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Systematic Review

Clinical effectiveness of Chinese patent medicines for functional constipation: insights from a systematic review and Bayesian network-meta-analysis

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ABSTRACT

Introduction In recent years, guidelines and consensus statements have recommended Chinese patent medicines (CPMs) for the treatment of functional constipation (FC). The latest Chinese Health Care Directory also lists CPMs for FC; however, the supporting evidence remains insufficient. In this study, we aimed to evaluate the effectiveness and safety of CPMs in the treatment of FC using a network-meta-analysis (NMA). **Methods** We searched for eligible randomized controlled trials (RCTs) published in the databases of PubMed, Cochrane Library, Embase, SinoMed, China National Knowledge Infrastructure, Wanfang, and Chinese Scientific Journals Database. Bayesian NMA and pairwise comparisons were performed to determine the frequency of spontaneous bowel movements, clinical effects, recurrence rate, dyschezia score, and defecation time score. **Results** A total of 61 studies were included. The methodological quality of the included studies was relatively poor, and the reliability of the synthetic outcomes was low. Our findings indicate that in older individuals, according to the self-established clinical efficacy criteria, Liuwei Anxiao combined with prokinetics demonstrated superior clinical effectiveness compared to prokinetic monotherapy (risk ratio [RR]: 1.46, 95% confidence interval [CI]: 1.17, 1.96), with lower scores for defecation times (mean difference: −0.30, 95% CI: −0.60, −0.02). Daitong granules combined with prokinetics showed better clinical efficacy than prokinetic monotherapy (RR: 1.59, 95% CI: 1.03, 2.53). In older participants, based on published clinical efficacy criteria, Shouhui Tongbian capsule combined with an osmotic laxative exhibited superior clinical effectiveness compared to osmotic laxative monotherapy (RR: 1.21, 95% CI: 1.00, 1.48). Reported adverse events included stomachache, diarrhea, and nausea. **Conclusions** Several positive outcomes were observed, including better clinical effects across different criteria and lower defecation frequency scores. However, the quality of the included studies and the conclusions on CPM coverage areas were limited. Future research should include more high-quality studies directly comparing the effects of different CPMs.

KEYWORDS

Chinese patent medicine, functional constipation, systematic review, network meta-analysis, traditional Chinese medicine

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1. Introduction

Constipation is a common gastrointestinal disorder affecting approximately 12%–19% of the general population,[1] with a higher prevalence in females and older individuals.[2] Functional constipation (FC) is the most common type of constipation, with an estimated global prevalence of 10%–15%,[3,4] and it may impair the quality of life of patients while imposing a substantial economic burden.[5] Several clinical practice guidelines and expert consensus have been published,[6] in which the oral administration of Macrogol 4000 powder and lactulose oral solution is commonly recommended.[7] Further, Chinese patent medicines (CPMs) and other traditional Chinese medicine (TCM) therapies, such as herbal decoctions, acupuncture, and Tuina, have also been recommended.[8,9]

According to TCM theory, different populations and age groups affected by constipation exhibit relatively fixed etiologies and pathogenesis. Unlike herbal decoctions, which are modified according to the pattern differentiation of individual patients, CPMs have a relatively fixed composition and formulation. Consequently, CPMs offer valuable opportunities for developing treatments targeting specific TCM patterns. Furthermore, in recent years, the use of CPMs has increased due to supportive policies and patient preferences.[10]

Given the promising potential of CPMs in the treatment of FC, evidence-based recommendations are needed to help users choose from an array of available CPM options.[11] Although meta-analyses investigating the effectiveness of CPMs for FC have been published,[12,13] they include only a limited range of CPMs and lack head-to-head comparisons. Therefore, in this study, we conducted a network-meta-analysis (NMA) to indirectly compare and simultaneously evaluate the effectiveness and safety of multiple CPMs for FC.[14]

2. Methods

This NMA was conducted under the guidance of the Cochrane Handbook of Systematic Reviews of Interventions[15] and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement, incorporating NMAs for healthcare interventions.[16]

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The study protocol was registered with INPLASY (https://inplasy.com/, INPLASY202250049).

2.1. Data sources and searches

A comprehensive literature search was conducted from database inception to December 2025 in seven electronic databases: PubMed, Cochrane Library, Embase, SinoMed, China National Knowledge Infrastructure (CNKI), Wanfang, and Chinese Scientific Journals Database (VIP). The search strategy was designed using a Boolean logic framework with three core conceptual blocks: disease (encompassing FC and other primary constipation disorders), intervention (including the general term "Chinese patent medicine" and specific products registered with the National Medical Products Administration (NMPA) for constipation treatment), and study design (limited to randomized controlled trials [RCTs]). The full search strategies employed for PubMed and CNKI are presented in Appendix 1.

2.2. Eligibility criteria

2.2.1. Participants

We focused on participants diagnosed with FC according to the Rome III, Rome IV, or other published criteria or guidelines.[17] There were no limitations on the type of FC, age, sex, or nationality. Children and pregnant women were excluded from the study. Participants with other constipation-related diseases, including irritable bowel syndrome, functional defecation disorders, and opioid-induced constipation, were excluded.

2.2.2. Interventions

We focused on CPMs registered with batch numbers beginning with "Z," approved by Chinese NMPA, and used alone or in adjuvant with "Western medicine" (e.g., polyethylene glycol, lactulose, bisacodyl, prucalopride succinate, probiotic, mosapride). There were no limitations on dosage, formulation, and route of administration of CPMs.

2.2.3. Comparators

Other registered CPMs used alone or "Western medicines" (e.g., polyethylene glycol, lactulose, bisacodyl, prucalopride succinate, or probiotic, mosapride) recommended by the latest clinical guidelines released by authorized organizations or placebo were eligible.[17-19]

2.2.4. Outcomes

The primary outcomes were the frequency of complete spontaneous bowel movements, spontaneous bowel movements, and clinical effects.[17] The secondary outcomes were Chinese medicine symptom scores (defecation time, dyschezia, etc.), adverse events, and recurrence rate.

2.2.5. Study design

Parallel RCTs were included. Conference abstracts were excluded if full articles were unavailable.

2.3. Study selection

Two reviewers (LKL and WJS) independently screened the study titles and abstracts and determined the final inclusion criteria after reading the full texts. Disagreements were resolved through discussion or consultation with a third author (YYZ) if necessary.

2.4. Data collection process and data items

Two reviewers (LKL and WJS) independently extracted information and data, including study ID, publication year, country, interventions, comparators, and outcome measures. Studies with more than two arms were excluded if one arm was not relevant to our analysis. Disagreements were resolved through discussion or consultation with a third author (YYZ) if necessary.

2.5. Risk-of-bias assessment

Two reviewers (LKL and WJS) independently evaluated the quality of the included RCTs using the Cochrane risk-of-bias tool 2.0.[15]

2.6. Statistical analysis

2.6.1. Pairwise meta-analyses

The R software (R version 4.40, https://www.r-project.org/, accessed November 20, 2025) with the meta package was used to perform pairwise meta-analyses. The effect estimate was presented as a relative ratio (RR) with a 95% confidence interval (CI) for dichotomous variables and a mean difference (MD) with a 95% CI for continuous variables. The I^2 statistic was used to estimate the proportion of variation across studies owing to heterogeneity, rather than chance. When there was no or low heterogeneity across the studies (I^2 < 25%), a fixed-effects model was used to pool the data. If there was substantial heterogeneity (25% < I^2 < 95%), but the clinical heterogeneity was acceptable, a random-effects model was used. We did not synthesize the data when statistical heterogeneity was large (I^2 > 95%) or clinical heterogeneity was significant.[15]

2.6.2. NMA

The R software with the gemtc package and Just Another Gibbs Sampler were used to perform Bayesian NMA to compare direct and indirect evidence. The Markov Chain Monte Carlo method was used to simulate the data, and chains and different iterations (number of annealing times) were set.[20] We set an uninformative prior distribution for four Markov chains running 50 000 iterations (burn-in iterations = 10 000; thinning factor = 1). The test models were random-effects consistency models. The model convergence was assessed using the Brooks Gelman–Rubin method with a potential scale reduction factor (PSRF). PSRF values close to 1 indicate a better convergence effect of the model, and PSRF values less than 1.05 are acceptable.[21] RR, MD, and 95% CI were used to summarize the data. The surface under the cumulative ranking curve (SUCRA) probability values were calculated to estimate the ranking of the interventions for different outcomes. According to the different outcomes, a higher SUCRA value reflected a better effect on the clinical effect rates and frequency of spontaneous bowel movements, whereas a lower SUCRA value reflected a better effect on the dyschezia score, defecation time, and recurrence rate. Considering the differences in clinical effect criteria in different studies and participants, the analysis will be performed according to the age of the participants and the actual or self-established criteria.

2.7. Consistency assessment and publication bias

The consistency of the NMA was assessed using the node-splitting analysis method. For closed loops, the inconsistency between direct and indirect evidence was assessed. Publication bias was evaluated using funnel plots and Egger's test using the R metafor package.[22]

3. Results

3.1. Study selection

A total of 7262 potential articles were identified during the initial search, and 1702 duplicate articles were removed. After excluding 5560 articles by screening their titles and abstracts, 134 full-text articles were read. Finally, 61[23–83] articles were included in this review (Figure 1).

3.2. Characteristics of the selected literature

The characteristics of the included studies are presented in Table 1. A total of 61 studies published between 2003 and 2025 were included. All included studies were conducted in China. The compositions and preparations of the CPMs in the included studies are presented in Appendix 2.

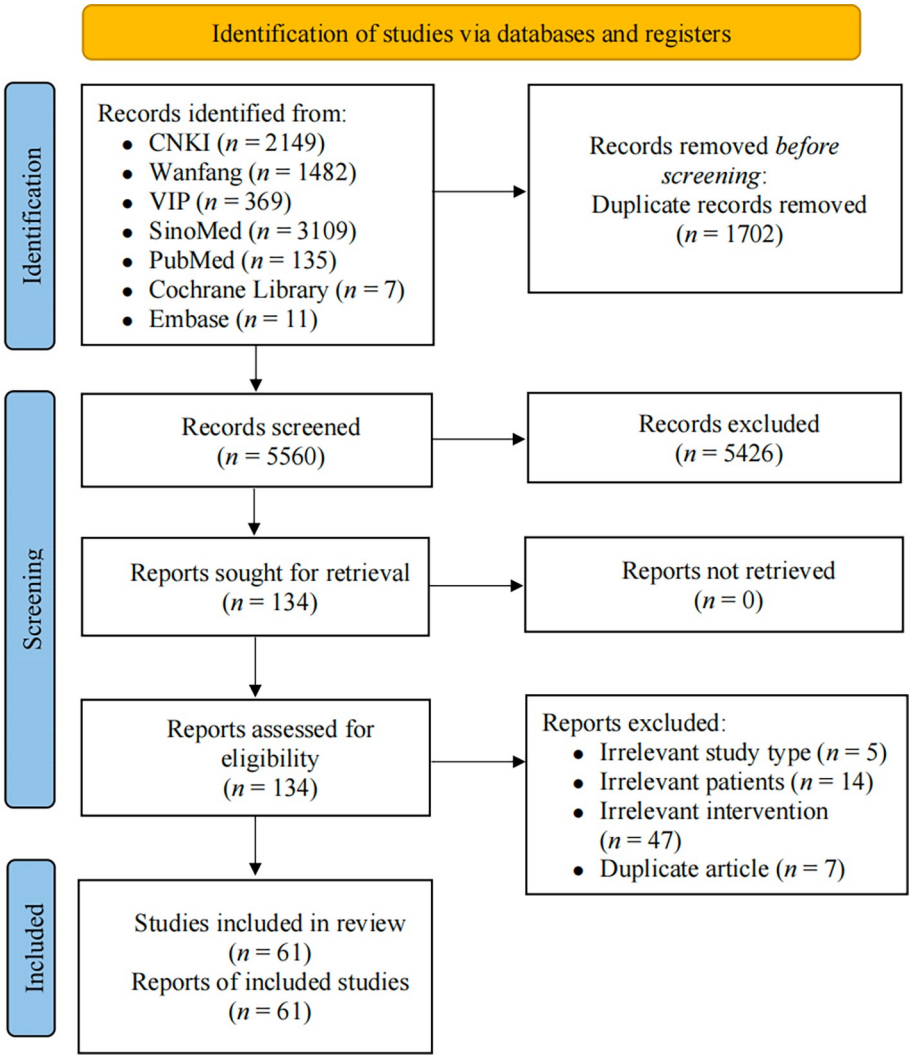

Figure 1 PRISMA flowchart of study selection

Notes: CNKI: China National Knowledge Infrastructure; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCTs: randomized controlled trials; VIP: Chinese Scientific Journals Database.

3.3. Methodological quality

As shown in Figure 2, the methodological quality of the included RCTs was assessed using the revised Cochrane risk-of-bias tool (ROB 2.0). The evidence base was rated as having a high risk-of-bias, with most studies raising significant concerns in multiple key domains. Concerning the randomization process, 74% of the studies were judged to have "some concerns." The predominant issues were inadequate reporting of the method used for random sequence generation (often limited to a statement of "randomized" without specifying the technique) and a pervasive lack of reporting or implementation of allocation concealment. Due to the inherent differences in formulation and appearance between CPMs and conventional control drugs, coupled with the fact that most studies did not describe blinding measures, such as the use of matched placebos, 67% of the studies were rated as having a "high risk" of bias due to deviations from the intended interventions. This introduces a substantial risk of performance bias. The risk-of-bias arising from missing outcome data was relatively low, with 79% of the studies rated as "low risk." This was primarily because of the short trial duration, which resulted in low attrition rates that were balanced across the treatment groups. In the domain of outcome measurements, 71% of the studies raised "some concerns." The main reason for this was the lack of blinding of outcome assessors to subjective outcome measures (e.g., clinical response rate), which poses a potential risk of detection bias. For the selection of reported results, most studies were rated as raising "some concerns" or, less frequently, "low risk." While the prespecified outcomes outlined in the study designs were reported completely, the unavailability of prospectively registered protocols for most studies prevented verification of full reporting integrity.

3.4. Pairwise meta-analysis

Direct comparisons were performed between CPMs and Western medicines (e.g., polyethylene glycol, lactulose, bisacodyl, prucalopride succinate, probiotics, and mosapride) for five outcomes. Detailed information and forest plots are presented in Appendices 3-6. We conducted subgroup and sensitivity analyses of the clinical effect rate, recurrence rate, dyschezia score, and defecation time score (Appendices 7-10). The number of studies and comparisons was insufficient in terms of the frequency of spontaneous bowel movements; therefore, a synthesis was not performed for this outcome.

Regarding the clinical effect rate, a subgroup analysis was conducted, benefiting from sufficient comparisons and studies. After an adjustment guided by sensitivity analysis and the removal of three early published studies, most comparisons were adjusted to acceptable heterogeneity ($I^2 < 50\%$). The clinical effect rate of Shouhui Tongbian capsules was better than that of *Lactobacillus casei* strain Shirota (LCS, RR: 1.21, 95%CI: 1.07, 1.37, $I^2 = 0\%$). Liuwei

Table 1 Characteristics of the included literature

Study ID	Participants (I/C, *n*)	Intervention	Comparator	Treatment duration (days)	Outcomes
Lu XR 2012[23]	39/42	Bianmitong, five pills, tid	Lactulose oral solution, one pack, tid	30	Clinical effect
Guan L 2013[24]	57/52	Qirong Runchang oral solution, 120 mL, tid	Maren capsule, two capsules, bid	7	Adverse events
Li YW 2005[25]	28/27	Biannaitong tea, one pack, bid	Tongle granules, 12 g, bid	14	Clinical effect
Ji MZ 2005[26]	102/102	Maren Wan, 6 g, tid	Mosapride, 5 mg, tid	28	Clinical effect, adverse events
Wang J 2017[27]	30/30	Jiaolong capsule (two capsules, tid) + LCB (four tablets, bid)	LCB, four tablets, bid	28	CSBM, frequency, straining score, adverse events
Zhang L 2006[28]	80/80	Liuwei Anxiao capsule, four capsules, tid	Maren pill, two pills, tid	14	CSBM, frequency
Yuan LH 2017[29]	55/55	Liuwei Anxiao capsule (three capsules/tablets, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	14	Clinical effect, stool consistency score, CSBM, frequency, defecation time score, straining score, adverse events
Jiang JH 2021[30]	39/39/38	Liuwei Anxiao capsule, three pills, tid; Liuwei Anxiao capsule (three pills, tid) + prucalopride (2 mg, tid)	Prucalopride, 2 mg, tid	28	Clinical effect, stool consistency score, CSBM, frequency, defecation time score, straining score, adverse events
Wei JJ 2018[31]	34/30	Maren capsule, two pills, qd	LCB, 2 g, tid	28	Clinical effect, stool consistency score, CSBM, frequency, defecation time score, straining score, adverse events
Chen JH 2016[32]	64/63	Maren pill (one pill, bid) + lactulose oral solution (10 mL, tid)	Lactulose oral solution, 10 mL, tid	35	Clinical effect, adverse events
Lin SH 2018[33]	18/18	Liuwei Anxiao capsule (1.5 mg, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	14	Clinical effect, stool consistency score, CSBM, frequency, defecation time score, straining score
Huo H 2016[34]	63/61	Liuwei Anxiao capsule (three pills, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	28	Clinical effect
Nian XL 2014[35]	23/23	Liuwei Anxiao capsule, four pills, tid	Lactulose oral solution, 10 mL, tid	28	Clinical effect, adverse events
Chen J 2009[36]	43/29	Liuwei Anxiao capsule, four pills, tid	Maren pill, 6 g, bid	14	Clinical effect, adverse events
Hu CH 2016[37]	25/25	Liuwei Anxiao capsule, three to five pills, tid	Lactulose oral solution, 10 mL, tid solution	28	Clinical effect, adverse events
Liu SC 2020[38]	39/39	Shouhui Tongbian capsule (two capsules, tid) + lactulose oral solution (15 mL, bid)	Lactulose oral solution, 15 mL, bid	14	Clinical effect, CSBM, frequency, straining score
Zhou AY 2021[39]	64/63	Shouhui Tongbian capsule (two capsules, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	28	Clinical effect, stool consistency score, defecation time score, straining score, adverse events
Gou LL 2006[40]	20/23	Maren Runchang pill, one pill, bid	Lactulose oral solution, 10 mL, bid	14	Clinical effect, adverse events
Ma JJ 2015[41]	150/150	Qihuang Tongbian capsule, three pills, bid	Maren capsule, one capsule, bid	21	Clinical effect, adverse events
Chung WC 2010[42]	60/60	Maren pill, 7.5 g, bid	Placebo, 7.5 g, bid	56	Clinical effect, stool consistency score, adverse events
Yuan B 2021[43]	75/75	Shouhui Tongbian capsule (0.7 g, tid) + lactulose oral solution (30 mL, qd)	Lactulose oral solution, 30 mL, qd	14	Clinical effect, stool consistency score, defecation time score, straining score, adverse events
Qiao XY 2008[44]	17/25/22/25	Maren pill, 10 g, tid	Bisacodyl (5–10 mg, qd), polyethylene glycol (10 g, bid), lactulose oral solution, 15 mL, bid	28	Clinical effect, adverse events
Wei JN 2012[45]	60/40	Jiangzhi Tongbian capsule, four pills, bid	Lactulose oral solution, 15 mL, bid	14	Clinical effect, adverse events
Chen H 2011[46]	39/37	Maren pill, 6 g, bid	Polyethylene glycol, 10 g, bid	28	
Li YH 2016[47]	30/30	Maren pill (9 g, qd) + polyethtlene (one pack, bid)	Polyethylene glycol, one pack, bid	28	Clinical effect, adverse events
Cao XR 2012[48]	47/45	Liuwei Anxiao capsule, four pills, tid	Maren Zipi pill, one pill, qd	15	Clinical effect, adverse events
Zhang X 2016[49]	30/30	Liuwei Anxiao capsule, two pills, tid	Polyethylene glycol, one pack, bid	28	Clinical effect, adverse events

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Study ID	Participants (I/C, *n*)	Intervention	Comparator	Treatment duration (days)	Outcomes
Shi ZD 2013[50]	40/40/40	Qirong Runchang oral solution, 20 mL, tid; Qirong Runchang oral solution (20 mL, tid) + lactulose oral solution (30–60 mL, bid)	Lactulose oral solution, 30–60 mL, bid	28	Clinical effect, adverse events
Zheng JY 2017[51]	20/20/20	Luhui Zhenzhu capsule, two capsules, bid; Luhui Zhenzhu capsule (two capsules, bid) + BCT (three tablets, tid)	BCT, three tablets, tid	28	TCM syndrome score, defecation time score, straining score, adverse events
Liu W 2015[52]	25/25/25	Danshitong capsule, four to six capsules, tid; Danshitong capsule (four to six capsules, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	21	Clinical effect
Ma J 2018[53]	53/53	Simotang oral solution (20 mL, tid) + bisacodyl (5 mg, qd)	Bisacodyl, 5 mg, qd	28	Clinical effect, adverse events
Huang CQ 2016[54]	30/30/30	Simotang oral solution, 20 mL, tid; Simotang oral solution (20 mL, tid) + lactulose oral solution (15 mg, qd)	Lactulose oral solution, 15 mg, qd	28	Clinical effect, adverse events
Wang YZ 2014[55]	45/45	Liuwei Anxiao capsule, three capsules, tid	Polyethylene glycol, one pack, bid	14	Clinical effect, stool consistency score
Yao XX 2011[56]	50/50	Liuwei Anxiao capsule (1.5 g, tid) + Polyethtlene (20 g, qd)	Polyethylene glycol, 20 g, qd	90	Clinical effect
Jia JC 2003[57]	38/36	Liuwei Anxiao capsule, 2 g, tid	Lactulose oral solution, 15 mL, bid	28	Clinical effect, adverse events
Gu Y 2015[58]	30/30/30	Congrong Tongbian capsule, 10 mL, bid; Congrong Tongbian capsule (10 mL, bid) + lactulose oral solution (15 mL, bid)	Lactulose oral solution, 15 mL, bid	28	Clinical effect, adverse events
Ju HY 2013[59]	75/75	Buzhong Yiqi pill (6 g, bid/tid) + cisapride (15–30 mg, bid/tid)	Cisapride, 15–30 mg, bid/tid	28	Clinical effect
Ren Q 2010[60]	46/38	Dalitong granule (one granule, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	14	Clinical effect, adverse events
Yan X 2006[61]	25/25	Liuwei Anxiao capsule (1 g, qd) + polyethylene glycol 4000 (10 g, bid)	Polyethylene glycol, 10 g, bid	28	Clinical effect, adverse events
Guan HP 2009[62]	25/28/26	Maren Runchang pill, two pills, bid; Maren Runchang pill (two pills, bid) + itopride (50 mg, tid)	Itopride, 50 mg, tid	14	Clinical effect, adverse events
Zhang JH 2012[63]	39/38/38	Liuwei Anxiao capsule, three capsules, tid; Liuwei Anxiao capsule (three capsules, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	28	Clinical effect, adverse events
Zhai QF 2008[64]	42/40/38	Liuwei Anxiao capsule, three capsules, tid; Liuwei Anxiao capsule (three capsules, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	14	Clinical effect, adverse events
Li SJ 2011[65]	32/32	Maren pill (three pills, tid) + cisapride (10 mg, tid)	Cisapride, 10 mg, tid	21	Clinical effect
Sun XJ 2018[66]	60/60	Maren capsule, 1.2 g, bid	Maren pill, 6 g, qd	7	Clinical effect, adverse events
Peng J 2011[67]	58/42	Liuwei Anxiao capsule, 1.5 g, tid	Maren pill, 6 g, bid	28	Clinical effect
Huang JL 2014[68]	28/31/30	Liuwei Anxiao capsule, three pills, tid; Liuwei Anxiao capsule (three pills, tid) + BSEF (500 mg, tid)	BSEF, 500 mg, tid	28	Clinical effect, adverse events
Su HX 2004[69]	26/26/26	Simotang oral solution, 20 mL (first 7 days) then 10 mL (next 21 days), tid; Simotang oral solution (20 mL [first 7 days] then 10 mL [next 21 days]) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	28	Clinical effect
Wang P 2014[70]	30/30	Tongbianling capsule, six capsules, qd	Lactulose oral solution, 30 mL, qd	14	Clinical effect
Shi JF 2003[71]	22/40	Maren pill, 6 g, bid	Cisapride, 10 mg, tid	21	Clinical effect
Xiao NP 2010[72]	48/42	Liuwei Anxiao capsule (two capsules, tid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	28	Clinical effect, adverse events
Jiang H 2011[73]	120/120	Qihuang Tongmi capsule (three capsules, bid) + placebo (one pill, bid)	Maren capsule (one capsule, bid) + placebo (three pills, bid)	21	Clinical effect, adverse events

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(Continued)

Study ID	Participants (I/C, *n*)	Intervention	Comparator	Treatment duration (days)	Outcomes
Xu ZX 2014[74]	30/30/30	Qirong Runchang oral solution, 20 mL, tid; Qirong Runchang oral solution (20 mL, tid) + polygluosan capsules (1.2 g, tid)	Polygluosan capsules, 1.2 g, tid	14	Clinical effect, adverse events
Lin MN 2009[75]	60/60	Liuwei Anxiao capsule, 1.5 g, tid	Polyethylene glycol, 10 g, bid	28	Clinical effect
Jiang XY 2010[76]	43/43	Liuwei Anxiao capsule, three to four capsules, tid	Mosapride, two tablets, tid	14	Clinical effect, adverse events
Yang MW 2015[77]	28/30/29	Danshitong capsule, five capsules, tid; Danshitong capsule (five capsules, tid) + mosapride (5 mg, bid)	Mosapride, 5 mg, bid	14	Clinical effect, adverse events
Liu SJ 2015[78]	40/40	Maren pill, 6 g, bid	Sixiao pill, 30–60 pills, tid	28	Clinical effect, adverse events
Zhou YY 2009[79]	38/38	Liuwei Anxiao capsule, three to four capsules, tid	Mosapride, two tablets, tid	14	Clinical effect, adverse events
Huang B 2015[80]	59/59	Houpo Paiqi Heji (50 mL, bid) + mosapride (5 mg, tid)	Mosapride, 5 mg, tid	14	Clinical effect
Zou Y 2024[81]	35/35	Shouhui Tongbian capsule, two capsules, bid	Maren capsule, two capsules, bid	28	Clinical effect, TCM syndrome score, stool consistency score, adverse events
Wu YF 2025[82]	30/30/	Niuhuang Shangqing capsule (three capsules, bid) + LCBL (2 g, tid)	LCBL, 2 g, tid	56	Clinical effect, TCM syndrome score, bowel frequency score
Tang XD 2025[83]	40/40	Simotang oral solution, 20 mL, tid	Placebo, 20 mL, tid	32	CSBM, frequency, responder rate, TCM syndrome score, stool consistency score, bowel frequency score, adverse events

Notes: BCT: *Bacillus coagulans* tablets; BSEF: live combined *Bacillus subtilis* and *Enterococcus faecium* Enteric-coated capsules; C: comparator; I: intervention; LCBL: live combined *Bifidobacterium lactobacillus* and *enterococcus* capsules; TCM: traditional Chinese medicine.

Anxiao had a better clinical efficacy rate than mosapride (RR: 1.20, 95%CI: 1.08, 1.32, I^2 = 28%). Liuwei Anxiao plus mosapride showed a better clinical efficacy rate than mosapride alone (RR: 1.22, 95%CI: 1.10, 1.34, I^2 = 45%). Liuwei Anxiao had a superior clinical effect rate compared with polyethylene glycol 4000 (PEG4000, RR: 1.21, 95%CI: 1.09, 1.33, I^2 = 0%). The Maren pill had an inferior clinical effect rate compared to LCS (RR: 0.80, 95%CI: 0.67, 0.95, I^2 = 0%). The Maren pill had an inferior clinical effect rate compared to PEG4000 (RR: 0.82, 95%CI: 0.70, 0.95, I^2 = 0%; Appendices 3 and 7).

Regarding the recurrence rate, the control group's Western medicine intervention (e.g., lactulose or bisacodyl) was subjected to subgroup analysis. The subgroup analysis of CPMs (e.g., Maren pill, Qirong Runchang oral solution, and Simotang oral solution *vs.* LCS revealed that CPMs had a lower recurrence rate than LCS (RR: 0.60; 95%CI: 0.35, 1.02; I^2 = 0%). According to the synthesis results, CPMs may have a lower recurrence rate than Western medicines (RR, 0.57; 95%CI: 0.40, 0.81; I^2 = 0%; Appendices 4 and 8).

Regarding dyschezia scores, the control group's Western medicine intervention (e.g., mosapride, lactulose) was used in the subgroup analysis. CPMs combined with mosapride or lactulose had lower dyschezia scores than mosapride alone (SMD: −2.01, 95%CI: −2.30, −1.71, I^2 = 0%). The subgroup of Shouhui Tongbian capsules combined with LCS *vs.* LCS alone revealed that the Shouhui Tongbian capsule had a lower dyschezia score than LCS (SMD: −1.46, 95%CI: −1.88, −1.04, I^2 = 48%). The heterogeneity of the synthesized results was substantial (I^2 = 75%), and the synthesized result that CPMs or CPMs combined with Western medicines have lower scores of dyschezia (SMD: −1.46, 95%CI: −1.82, −1.09, I^2 = 75%) cannot be guaranteed to be reliable (Appendices 5 and 9).

Regarding the defecation time score, the control group's Western medicine intervention (e.g., mosapride or lactulose) was used for subgroup analysis. The subgroup of Liuwei Anxiao combined with mosapride *vs.* mosapride revealed that Liuwei Anxiao combined with mosapride have lower scores for defecation time than mosapride (SMD: −1.54, 95%CI: −2.26, −0.81, I^2 = 62%). The heterogeneity of this subgroup was substantial (I^2 = 62%), and the results were not guaranteed to be reliable. The subgroup analysis of Luhui Zhenzhu capsules alone or in combination with *Bacillus coagulans* tablets (BCT) *vs.* BCT revealed that Luhui Zhenzhu capsules alone or in combination with BCT had a lower defecation time score than BCT (SMD: −0.67, 95%CI: −1.31, −0.03, I^2 = 49%). The heterogeneity of the synthesized results was substantial (I^2 = 69%), and CPMs alone or CPMs combined with Western medicine resulted in a lower defecation time score (SMD: −1.20, 95%CI: −1.67, −0.73; Appendices 6 and 10).

Due to insufficient comparisons and studies, we instead described a synthesis of the frequency of spontaneous bowel movements (Appendix 11).

Maren pill caused more adverse events than cisapride (RR: 4.47, 95%CI: 1.21, 16.58, I^2 = 0%) and fewer than LCS (RR: 4.47, 95%CI: 1.21, 16.58, I^2 = 7%). No significant differences were found between the other comparisons and the synthesized results. Due to the different reporting standards for adverse events, a detailed subgroup or NMA was not performed. The results of the pairwise meta-analysis are presented in Appendix 12.

3.5. NMA results

Networks for the comparison of clinical effects, recurrence rate, dyschezia score, defecation time score, and frequency of spontaneous bowel movements are presented in Figures 3 and 4. Tables 2 and 3 summarize the detailed results of the comparisons, and Table 4 summarizes the SUCRA values for all outcomes analyzed. All PSRF values ranged from 1.00 to 1.05, indicating complete convergence, good iterative effects, and stable model results.

3.5.1. Clinical effectiveness rate

Among the included studies, a substantial number assessed treatment efficacy solely using the indirect measure of "clinical response rate," for which the defining criteria were not fully consistent across trials and were sometimes even based on non-standardized, investigator-defined criteria. Given that the pathogenesis of constipation in TCM theory is influenced by patient constitution, age, and other factors, we conducted subgroup analyses based on patient age and whether a reference standard was used for the clinical response rate.

In addition, the control interventions across the studies were heterogeneous and involved various pharmacological agents. To address this, control

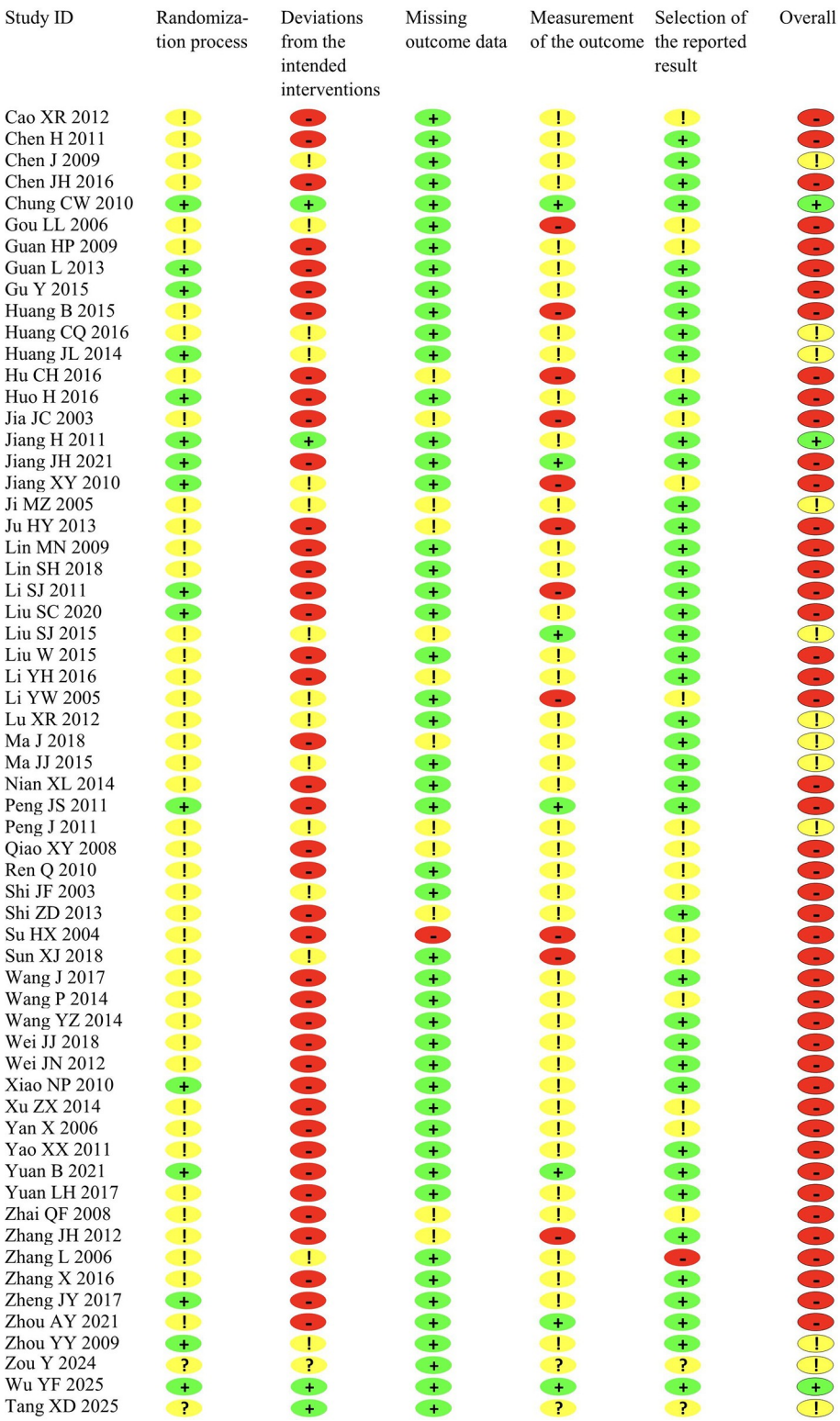

Figure 2 The risk-of-bias of included randomized controlled trials

drugs were pooled into categories based on their primary mechanism of action for analysis: osmotic laxatives (PEG4000, and lactulose), prokinetic agents (mosapride, cisapride, and itopride), and probiotics (e.g., *Bifidobacterium*, *Lactobacillus*, *Bacillus subtilis*, and *Bacillus coagulans*). A detailed schema of these subgroups and node categorizations is shown in Figure 3. Results that were not statistically significant are provided in Appendix 13.

As shown in Table 2, in the subgroup comprising studies of mixed-age populations that used self-defined criteria for clinical response, two combination therapies demonstrated superior efficacy compared to prokinetic monotherapy: Dalitong granules plus a prokinetic agent (RR: 1.59, 95% CI: 1.03, 2.53) and Liuwei Anxiao capsule plus a prokinetic agent (RR: 1.46, 95% CI: 1.17, 1.96).

Conversely, in the subgroup of studies exclusively involving older patients that applied a referenced standard for clinical response, Shouhui Tongbian

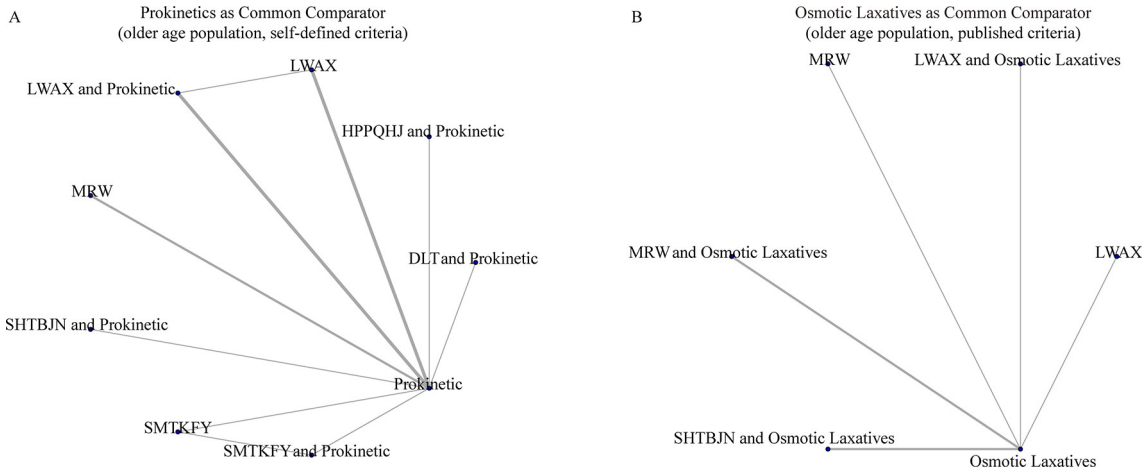

Figure 3 Network plot of clinical efficacy: (A) prokinetics; (B) osmotic laxatives.

Notes: DLT: Dalitong granule; HPPQHJ: Houpo Paiqi Heji; LWAX: Liuwei Anxiao capsule; MRW: Maren Wan; SHTBJN: Shouhui Tongbian Jiaonang; SMTKFY: Simotang Koufuye.

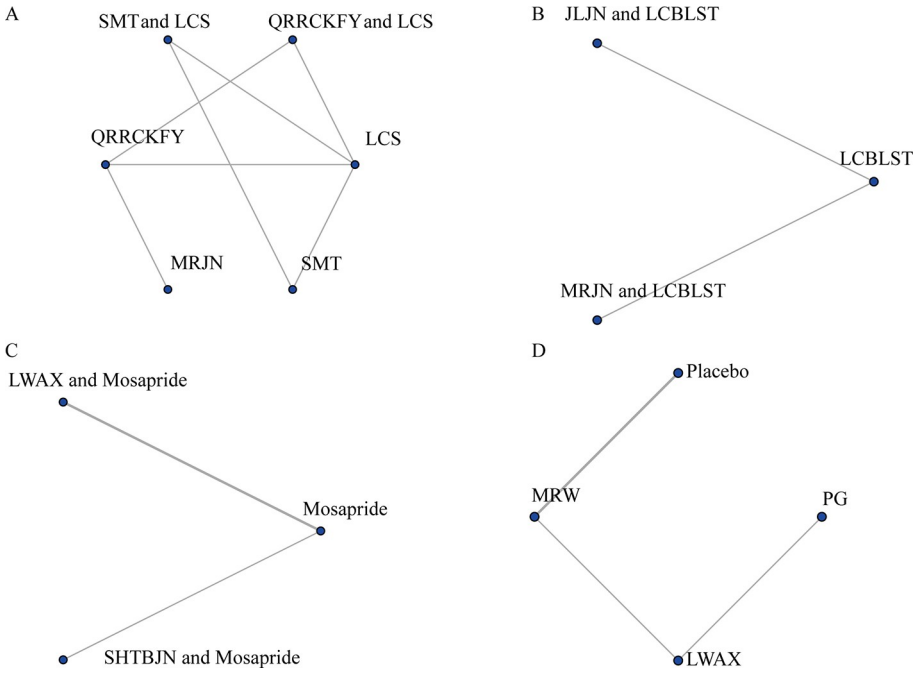

Figure 4 Network plots of clinical outcomes: (A) recurrence rate; (B) dyschezia score; (C) defecation time score; (D) frequency of spontaneous bowel movements.

Notes: JLJN: Jiaolong Jiaonang; LCBLST: live combined *Bifidobacterium*, *Lactobacillus*, *Streptococcus*/*Enterococcus* triple; LCS: *Lactobacillus casei* strain Shirota; LWAX: Liuwei Anxiao capsule; MRJN: Maren Jiaonang; MRW: Maren Wan; PG: polyethylene glycol; QRRCKFY: Qirong Runchang Koufuye; SHTBJN: Shouhui Tongbian Jiaonang; SMT: Simotang oral solution. Each point represents a treatment, and the connections between nodes indicate direct comparisons; the thickness of the connections reflects the number of studies involved in each comparison.

capsule combined with an osmotic laxative showed a favorable trend compared to osmotic laxative monotherapy (RR: 1.21, 95% CI: 1.00, 1.48). No other statistically significant differences were observed in the remaining comparisons, which was likely because of the limited number of studies and their low methodological quality.

3.5.2. Recurrence rate

No statistically significant differences were observed between the different treatments for this outcome. The SUCRA values at the top of the heap listed in Table 4 were as follows: LCS (69.02%) > Maren capsule (68.34%) > Qirong Runchang oral solution (60.16%) > Simotang oral solution (58.61%) > Qirong Runchang oral solution and LCS (23.12%) > Simotang oral solution and LCS (20.75%). A lower SUCRA value indicates a lower recurrence rate for the treatment.

3.5.3. Defecation time score

Liuwei Anxiao combined with mosapride resulted in a shorter defecation time compared to mosapride alone. No statistically significant differences were observed among the other treatments. The SUCRA values at the top of the heap listed in Table 4 were as follows: mosapride (97.62%), Liuwei Anxiao capsule and mosapride (38.04%), and Shouhui Tongbian capsule and mosapride (14.34%). A lower SUCRA value indicates that the treatment may

Table 2 Network meta-analysis comparisons for recurrence rate; dyschezia and defecation time scores; and frequency of spontaneous bowel movement

Recurrence rate					
LCS					
2.85 (0.55, 18.21)	Qirong Runchang oral solution + LCS				
3.32 (0.55, 31.83)	1.18 (0.09, 18.49)	Simotang oral solution + LCS			
1.13 (0.26, 5.03)	0.40 (0.06, 2.13)	0.33 (0.02, 3.55)	Qirong Runchang oral solution		
0.87 (0.07, 9.37)	0.30 (0.02, 3.88)	0.25 (0.01, 5.45)	0.77 (0.11, 5.09)	Maren capsule	
1.22 (0.26, 6.27)	0.43 (0.04, 4.40)	0.36 (0.04, 2.43)	1.09 (0.12, 9.76)	1.40 (0.08, 26.14)	Simotang oral solution
Dyschezia score					
LCBLST					
0.90 (−0.33, 2.13)	Jiaolong capsule + LCBLST				
0.98 (−0.32, 2.27)	0.08 (−1.71, 1.87)	Maren capsule + LCBLST			
Defecation time score					
Mosapride					
0.30 (0.02, 0.60)	Liuwei Anxiao capsule and mosapride				
0.39 (−0.01, 0.79)	0.09 (−0.41, 0.57)	Shouhui Tongbian Jiaonang and mosapride			
Frequency of spontaneous bowel movement					
placebo					
−2.07 (−5.12, 0.96)	PEG4000				
−1.68 (−4.04, 0.74)	0.39 (−2.91, 3.77)	Maren pill			
−2.98 (−6.29, 0.36)	−0.91 (−3.92, 2.16)	−1.29 (−4.34, 1.73)	Liuwei Anxiao capsule		

Notes: LCBLST: live combined *Bifidobacterium*, *Lactobacillus*, *Streptococcus*/*Enterococcus* triple; LCS: *Lactobacillus casei* strain Shirota; PEG4000: polyethylene glycol 4000.

have a lower dyschezia score. The result of the SUCRA value comprises network and pairwise meta-analyses that Liuwei Anxiao plus mosapride has a lower dyschezia score than mosapride.

3.5.4. Dyschezia score

No statistically significant differences were observed between the different treatments for this outcome. The top three SUCRA values in Table 4 are live combined *Bifidobacterium*, *Lactobacillus*, *Streptococcus*/*Enterococcus* triple (LCBLST, 94.44%), Jiaolong capsule + LCBLST (30.80%), and Maren capsule + LCBLST (24.77%). A lower SUCRA value indicates that the treatment may have a lower dyschezia score.

3.5.5. Frequency of spontaneous bowel movements

No statistically significant differences were observed across the treatments for this outcome. The SUCRA values at the top of the heap, as listed in Table 4, were as follows: Liuwei Anxiao capsule (90.36%) > Maren pill (67.91%) > PEG4000 (21.09%) > placebo (20.63%). A higher SUCRA value indicates that the treatment may have a higher frequency of spontaneous bowel movements.

4. Discussion

4.1. Main findings

To the best of our knowledge, this is the first study to apply a NMA to evaluate the efficacy and safety of CPMs for FC. This NMA explored 26 types of CPMs used alone or as adjunctive therapies. Among the Western medicine control groups, polyethylene glycol and lactulose oral solutions were the most commonly used comparators in the studies conducted in China. Our findings indicate that in older participants, according to the self-established clinical efficacy criteria, Liuwei Anxiao combined with prokinetics demonstrated superior clinical effectiveness and lower scores for defecation difficulty and defecation time compared with prokinetic monotherapy. Dalitong granules combined with prokinetics showed better clinical efficacy than prokinetic monotherapy. In older participants, according to the published clinical efficacy criteria, the Shouhui Tongbian capsule combined with an osmotic laxative exhibited superior clinical effectiveness compared to osmotic laxative monotherapy.

The quality of the included studies was low. According to the risk-of-bias 2.0 tool, inadequate reporting of blinding of participants and outcome assessors, as well as allocation concealment, were the primary reasons for studies being judged as having a high or unclear risk-of-bias. Furthermore, information regarding disease subtypes, study protocol registration, and conflicts of interest was insufficient. These methodological flaws undermine the authenticity and reliability of our findings. Therefore, the main findings derived from the quantitative synthesis are insufficient to support definitive conclusions regarding the effectiveness and safety of CPMs.

Three previous meta-analyses investigated the effects of CPMs on FC;[12,13,84] however, these were limited to traditional pairwise meta-analyses. Several NMA have also been published, but the types of CPMs included are insufficient.[85,86] Their synthesis methods broadly categorized CPMs and Western medicines, overlooking the specific treatment regimens or efficacy criteria used in different trials. Consequently, the reliability of their findings is constrained by the coarse synthesis criteria.[87] In contrast, our study used a broader search strategy and applied more advanced methodological approaches to synthesize evidence on specific interventions, providing more rigorous evidence. Our research represents an update and advancement of previous studies in this field.

Some network plots were open and failed to form a closed network struc-

Table 3 Network meta-analysis comparisons for clinical effects under different criteria, with significant differences

Prokinetics as common comparator (older age population, self-defined criteria)								
Dalitong granules + Prokinetic								
1.30 (0.73, 2.37)	Houpo Paiqi Heji + Prokinetic							
1.36 (0.81, 2.22)	1.05 (0.65, 1.57)	Liuwei Anxiao capsule						
1.09 (0.64, 1.79)	0.84 (0.51, 1.27)	0.80 (0.59, 1.07)	Liuwei Anxiao capsule + Prokinetic					
2.02 (1.20, 3.44)	1.55 (0.96, 2.47)	1.48 (1.06, 2.19)	1.85 (1.32, 2.80)	Maren pill				
1.37 (0.77, 2.48)	1.05 (0.61, 1.79)	1.00 (0.66, 1.62)	1.26 (0.82, 2.05)	0.68 (0.42, 1.08)	Shouhui Tongbian capsule + Prokinetic			
1.42 (0.71, 2.86)	1.09 (0.56, 2.09)	1.05 (0.59, 1.90)	1.31 (0.73, 2.42)	0.70 (0.38, 1.30)	1.04 (0.54, 1.99)	Simotang oral solution		
1.06 (0.54, 2.01)	0.82 (0.43, 1.46)	0.78 (0.46, 1.33)	0.98 (0.57, 1.70)	0.53 (0.30, 0.90)	0.78 (0.41, 1.40)	0.75 (0.45, 1.15)	Simotang oral solution + Prokinetic	
1.59 (1.03, 2.53)	1.22 (0.84, 1.79)	1.17 (0.96, 1.52)	**1.46 (1.17, 1.96)**	0.79 (0.60, 1.05)	1.16 (0.80, 1.71)	1.12 (0.65, 1.94)	1.50 (0.96, 2.50)	Prokinetic
Osmotic laxatives as common comparator (older age population, published criteria)								
Liuwei Anxiao capsule								
0.99 (0.67, 1.45)	Liuwei Anxiao capsule + Osmotic laxatives							
1.41 (0.97, 2.10)	1.44 (0.97, 2.19)	Maren pill						
1.00 (0.72, 1.36)	1.01 (0.72, 1.42)	0.71 (0.49, 0.98)	Maren pill + Osmotic laxatives					
0.96 (0.70, 1.34)	0.98 (0.69, 1.39)	0.68 (0.48, 0.96)	0.97 (0.74, 1.28)	Shouhui Tongbian capsule + Osmotic laxatives				
1.17 (0.90, 1.52)	1.18 (0.89, 1.58)	0.83 (0.61, 1.09)	1.17 (0.98, 1.43)	**1.21 (1.00, 1.48)**	Osmotic laxatives			

Table 4 SUCRA value of each treatment in terms of recurrence rate; dyschezia and defecation time scores; and frequency of spontaneous bowel movement

Rank	Recurrence rate		Dyschezia score		Defecation time score		Frequency of spontaneous bowel movement	
	Intervention	SUCRA (%)	Intervention	SUCRA (%)	Intervention	SUCRA (%)	Intervention	SUCRA (%)
1	LCS	69.02%	LCBLST	94.44%	mosapride	97.62%	Liuwei Anxiao capsule	90.36%
2	Maren capsule	68.34%	Jiaolong capsule + LCBLST	30.80%	Liuwei Anxiao capsule + Mosapride	38.04%	Maren pill	67.91%
3	Qirong Runchang oral solution	60.16%	Maren capsule + LCBLST	24.77%	Shouhui Tongbian capsule + Mosapride	14.34%	PEG4000	21.09%
4	Simotang oral solution	58.61%	NA	NA	NA	NA	Placebo	20.63%
5	Qirong Runchang oral solution + LCS	23.12%	NA	NA	NA	NA	NA	NA
6	Simotang oral solution + LCS	20.75%	NA	NA	NA	NA	NA	NA

Notes: LCBLST: live combined *Bifidobacterium*, *Lactobacillus*, *Streptococcus*/*Enterococcus* triple; LCS: *Lactobacillus casei* strain Shirota; NA: not applicable; PEG4000: polyethylene glycol 4000; SUCRA: surface under the cumulative ranking curve.

ture, with most treatment arms supported only by single-study comparisons. Direct comparisons between interventions were insufficient. Consequently, inconsistency tests were not performed for these outcomes, which reduced the certainty of our analysis; thus, the results should be interpreted with caution.

4.2. Strengths and limitations

This study had limitations. First, despite conducting a comprehensive search, the complex nature of CPM concepts and the restriction of the search to Chinese and English databases may have resulted in the failure to retrieve all relevant literature. In addition, the limited number of studies included and

the small sample sizes constrained the evidence synthesis. Due to insufficient head-to-head comparisons, funnel plots were generated only for the outcome of clinical effectiveness to detect potential publication bias. Studies have typically reported the number of adverse events without providing specific counts for each type; therefore, evidence on specific adverse events is limited, precluding the synthesis of evidence for these outcomes. Furthermore, owing to regulatory and acceptance factors, all the included studies were conducted in China with Chinese participants whose physical constitutions and lifestyle habits may differ from those of other populations, potentially limiting the generalizability of our findings.

Recommendations for adverse event reporting[88] and methodological guidance for synthesizing rare or zero events[89,90] have been published, offering promise for future high-quality studies. Second, the effectiveness of CPMs may be influenced by their formulation, dosage, and administration duration; however, the current evidence is insufficient to support more detailed analyses or additional conclusions, indicating a gap for future research.[91] Third, over the past two decades of CPM development for FC, the diagnostic criteria and treatment approaches have evolved considerably, including the prohibition of phenolphthalein tablets and the publication of the Rome III and IV criteria,[92,93] which inevitably affected the consistency of study designs and outcome measurements across the included studies. In addition, clinical effectiveness represents a typical case. As a composite outcome indicator widely used in Chinese clinical studies, the definition of "clinical effectiveness" originated from the Guiding Principles for Clinical Research of New Chinese Medicine. It assesses overall improvement in constipation symptoms or changes in TCM syndrome scores rather than precise measurements, such as the frequency of complete spontaneous bowel movements from baseline to endpoint. Researchers have identified the drawbacks of such composite outcomes, and the definition of "clinical effectiveness" has since evolved to place greater emphasis on patient-centered outcomes.[94]

The significance of this study extends beyond evidence synthesis, providing insights into the clinical applications of CPMs and future research directions. Numerous studies were excluded from our analysis because of the implementation of pseudo-randomization in their clinical research (e.g., randomization based on the patients' treatment sequence). Many of the included studies were assessed as having a high risk-of-bias in the blinding of outcome assessors or participants owing to inadequate reporting and differences in drug formulations. The Consolidated Standards of Reporting Trials (CONSORT) statement should serve as a fundamental benchmark for future clinical research, and investigators should strive for standardization throughout the research process, from design to conclusion. Furthermore, researcher-defined outcomes cannot be ignored. With the publication of guidelines and expert consensus, future researchers should adopt more rigorous and standardized study designs to reduce the use of self-defined outcome measures. This study is the first to compare different CPMs for the treatment of FC. Although constrained by the scarcity of high-quality studies and insufficient direct comparisons, our research, conducted under relatively standard and rigorous methodological frameworks, offers a valuable reference for clinical practice by highlighting the effects of different CPMs on various outcomes, along with their safety profiles. Our study not only provides evidence on the effectiveness and safety of several CPMs but also identifies those that remain underexplored, with limited comparisons and trials. Moreover, based on the current evidence and identified knowledge gaps, this study may inform future investigations.[95,96] The common problems revealed in our study, such as methodological inadequacies and insufficient attention to newer CPMs (e.g., lack of description of randomization methods, absence of blinding, and use of self-defined outcomes), along with targeted recommendations, will contribute to advancing the standardization and internationalization of CPMs.

5. Conclusion

To the best of our knowledge, this is the first systematic review and NMA to investigate the effectiveness and safety of CPMs in treating FC. Our findings indicate that in older participants and according to self-established clinical efficacy criteria, compared with Western medicine, such as prokinetics or monotherapy, Liuwei Anxiao and Dalitong granules combined with Western medicine demonstrated better clinical effectiveness. In older participants, according to published criteria, Shouhui Tongbian capsules combined with an osmotic laxative exhibited superior clinical effectiveness compared to osmotic laxative monotherapy. Several positive outcomes were also observed, such as lower defecation difficulty and defecation time scores. However, compared with the substantial number of CPMs available in the market, the quality of the included studies and the scope of CPMs covered in our conclusions remain insufficient. Future research should include more high-quality studies that directly compare different CPMs.

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Data Availability

Additional data related to this paper may be obtained from the corresponding author upon reasonable request.

Author Contribution Statement

You-you Zheng: Conceptualization, methodology, software, formal analysis, visualization, and writing – original draft. **Ning Liang:** Writing – original draft, methodology, and writing – review & editing. **Long-kun Liu:** Data curation, methodology, and investigation. **Wei-jia Sun:** Data curation, methodology, and investigation. **Xue-hui Wang:** Methodology and formal analysis. **Yu-xin Sun:** Methodology and visualization. **Yun-ru Chen:** Software and visualization. **Xiao-xia Han:** Writing – review & editing. **Zhao-lan Liu:** Conceptualization, funding acquisition, project administration, supervision, and writing – review & editing.

Use of AI Statement

None.

Declaration of Competing Interest

The authors have no competing interests to declare that are relevant to the content of this article.

Electronic Supplementary Material

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