

# 中药治疗轻度认知障碍的系统评价与Meta分析



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**【摘要】目的** 系统评价中药对轻度认知障碍(MCI)的治疗效果和安全性。**方法** 通过计算机检索中英文数据库中关于中药治疗MCI的临床随机对照试验,检索时限为数据库成立截止至2025年12月31日。采用Cochrane偏倚风险评价工具对纳入文献进行质量评价,使用Stata 17.0软件进行Meta分析。**结果** 共纳入77项研究,包含7997例患者。研究结果表明,中药显著提高患者认知水平[标准平均差(SMD)=0.78, 95%CI(0.67, 0.89),  $P<0.001$ ]和日常生活活动能力(ADL)[SMD=-0.64, 95%CI(-0.90, -0.38),  $P<0.001$ ]。亚组分析结果显示,中西药联合效果较佳,但在ADL方面,中药vs.西药和中药vs.空白/安慰剂差异无统计学意义( $P>0.05$ )。29项研究报告了安全性数据,中药组不良反应发生率与对照组差异无统计学意义[相对危险度(RR)=0.72, 95%CI(0.51, 1.02),  $P=0.066$ ]。**结论** 中药可有助于改善MCI患者的认知水平以及ADL,其中以中西药联合效果相对更佳。但由于一些研究样本量较小和方法不严谨,因此需要采用严格的方法进一步验证。

**【关键词】** 中药; 认知功能; 轻度认知功能障碍; 日常生活活动能力; Meta分析; 随机对照试验; 不良反应; 安全性

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**【文献标识码】** A

## Systematic review and Meta-analysis of traditional Chinese medicine in the treatment of mild cognitive impairment

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**【Abstract】Objective** To methodically evaluate the therapeutic effect and safety of traditional Chinese medicine (TCM) in the treatment of mild cognitive impairment (MCI). **Methods**

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A computerized search was conducted in Chinese and English databases for clinical randomized controlled trials on the treatment of MCI with TCM. The search was limited to studies published from the establishment of the database up to December 31, 2025. The Cochrane risk of bias assessment tool was used to evaluate the quality of the included studies, and Stata 17.0 software was employed for Meta-analysis. **Results** A total of 77 studies involving 7,997 patients were included. The results indicated that TCM significantly improved patients' cognitive function [standardized mean difference (SMD)=0.78, 95%CI (0.67, 0.89),  $P<0.001$ ] and activities of daily living (ADL) [SMD=-0.64, 95%CI (-0.90, -0.38),  $P<0.001$ ]. Subgroup analysis revealed that the combination of TCM and Western medicine yielded better results. However, in terms of ADL, there was no statistically significant difference between TCM vs. Western medicine and TCM vs. placebo/blank ( $P>0.05$ ). 29 studies reported safety data, and there was no significant difference in the incidence of adverse reactions between the TCM group and the control group [relative risk (RR)=0.72, 95%CI (0.51, 1.02),  $P=0.066$ ]. **Conclusion** TCM can help improve cognitive function and ADL in patients with MCI, with the combination of TCM and Western medicine showing relatively better results. However, due to the small sample size and imprecise methods in some studies, further rigorous research is needed to validate these findings.

**【Keywords】** Traditional Chinese medicine; Cognitive function; Mild cognitive impairment; Activities of daily living; Meta-analysis; Randomized controlled trial; Adverse reaction; Safety

轻度认知障碍 (mild cognitive impairment, MCI) 是痴呆症的临床前阶段, 其特征是至少在一个领域存在认知缺陷, 并伴有日常生活活动能力 (activity of daily living, ADL) 的轻微下降。随着年龄的增长, MCI 的患病率逐渐上升, 从 60~65 岁的 6.7% 至 80~84 岁的 25.2% 不等<sup>[1]</sup>。此外, 患有 MCI 的个体比同龄的健康个体患痴呆的风险更高, 超过 50% 的 MCI 患者在 4~6 年内发展为阿尔茨海默病、路易体痴呆或其他类型的痴呆<sup>[1-2]</sup>。一项流行病学研究 Meta 分析显示, 中国 50 岁及以上人群中 MCI 的患病率为 15.4%<sup>[3]</sup>。因此, 为提高 MCI 患者的生活质量, 减少痴呆的发病率, 减轻社会的经济和医疗负担, 对 MCI 进行优先干预至关重要。目前, MCI 发病机制复杂, 尚无有效治疗方法<sup>[4]</sup>。现阶段临床最常用的两种药物是胆碱酯酶抑制剂 (如多奈哌齐、卡巴拉汀、加兰他敏等) 和谷氨酸受体拮抗剂 (美金刚), 其他药物, 如钙通道阻滞剂、单胺能受体激动药物和改善脑循环、脑代谢的药物, 也可以改善认知功能, 但这些药物作用有限, 且部分药物存在严重不良反应<sup>[5]</sup>。

近年来, 中药因其疗效较好、不良反应较少, 在治疗 MCI 方面受到了广泛关注<sup>[6]</sup>。MCI 属于中医的“失忆”范畴, 包括“语言错误”“失忆”、“白痴”和“思维迟钝”。发病机制涉及虚、痰、郁。大脑是受累的主要器官, 但也会累及肾脏、心

脏、肝脏和脾脏<sup>[7]</sup>。基于中医理论基础, 辨证应用中药治疗 MCI 取得了一定进展。目前中医药治疗 MCI 的研究水平参差不齐。因此, 本研究通过系统评价与 Meta 分析, 评估中药治疗 MCI 患者的疗效及安全性, 为临床治疗提供参考。

## 1 资料与方法

### 1.1 纳入与排除标准

纳入标准: ①研究对象: MCI 患者, 诊断依据参照国际或国内公认的临床诊断标准, 包括但不限于《中国痴呆与认知障碍诊治指南》<sup>[8]</sup>; ②干预措施: 中药单独应用或与西药及其他疗法的共同干预; ③对照组: 西药疗法、安慰剂或无干预。④研究类型: 随机对照试验 (randomized controlled trials, RCT); ⑤结局指标: 主要结局是认知功能的变化或改善情况, 次要结局是 ADL 的改变, 安全性指标是不良反应发生状况。

排除标准: ①除 MCI 之外的其他形式认知功能障碍 (痴呆)、诊断不明确或合并精神疾病及其他严重并发症的患者; ②对照组干预措施中包含了中药的研究; ③研究方案、评论、综述、会议摘要、系统评价、学位论文、动物实验、正在进行的试验和无足够数据进行分析的研究; ④随访时间 < 3 月或样本量 < 50 例的研究; ⑤低质量研究 (如试验过程不清, 统计方法错误, 结果数据不全或存在明显错误等)。

## 1.2 文献检索策略

对 PubMed、Web of Science、Cochrane Library、Embase、ClinicalTrials.gov、万方、维普 (VIP)、中国知网 (CNKI) 和中国生物医学文献数据库 (SinoMed) 进行系统检索。检索时间为数据库成立至 2025 年 12 月 31 日。中文检索词包括“轻度认知障碍”“中药”“随机对照”, 英文检索词包括“mild cognitive impairment”“Chinese traditional medicine”“randomized controlled trial”。为了扩大搜索范围, 采用医学主题词搭配自由词进行检索。以中国知网为例, 检索策略见框 1。

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SU=("MCI"+"轻度认知障碍"+"轻度认知损害"+"轻度认知损伤"+"轻度认知缺损"+"轻度认知减退"+"轻度认知受损"+"轻度认知功能损害"+"轻度神经认知障碍"+"轻度认知功能障碍"+"轻度认知功能损害"+"轻度认知功能损伤"+"轻度认知功能缺损"+"轻度认知功能减退"+"轻度认知功能受损"+"轻度认知功能损害"+"轻度神经认知功能障碍") AND SU=("中药"+"草药"+"中草药"+"中成药"+"成药"+"方剂"+"汤药"+"复方"+"自拟方"+"汤剂"+"煎剂"+"中西医"+"中医"+"中医药") AND AB=("随机"+"安慰剂"+"盲法")
```

框1 中国知网检索策略  
Box 1. CNKI search strategy

## 1.3 文献筛选及提取流程

2 名作者独立进行文献筛选, 确定最终纳入的研究。数据提取包括作者、发表日期、地点、随机方法、样本量、参与者年龄、性别、干预措施 (剂量、时间)、随访时间、结局指标等。采用蒙特利尔认知评估量表 (Montreal Cognitive Assessment, MoCA)、简易精神状态量表 (Mini-Mental State Examination, MMSE) 或其他认知量表等评估患者 MCI 状况。ADL 用于评估患者独立完成穿衣、进食、洗漱、行走等基本生活行为的能力, 是反映 MCI 患者功能状态的重要指标。若试验的主要结局是认知评分的变化或认知和功能评分的组合, 本研究在分析中提取主要结局; 在认知评分变化为次要结果的情况下, 本研究从 3 个量表 [MMSE、MoCA 或阿尔茨海默病评估量表-认知分量表 (Alzheimer's Disease Assessment Scale-Cognitive Subscale, ADAS-Cog)] 中的 1 个提取相关数据。如有争议, 通过讨论或与第三方协商后解决。

## 1.4 文献质量评价

文献质量评估采用 Cochrane 偏倚风险评价工具<sup>[8]</sup>。评估内容主要涵盖 7 个核心维度, 分别为:

随机序列生成、分配隐藏、受试者与研究者盲法、结局评估盲法、结局数据的完整性、选择性报告结局以及其他偏倚。每个评估维度均按照“低风险”“高风险”“不确定”3 个等级进行判定。

## 1.5 数据分析

由于认知功能和 ADL 常采用不同的评定量表进行评估, 故将结果转换成标准平均差 (standardized mean differences, SMD) 和 95%CI。测量认知功能和 ADL 的不同量表可能有不同的解释。如在 MMSE 和 MoCA 中, 更高的分数表明更好的表现, 而在 ADAS-Cog 中, 更低的分数表明更好的结果。因此, 在认知功能中, 当结果有利于干预时, 将 SMD 定义为正值; 在 ADL 中, 当结果有利于干预时, 将 SMD 定义为负值。对于二分类变量采用相对危险度 (relative risk, RR) 和 95%CI 表示。采用  $\chi^2$  检验和  $I^2$  统计量分析异质性。依据 Cochrane 系统评价手册,  $I^2$  值的判定标准如下: 0%~25% 提示轻微异质性; 25%~50% 提示中度异质性; 50%~75% 提示实质性异质性; 75%~100% 提示高度异质性, 本研究选用随机效应模型。为探索异质性来源及评估结果的稳定性, 本研究进行以下亚组变量进行分析: ①干预措施类型 (中药 vs. 西药、中西医结合 vs. 西药、中药 vs. 空白/安慰剂); ②随访时间 (< 6 个月 vs.  $\geq$  6 个月); ③疾病类型 (单纯 MCI vs. MCI 合并其他基础疾病)。同时, 采用逐一剔除文献法进行敏感性分析。当某一结局指标纳入的文献数量  $\geq$  10 篇时, 绘制漏斗图并采用 Egger's 线性回归法检验是否存在潜在的发表偏倚。使用 Stata 17.0 软件对结果进行 Meta 分析, 以  $P < 0.05$  为差异有统计学意义。

## 2 结果

### 2.1 一般情况

初始检索 2 439 篇文献, 经筛选后最终纳入 77 篇文献, 其中英文文献 5 篇 (6.49%), 中文文献 72 篇 (93.51%)。具体文献筛选流程见图 1。

### 2.2 纳入文献的基本特征

纳入的 77 篇文献中 4 篇文献为 3 臂试验, 因此, 本研究拆分为两个比较组后共计 81 个比较组。36 个比较组为中西医结合 vs. 西药, 20 个比较组为中药 vs. 空白对照或安慰剂, 25 个比较组为中药 vs. 西药。研究共包含 7 997 例患者, 治

疗组 4 179 例，对照组 3 818 例。患者年龄 ≥34 岁，随访时间 3~36 月。只有 1 项试验在德黑兰开展，其余均在中国开展。所有文献均报道了认知功能结果，有 30 篇文献报道了 ADL 结果，49 篇文献报道了安全性结局，其中 29 篇文献报道了不良反应的具体例数。纳入文献的基本特征见表 1。

### 2.3 纳入文献的风险偏倚评估

对 77 项试验进行了偏倚风险评估。① 对于选择偏倚，使用 SAS 软件或随机数字表法生成随机化序列的 45 项试验被评估为低偏倚风险，其余 32 项试验未指定随机化方法，因此被评估为不清楚。② 大多数纳入的试验没有报道隐藏分配的方法，只有 4 项试验在分配隐藏方面被评估为低风险。③ 15 项试验对参与者和人员进行了充分的盲法；其余 62 项试验被评估为高风险。④ 2 项试验对结果评估者进行了充分的盲法；其余 75 项试验没有描述结果评估者的盲法。⑤ 69 项试验报告无缺失数据，并将所有参与者纳入数据分析，因此评估为低风险，1 项试验存在高风险，7 项试验未报告退出信息被评估为不清楚。⑥ 1 项试验的选择性报道的风险较低，其余 76 项试验由于缺乏预先发表的试验方案被评估为不清楚。⑦ 16 项

试验未报告资助被评估为不清楚，其余 61 项试验被评为低风险。纳入文献的总体质量评价具体见图 2。

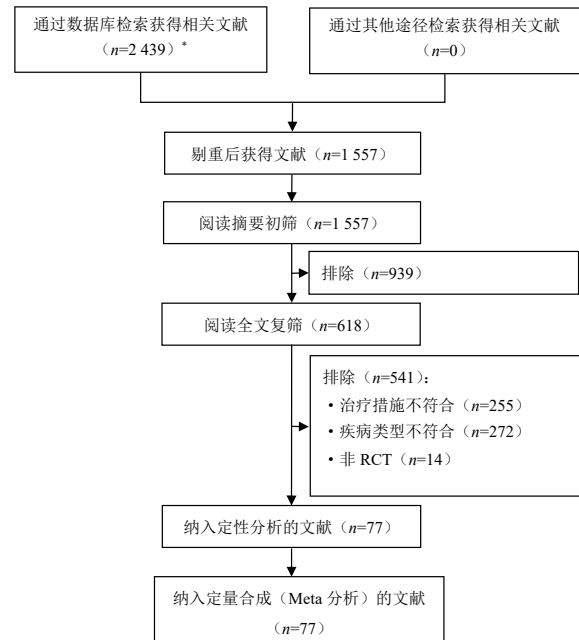


图 1 文献筛选流程及结果

Figure 1. Flow chart of literature screening

注：\*所检索的数据库及检出文献数具体如下：Embase (n=64)、PubMed (n=80)、the Cochrane Library (n=131)、Web of Science (n=492)、ClinicalTrial.gov (n=35)、CNKI (n=424)、VIP (n=295)、万方 (n=752)、SinoMed (n=166)。

表 1 纳入研究的基本特征

Table 1. Basic characteristics of included studies

研究	样本量 (T/C, 例)	性别 (男/女)	年龄 (T/C, 岁)	干预措施		随访时间 (个月)
				T	C	
俞金鑫 2022 <sup>[9]</sup>	42/42	45/39	61~84/62~83	肾健脾活血方+阿司匹林肠溶片	阿司匹林肠溶片	3
王小菊 2021 <sup>[10]</sup>	30/30	33/27	68.8/68.5	三补方+盐酸多奈哌齐片	盐酸多奈哌齐片	3
田曼 2021 <sup>[11]</sup>	40/40	45/35	60~75/62~75	交泰丸+奥拉西坦胶囊	奥拉西坦胶囊	3
谭文澜 2020 <sup>[12]</sup>	40/40	51/29	52~78/50~76	多巴丝肼+抗震胶囊	多巴丝肼	3
郭伟 2020 <sup>[13]</sup>	51/51	51/51	61~78/62~78	西格列汀+津力达颗粒	西格列汀	3
沈丽萍 2020 <sup>[14]</sup>	50/52	65/37	66.7/67.2	多巴胺能药物+滋阴祛痰开窍方	多巴胺能药物	6
刘照龙 2019 <sup>[15]</sup>	50/50	57/43	35~69/34~68	祛痰通络醒神汤+多索茶碱片	多索茶碱片	6
刘扬 2015 <sup>[16]</sup>	60/60	65/55	56~83/55~85	银杏叶片+盐酸多奈哌齐	盐酸多奈哌齐	9
石燕芳 2018 <sup>[17]</sup>	40/38	37/41	62~76/61~75	益肾化痰祛痰方	尼莫地平片	6
王丽丽 2018 <sup>[18]</sup>	45/45	45/45	64~78/62~80	养血清脑颗粒+盐酸多奈哌齐	盐酸多奈哌齐	3
陆征宇 2018 <sup>[19]</sup>	52/51	51/38	57~77/55~79	补肾填精方+左旋多巴制剂	左旋多巴	11
谢步霓 2018 <sup>[20]</sup>	32/32	42/22	60~77/55~80	补肾祛毒丸	尼莫地平片	12
曹畅 2017 <sup>[21]</sup>	40/40	45/35	59~77/58~79	补益肝肾汤+美多巴	美多巴片	6
郜风清 2017 <sup>[22]</sup>	60/60	70/50	51~72/52~74	滋肾祛湿化痰中药+盐酸多奈哌齐	盐酸多奈哌齐	6
富宏 2017 <sup>[23]</sup>	40/40	39/41	47~80/43~80	补肾活血方+尼莫地平	尼莫地平片	3
杨丽静 2017 <sup>[24]</sup>	64/64	77/51	70.7/71.1	复方菖蒲益智汤	尼莫地平片	3
肖娟 2017 <sup>[25]</sup>	50/50	45/55	62.3/61.1	复方活脑舒胶囊+多巴丝肼片	多巴丝肼片	3
狄子晖 2017 <sup>[26]</sup>	33/33	28/38	71.4/70.8	盐酸多奈哌齐+银杏叶片	盐酸多奈哌齐	12
于恩彦 2017 <sup>[27]</sup>	60/60	41/52	76.1/75.7	复办海蛇胶囊	自然观察	24
姬琳 2016 <sup>[28]</sup>	30/30	45/15	59.1 <sup>c</sup>	清脑益智颗粒	尼莫地平片	3
金香兰 2016 <sup>[29]</sup>	104/96	115/85	64.0/63.9	复方苻蓉益智胶囊+中医特色疗法+基础治疗	基础治疗	9
何迎春 2015 <sup>[30]</sup>	50/50	69/31	65~85	健脾填精方颗粒剂	安慰剂	6

续表1

研究	样本量 (T/C, 例)	性别 (男/女)	年龄 (T/C, 岁)	干预措施		随访时间 (个月)
				T	C	
刘洋 2015 <sup>[31]</sup>	50/50	56/44	71.1/72.3	银杏叶片+盐酸多奈哌齐	盐酸多奈哌齐	9
郭明冬 2015 <sup>[32]</sup>	40/40	41/37	70.1/70.0	心脑宁胶囊	尼莫地平片	6
赵欢 2014 <sup>[33]</sup>	43/42	41/44	45~75/50~72	补肾活血开窍方+阿司匹林	阿司匹林	18
徐素芝 2014 <sup>[34]</sup>	30/30	39/21	52~75/54~76	强力增智饮+尼莫地平片	尼莫地平片	3
赵建军 2012 <sup>[35]</sup>	90/90	98/82	—	补肾益髓活血化痰解毒法拟中药汤剂	尼莫地平片	3
况时祥 2011 <sup>[36]</sup>	45/30	33/42	73.2/71.8	补脑 I 号	吡拉西坦	3
肖世源 2011 <sup>[37]</sup>	54/44	36/62	61~83/55~85	银杏叶片G	自然观察	6
阚佑骞 2010 <sup>[38]</sup>	63/63	65/61	61~82/60~80	九味益智汤	尼莫地平片	3
李彤 2010 <sup>[39]</sup>	30/30	—	50~80 <sup>c</sup>	中药补肾通络汤	空白对照	36
李福海 2022 <sup>[40]</sup>	86/86	83/89	68.1/67.8	尼麦角林、胞磷胆碱、奥拉西坦胶囊+自拟升清益智汤	尼麦角林、胞磷胆碱、奥拉西坦胶囊	3
周建华 2021 <sup>[41]</sup>	63/63	68/58	55~73/58~78	自拟补肾活血汤+多巴丝肼片+盐酸多奈哌齐片	多巴丝肼片+盐酸多奈哌齐片	3
周如倩 2007 <sup>[42]</sup>	42/38	37/43	53~79/56~79	参银口服液	维生素E	12
周如倩 2007 <sup>[42]</sup>	42/37	41/38	53~79/54~78	参银口服液	安慰剂	12
田金洲 2003 <sup>[43]</sup>	30/30	17/43	45~69/45~69	中药复方制剂金思维+安慰剂	脑复康片+安慰剂	12
田金洲 2003 <sup>[43]</sup>	30/15	11/34	45~69/46~69	中药复方制剂金思维+安慰剂	安慰剂	12
钟剑 2007 <sup>[44]</sup>	83/83	64/102	64.6/64.4	参乌胶囊	茴拉西坦胶囊	3
沈英 2019 <sup>[45]</sup>	44/44	53/28	51~79/50~79	水火既济组方	茴拉西坦胶囊	3
罗玮 2016 <sup>[46]</sup>	30/30	31/29	49~75/48~74	加味涤痰汤+尼莫地平片	尼莫地平片	3
高磊 2015 <sup>[47]</sup>	67/66	88/65	51~79/50~80	复方苻蓉益智胶囊	尼莫地平片	6
韩自力 2016 <sup>[48]</sup>	60/60	41/79	72.3/71.3	基础治疗+银杏叶片	基础治疗	12
沈婷 2021 <sup>[49]</sup>	65/63	86/72	50~85	辨证分型治疗	茴拉西坦胶囊	6
吴正治 2010 <sup>[50]</sup>	65/63	77/51	74.3/74.4	天泰1号	安慰剂	6
董振华 2012 <sup>[51]</sup>	58/55	40/73	62~83/61~84	银杏叶片+基础治疗	基础治疗	12
李乐军 2016 <sup>[52]</sup>	30/30	33/27	60~78/61~79	参乌颗粒+服脑复康片安慰剂	脑复康片+参乌颗粒安慰剂	3
代建峰 2011 <sup>[53]</sup>	25/25	22/28	70.5/69.3	益智健脑颗粒	安慰剂	4
刘芳 2010 <sup>[54]</sup>	35/35	47/23	79.3 <sup>c</sup>	阿司匹林、他汀类等+养血清脑颗粒	阿司匹林、他汀类等	4
张春燕 2010 <sup>[55]</sup>	34/34	29/49	60~83/60~85	培元益智方中药+一般宣教	一般宣教	3
顾超 2020 <sup>[56]</sup>	43/43	38/45	63.0/62.9	地黄益智颗粒	茴拉西坦胶囊	6
赵鑫 2022 <sup>[57]</sup>	40/40	44/36	66.9/67.1	补肾益髓汤联合针刺治疗	奥拉西坦胶囊	3
刘学飞 2017 <sup>[58]</sup>	36/36	—	50~80 <sup>c</sup>	尼莫地平+奥拉西坦胶囊+中药复方菖蒲益智颗粒	尼莫地平+奥拉西坦胶囊	6
李乐军 2010 <sup>[59]</sup>	30/30	34/26	60~78/61~76	通脉益智丸+脑复康胶囊安慰剂	脑复康胶囊+通脉益智丸安慰剂	3
朱黎明 2010 <sup>[60]</sup>	50/50	53/47	60~87/61~89	眩晕宁片	吡拉西坦片	3
黄海燕 2015 <sup>[61]</sup>	30/30	24/36	64.5/64.5	益智健脑颗粒	茴拉西坦片	3
赵肇 2020 <sup>[62]</sup>	51/49	57/43	40~75/41~76	常规生活方式干预+自拟祛痰通络醒神汤	常规生活方式干预	6
戢运建 2017 <sup>[63]</sup>	42/42	45/39	45~78/46~79	活血化痰方+尼莫地平	尼莫地平片	6
张允岭 2010 <sup>[64]</sup>	39/39	34/44	54~79/54~80	生活方式调理+基础病治疗+复方苻蓉益智胶囊	生活方式调理+基础病治疗	3
张艳霞 2014 <sup>[65]</sup>	100/100	—	50~80 <sup>c</sup>	基础治疗+复方苻蓉益智胶囊+中医特色疗法	基础治疗	9
石敏 2015 <sup>[66]</sup>	35/35	44/26	50~82/48~85	益智煎免煎颗粒	淀粉颗粒	3
顾超 2015 <sup>[67]</sup>	50/50	49/51	56~80/59~78	地黄益智方	茴拉西坦片	3
陈炜 2018 <sup>[68]</sup>	30/30	36/24	60~83/62~85	壮医五桃土参方颗粒剂	盐酸多奈哌齐片	3
叶青 2016 <sup>[69]</sup>	40/38	48/30	67.6/65.9	左旋多巴+益智平颤方	左旋多巴	3
郑恩香 2014 <sup>[70]</sup>	75/74	84/65	61~81/60~80	银丹心脑通软胶囊+茴拉西坦	茴拉西坦片	3
王安安 2022 <sup>[71]</sup>	41/41	43/39	53~79/52~77	盐酸多奈哌齐片+清灵方	盐酸多奈哌齐片	3
崔格 2021 <sup>[72]</sup>	42/42	43/41	52.7/53.1	盐酸多奈哌齐片+自拟益智通窍汤	盐酸多奈哌齐片	3
梁兴伦 2017 <sup>[73]</sup>	40/42	47/35	65.2/64.4	四高颗粒	尼莫地平片	6
梁兴伦 2017 <sup>[73]</sup>	40/42	43/39	65.8/64.4	尼莫地平片和四高颗粒	尼莫地平片	6
杨丽静 2017 <sup>[74]</sup>	42/42	59/25	65.4/61.9	复方菖蒲益智汤+尼莫地平	尼莫地平片	3
张允岭 2015 <sup>[75]</sup>	104/96	115/89	64.0/63.9	复方苻蓉益智胶囊+中医特色疗法+基础治疗	基础治疗	9
石燕芳 2023 <sup>[76]</sup>	62/62	69/55	46~75/45~75	益气聪明汤+吡拉西坦	吡拉西坦	3
曹玲 2024 <sup>[77]</sup>	64/64	72/56	59~81/57~82	复方活脑舒胶囊+多奈哌齐	多奈哌齐	3

续表1

研究	样本量 (T/C, 例)	性别 (男/女)	年龄 (T/C, 岁)	干预措施		随访时间 (个月)
				T	C	
龙华君 2025 <sup>[78]</sup>	30/30	32/28	67.0/64.1	柔肝醒神汤+盐酸多奈哌齐	盐酸多奈哌齐	3
吴冬月 2025 <sup>[79]</sup>	44/44	28/60	66.1/65.4	补肾健脾化痰颗粒	安慰剂	3
周子钦 2025 <sup>[80]</sup>	47/46	53/40	75.4/74.5	复方通络饮+尼莫地平片	尼莫地平片	3
Gu 2017 <sup>[81]</sup>	50/50	115/89	59~78/56~80	地黄益智方	茴拉西坦	12
Tian 2019 <sup>[82]</sup>	174/70	125/119	63.2/64.2	清宫寿桃丸	安慰剂	12
Tian 2019 <sup>[82]</sup>	104/70	81/93	64.4/64.2	银杏叶提取物	安慰剂	12
Zhang 2016 <sup>[83]</sup>	30/30	28/32	66.0/63.3	复方中药补肾胶囊	安慰剂	24
Pakdaman 2017 <sup>[84]</sup>	34/36	40/30	70.9/70.3	MLC601	安慰剂	6
Tian 2017 <sup>[85]</sup>	215/107	134/188	55~80 <sup>c</sup>	参乌胶囊	盐酸多奈哌齐	6

注：T：治疗组；C：对照组；a与b表示同一RCT拆分的不同臂研究；年龄表示为范围或平均年龄；c表示纳入总人群年龄；“—”表示未报告。

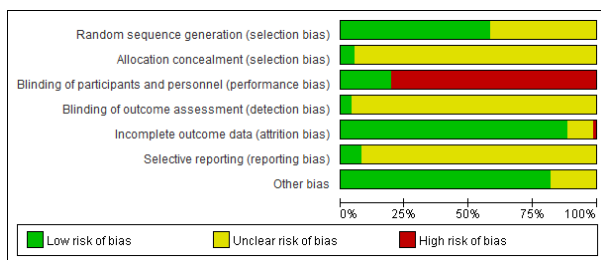


图2 纳入文献的总体质量评价

Figure 2. Overall quality assessment of included literature

## 2.4 Meta分析结果

### 2.4.1 认知功能

纳入的 77 篇文献均报道了认知功能，其中 36 项 RCT 为中西药联合 vs. 西药，20 项 RCT 为中药 vs. 空白或安慰剂，25 项 RCT 为中药 vs. 西药。研究结果显示，中药干预可有效提高患者认知水平 [SMD=0.78, 95%CI (0.67, 0.89),  $P < 0.001$ ]。不同干预措施、疾病类型、随访时间亚组分析结果均显示，中药干预可有效提高患者认知功能，

具体结果见表 2。通过逐篇排除文献法进行敏感性分析，均对主分析结果影响较小，结果稳健。

### 2.4.2 ADL

共有 30 项 RCT 报道了治疗前后 ADL 评分变化观察日常生活自立能力改善情况，其中 15 项 RCT 为中西药联合 vs 西药，4 项 RCT 为中药 vs. 空白/安慰剂，11 项 RCT 为中药 vs. 西药。Meta 分析结果显示，中药治疗可提高患者的 ADL [SMD=-0.64, 95%CI (-0.90, -0.38),  $P < 0.001$ ]。干预措施的亚组分析结果显示，中药 vs. 西药组或中药 vs. 空白/安慰剂差异无统计学意义 ( $P > 0.05$ )。具体结果见表 2。

### 2.4.3 发表偏倚

经 Egger's 检验 ( $P=0.048$ ) 中药治疗 MCI 认知功能研究存在发表偏倚，漏斗图显示存在不对称 (图 3)。中药治疗 MCI、ADL 的 Egger's 检验 ( $P < 0.001$ ) 同样提示研究存在发表偏倚，漏斗图显示存在不对称 (图 4)。

表2 中药治疗轻度认知障碍认知功能和ADL亚组分析

Table 2. Subgroup analysis of cognitive function and ADL in mild cognitive impairment treated with TCM

结局	亚组	纳入RCT (项)	SMD (95% CI)	I <sup>2</sup> (%)	P	
认知功能	干预措施					
		总效应值	81	0.78 (0.67, 0.89)	81.45	<0.001
		中药+西药vs.西药	36	0.93 (0.77, 1.09)	78.54	<0.001
		中药vs.西药	25	0.51 (0.35, 0.66)	71.89	<0.001
		中药vs.空白/安慰剂	20	0.84 (0.63, 1.05)	80.76	<0.001
		疾病类型				
		MCI	42	0.71 (0.56, 0.87)	82.88	<0.001
		MCI合并其他疾病	39	0.85 (0.70, 1.00)	79.43	<0.001
		随访时间 (个月)				
		<6	43	0.80 (0.66, 0.93)	77.09	<0.001
	≥6	38	0.76 (0.59, 0.93)	84.96	<0.001	

续表2

结局	亚组	纳入RCT (项)	SMD (95% CI)	I <sup>2</sup> (%)	P	
ADL	干预措施					
		总效应值	30	-0.64 (-0.90, -0.38)	92.08	<0.001
		中药+西药vs.西药	15	-1.19 (-1.63, -0.75)	92.34	<0.001
		中药vs.西药	11	-0.11 (-0.27, 0.06)	49.24	0.206
		中药vs.空白/安慰剂	4	-0.16 (-0.37, 0.05)	47.35	0.148
	疾病类型					
		MCI	16	-0.36 (-0.61, -0.10)	84.36	<0.001
		MCI合并其他疾病	14	-0.98 (-1.46, -0.51)	94.84	<0.001
	随访时间 (个月)					
		<6	16	-0.67 (-1.04, -0.30)	90.82	<0.001
	≥6	14	-0.61 (-0.99, -0.24)	93.13	<0.001	

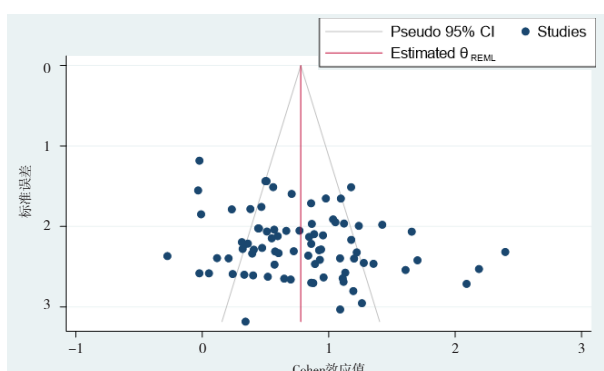


图3 中药治疗MCI患者认知功能的漏斗图  
Figure 3. Funnel plot of cognitive function in MCI patients treated with TCM

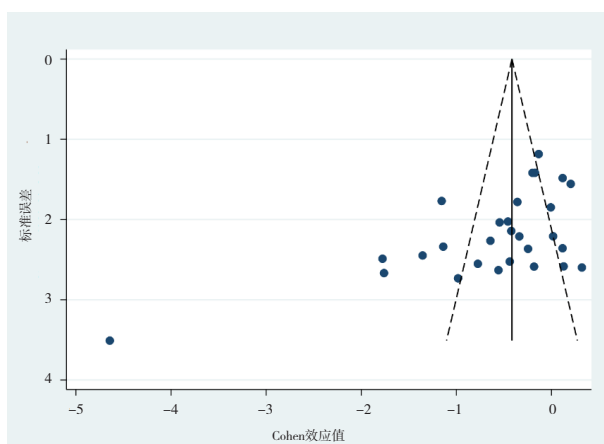


图4 漏斗图  
Figure 4. Funnel plot

### 2.4.3 不良反应发生率

共有 51 项 RCT 涉及不良反应的报道，其中 21 项 RCT 报道未见任何不良反应，29 项 RCT 报道了具体的不良反应例数，1 项 RCT 仅报道了治疗组的不良反应例数，未报道对照组的不良反应例数。分析结果显示，中药干预 MCI 患者的

不良事件发生率与对照组比较差异无统计学意义 [RR=0.72, 95%CI (0.51, 1.02), P=0.066]。亚组分析结果显示，中药与西药相比，中药的不良反应发生率较低 [RR=0.33, 95%CI (0.24, 0.44), P<0.001]; 而其他干预方式差异无统计学意义 (P>0.05)。具体结果见图 5。

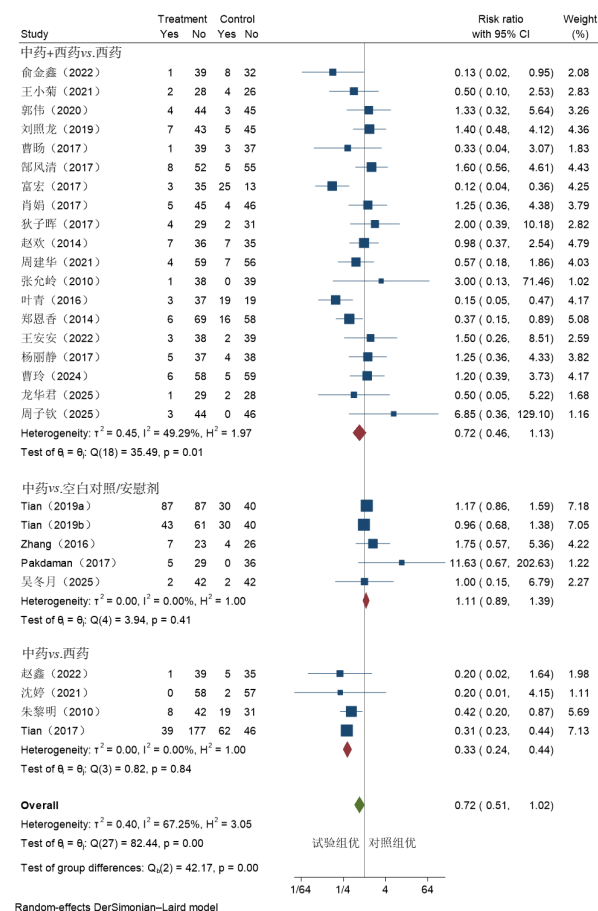


图5 中药治疗MCI不良反应发生率的森林图  
Figure 5. Forest plot of adverse reaction incidence in MCI treated with TCM

### 3 讨论

本系统评价纳入了 77 项 RCT，涉及 7 997 例患者，分析结果显示无论是单独使用中药还是中西医结合治疗，均能显著改善 MCI 患者的认知功能和 ADL。亚组分析结果显示，中西药联合效果更佳。此外，安全性分析结果显示中药组的不良反应发生率与西药组差异无统计学意义，未发现明显的不良反应风险。

既往虽有关于中药治疗 MCI 的系统评价研究<sup>[1, 4, 86-88]</sup>，但本文通过优化纳入排除标准与更新证据体量，提供了更为全面且稳健的循证证据。首先，针对不同研究采用 MMSE、MoCA 等不同量表导致难以合并的问题，以往的 Meta 分析多采用分开描述或分别分析的策略，这在一定程度上分散了统计学功效。本研究采用 SMD 作为效应指标，有效整合了不同量表的结局数据，从而更准确地评估了中药对认知功能的整体改善效应。其次，在比较模式上，Yu 等<sup>[1]</sup>主要聚焦于“中药联合多奈哌齐”的增效作用，这种设计难以剥离中药作为单一疗法的绝对效应。相比之下，本研究纳入了“中药 vs. 安慰剂/空白”及“中药 vs. 西药”的多种对比模式，不仅证实了中西药联合方案的疗效较好，也明确了中药单药治疗的临床价值。此外，鉴于该领域临床试验增长迅速，本研究将检索时间延伸至 2025 年 12 月，纳入了此前 Meta 分析未能涵盖的大量研究<sup>[4, 86]</sup>。最终纳入的 77 项研究显著提升了 Meta 分析的统计效能，克服了小样本量研究结果不稳定的缺陷。

尽管 MCI 被认为是阿尔茨海默病防治的“黄金窗口期”，但目前临床治疗方案仍面临严峻挑战。虽然美国食品药品监督管理局（U.S. Food and Drug Administration, FDA）近期批准了针对  $\beta$ -淀粉样蛋白病理的疾病修饰药物（如 Lecanemab 和 Donanemab）用于早期阿尔茨海默病（含 MCI 阶段）<sup>[89-90]</sup>，但其高昂的治疗成本、严格的输注要求以及潜在的淀粉样蛋白相关影像学异常风险，限制了其在广泛人群中的普及应用。相比之下，传统胆碱酯酶抑制剂（如多奈哌齐）虽被指南推荐超适应症使用，但其仅能提供暂时的症状缓解，且长期使用的胃肠道副作用往往导致患者依从性下降<sup>[91-92]</sup>。本研究的亚组分析显示，“中西医结合治疗”的效果较好，西药针对单一神经递

质传递进行快速干预，而中药通过多成分发挥神经保护和全身调节作用，两者结合可能产生了协同作用。

中药的多种有效成分对 MCI 的多种致病因素和病理改变发挥着多种生物学效应。目前，中药已被证明可通过延缓  $\beta$ -淀粉样蛋白沉积和 Tau 病变、调节胆碱能神经递质、改善脑循环脑代谢、防止海马神经元凋亡等途径改善认知功能<sup>[6]</sup>。如复方菖蒲益智汤可降低血清乙酰胆碱脂酶活性与同型半胱氨酸水平，从而提高患者认知功能与生活质量；丹参酮 IIA 可降低皮层氧化应激水平，上调谷氨酸和  $\gamma$ -氨基丁酸水平，达到抗炎和神经保护作用等<sup>[93]</sup>。

本研究也存在一些不足：第一，纳入的部分研究存在较高偏倚风险，可能会影响研究结果的可信度；第二，统计分析结果显示存在较高的异质性，这可能与研究之间的纳入人群、不同的中药干预、结局的评定方式、随访时间等相关；第三，漏斗图显示研究结果具有发表偏倚，对研究结果存在一定的影响。由于阴性结果往往难以发表，发表偏倚常常难以避免；第四，安全性结局报告不足，仅有 25 项试验报告了具体不良事件的数据，影响安全性评价的准确性；第五，本研究的纳入与排除标准可能会剔除一些小样本或发表在非核心期刊上的研究，这可能会对研究结果的全面性产生一定影响。

综上所述，中药可有助于提高 MCI 患者的认知水平和 ADL，其中以中西药联合治疗效果相对更佳，且中药不良反应发生率低于西药。虽然本研究纳入研究数量较多，但由于文献质量偏低，未来需要更大规模、高质量的研究以进一步验证中药是否有益于 MCI，为临床治疗方案的选择提供更科学的依据。

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