study will include only randomized controlled trials combining Acupoint herbal patching for gastroesophageal reflux disease.

### Eligibility criteria

Inclusion Criteria:

The participants were diagnosed as functional dyspepsia. The type of studies was randomized controlled trial. For the types of intervention, the experimental group was treated with Acupoint herbal patching or Acupoint herbal patching combined with other treatment methods, while the control group was treated with other treatment methods besides acupoint herbal patching alone. The outcome indicators included at least effectiveness and safety evaluation.

Exclusion Criteria: The type of studies was non-randomized controlled trial, such as animal trials, disease cases, reviews, expert experience elaborations, systematic evaluations. The literatures repeated published. Studies had Three or more groups.

**Information sources** We will search the databases of MEDLINE, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wan-Fang Database, China Biomedical Literature Service System, and Chongqing VIP Chinese Science.

**Main outcome(s)** We will record the basic information included: title, year of publication, the first author, age of participants, disease course, study cases of experimental group and the control group, results risk of bias evaluation tools, outcome indicators, and other information. In addition, we will also record result of effectiveness and safety evaluation, Such as symptom score, adverse reactions, etc.

**Data management** Two researchers will independently search and screen the relevant

literature, first removing duplicates studies by the software EndNote (version X9, Clarivate Analytics), excluding apparently irrelevant literature by reading questions and abstracts, then reading the full text, excluding ineligible literatures again according to the inclusion criteria, and recording the reasons for the deletion. Cross-check the information, and finally be determined by the third researcher in case of differences. We will use Excel recording the basic information to find an extraction table, the basic information included: title, year of publication, the first author, study cases of treatment group and the control group, disease course, intervention measures, results risk of bias evaluation tools, outcome indicators, and other information. In case of disagreement, all researchers participated in the discussions to resolve the issue.

**Quality assessment / Risk of bias analysis** Two independent researchers will assess the included studies for risk of bias using the Cochrane risk of bias tool, the contents included blinding of outcome assessment, allocation sequence concealment, blinding of participants and personnel, incomplete outcome data, selective reporting, and other sources of bias. The seven domains was assigned a judgment relating to the risk of bias for that study classified as low, high, or unclear risk. The disagreements will be resolved by consensus or by a discussion with a third author. We will evaluate publication bias by funnel plot or Egger test.

**Strategy of data synthesis** All included literatures will be calculated risk ratios (for dichotomous outcomes), mean differences or standardised mean differences (for continuous outcomes) by Review Manager 5.2. The heterogeneity test will be performed for all data using the  $I^2$  statistic and chi-square test. It was considered low or no heterogeneity if  $I^2 < 50\%$ ,  $P > 0.1$ ; otherwise, when  $I^2 \geq 50\%$ ,  $P \leq 0.1$ , we believe that there was obvious heterogeneity.

**Subgroup analysis** When there shows significant heterogeneity, we will conduct a subgroup analysis to analyze the sources of heterogeneity according to the factors affecting the results. Subgroup analysis were performed by Stata 16.0.

**Sensitivity analysis** Sensitivity analysis should be carried out to find the source of heterogeneity. Sensitivity analysis were performed by Stata 16.0.

**Language restriction** Language is English and Chinese.

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**Country(ies) involved** China/ Shandong University of Traditional Chinese Medicine; Linyi Health School of Shandong Province.

**Keywords** Systematic review; meta analysis; Acupoint herbal patching; Functional dyspepsia.

**Contributions of each author**

Author 1 - Bingyu Pu - Author 1 drafted the manuscript.

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Author 2 - Hao Wu - Author 2 provided statistical expertise and read, provided feedback and approved the final manuscript.

Author 3 - Lei Yang - Author 3 contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 4 - Chongjing Ren - Author 4 provided statistical expertise.

Author 5 - Tongyun Li - Author 5 contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 6 - Jian Wang - Author 6 read and provided feedback.