

非药物干预改善脑卒中后失眠症状疗效的网状Meta分析



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【摘要】目的 采用网状 Meta 分析方法评价非药物干预改善脑卒中后失眠症状的疗效。方法 检索 PubMed、The Cochrane Library、Embase、Web of Science、中国知网、万方、维普、中国生物医学文献数据库 (CBM) 中自建库至 2024 年 5 月有关非药物干预改善脑卒中后失眠症状的随机对照试验 (randomized controlled trial, RCT), 由两名研究人员对文献进行筛选、提取资料并评价纳入研究的偏倚风险后, 采用 Stata 15.0 软件进行网状 Meta 分析。结果 共纳入 42 项 RCT, 包括 2 945 例患者, 涉及 9 种非药物干预措施 (耳穴贴压、高压氧疗法、重复经颅磁刺激、穴位贴敷、中药浴足、针刺疗法、电针、五音疗法、艾灸)。网状 Meta 分析结果显示, 在 PSQI 评分方面, 中药浴足 [MD=-3.70, 95%CI (-6.04, -1.36)]、电针 [MD=-3.50, 95%CI (-5.36, -1.64)]、重复经颅磁刺激 [MD=-3.33, 95%CI (-4.70, -1.95)]、针刺疗法 [MD=-2.95, 95%CI (-3.72, -2.19)]、耳穴贴压 [MD=-2.93, 95%CI (-4.38, -1.47)] 效果优于镇静安眠西药 ($P < 0.05$), 中药浴足效果最佳; 在总有效率方面, 电针 [OR=6.32, 95%CI (2.97, 13.47)]、针刺疗法 [OR=4.41, 95%CI (3.01, 6.48)]、耳穴贴压 [OR=3.63, 95%CI (1.91, 6.87)] 优于镇静安眠西药 ($P < 0.05$), 电针效果最佳。结论 现有证据表明, 中药浴足在改善脑卒中后睡眠质量的 PSQI 评分方面, 以及电针在改善脑卒中后失眠症状的总有效率方面具有一定优势, 但此结论仍需更多高质量、大样本的 RCT 进一步验证。

【关键词】脑卒中; 失眠; 非药物干预; 网状 Meta 分析; 随机对照试验

Efficacy of non-drug intervention in improving insomnia symptoms after stroke: a network Meta-analysis

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【Abstract】Objective To evaluate the efficacy of non-drug intervention in improving insomnia symptoms after stroke by a network Meta-analysis. **Methods** PubMed, The Cochrane Library, Embase, Web of Science, CNKI, WanFang Data, VIP and CBM were searched for the randomized controlled trials (RCTs) about the improvement of post-stroke insomnia symptoms

DOI: 10.12173/j.issn.1004-4337.202404043

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by non-drug intervention from the inception of the databases to May 2024. Two researchers screened the literature, extracted data, and evaluated the risk of bias of the included studies. Stata 15.0 software was used to perform a network Meta-analysis. **Results** A total 42 RCTs, including 2 945 patients, involving nine non-pharmaceutical interventions (auricular application pressure, hyperbaric oxygen therapy, repetitive transcranial magnetic stimulation, point application, Chinese medicine foot bath, acupuncture, acusector, five-tone therapy, moxibustion). Results of the network Meta-analysis showed that, in the aspects of PSQI scores, the effects of Chinese medicine foot bath [MD=-3.70, 95%CI(-6.04, -1.36)], acusector [MD=-3.50, 95%CI(-5.36, -1.64)], repetitive transcranial magnetic stimulation [MD=-3.33, 95%CI(-4.70, -1.95)], acupuncture [MD=-2.95, 95%CI(-3.72, -2.19)] and auricular application pressure [MD=-2.93, 95%CI(-4.38, -1.47)] were better than that of western medicine for sedation and sleep ($P<0.05$). The effect of Chinese medicine foot bath was the best. In terms of total effective rate, acusector [OR=6.32, 95%CI(2.97, 13.47)], acupuncture [OR=4.41, 95%CI(3.01, 6.48)] and auricular application pressure [OR=3.63, 95%CI(1.91, 6.87)] were superior to western medicine for sedation and sleep ($P<0.05$). Acusector had the best effect. **Conclusion** The existing evidence showed that Chinese medicine foot bath could improve the PSQI score of sleep quality after stroke, and acusector had certain advantages in improving the total effective rate of insomnia symptoms after stroke, but more high-quality and large sample randomized controlled studies are needed to further verify this conclusion.

【Keywords】 Stroke; Insomnia; Non-drug intervention; Network Meta-analysis; Randomized controlled trial

世界卫生组织 (World Health Organization, WHO) 2019 年公布的《全球卫生估计报告》显示, 脑卒中是仅次于缺血性心脏病的全球第二大死亡及致残原因, 每年约有 150~200 万新发病例, 且呈现逐步年轻化的趋势, 也是我国成人致死、致残的首位病因, 具有高发病率、高致残率、高死亡率、高复发率、高经济负担五大显著特点^[1-3]。相关流行病学调查显示, 18~45 岁青年脑卒中患者约占全球脑卒中患者的 10%, 而老年脑卒中患者占比达 60% 以上^[4-5]。脑卒中幸存者在渡过卒中急性期后常受到多种后遗症的困扰, 如吞咽、记忆、空间视觉及直觉的缺损, 同时易遭受一系列精神健康问题, 如焦虑、抑郁、失眠等^[6-7], 给个人及家庭造成沉重的经济及精神负担。卒中后失眠是以入睡困难、睡眠中断等为主要临床表现的卒中后常见并发症^[8]。相关研究显示, 卒中后失眠发生率约为 20%~59.5%, 不仅会对患者的精神心理健康、四肢躯体功能恢复、生活质量等产生负面影响, 还与脑卒中的预后密切相关^[9-10]。相关证据表明, 脑卒中与睡眠之间存在双向关系, 睡眠质量差是脑卒中的风险因素, 一定程度上会

恶化脑卒中预后^[11]。目前临床大多使用镇静安眠类西药如苯二氮卓类药物干预卒中后失眠, 但长期服用此类药物会导致患者出现肌张力升高、糖类代谢紊乱等一系列副作用, 且易产生成瘾及耐药性^[12-13], 不利于卒中后患者进一步康复。非药物干预手段如耳穴贴压、针刺、音乐疗法等改善脑卒中后失眠的效果已得到相关研究验证^[14-16], 然而, 由于干预手段众多且不统一, 何种非药物干预措施对于改善卒中后失眠的效果最佳尚无明确定论。网状 Meta 分析近年来逐渐受到研究人员的重视, 其最大优势在于可对众多干预措施进行间接比较及定量分析, 并依照各结局指标疗效筛选出最佳治疗手段^[17]。本研究采用网状 Meta 分析方法探讨非药物干预手段改善脑卒中后失眠症状的效果, 以期为临床实践及护理选择最佳的非药物干预方法提供依据。

1 资料与方法

1.1 纳入与排除标准

1.1.1 纳入标准

① 研究类型: 随机对照试验 (randomized

controlled trial, RCT)；②研究对象：诊断明确的卒中患者，患者的年龄、性别、种族不限。卒中诊断主要参照《中国各类主要脑血管病诊断要点 2019》^[18]中的卒中诊断标准或经 CT、MRI 检查确诊为卒中；失眠诊断主要参考《中国成人失眠诊断与治疗指南（2017 版）》^[19]中有关标准或根据第 3 版《中国精神障碍分类与诊断标准》^[20]判断；③干预措施：试验组采用非药物干预措施，对照组采用不同于试验组的干预措施如镇静安眠类西药（包括阿普唑仑、艾司唑仑、唑吡坦、地西洋、佑佐匹克隆等）、常规针刺等；④结局指标：总有效率〔痊愈 + 显效 + 有效〕/ 样本量^[21]、匹兹堡睡眠指数量表评分（pittsburgh sleep quality index, PSQI）、不良反应报告。

1.1.2 排除标准

①采用联合或混合干预方法进行干预；②综述、动物实验、会议论文；③数据重复、有误或无法提取；④非中、英文。

1.2 文献检索策略

采用主题词与自由词相结合的方式，检索 PubMed、The Cochrane Library、Embase、Web of Science、中国知网、万方、维普及中国生物医学期文献数据库（CBM），搜集自建库至 2024 年 5 月有关非药物干预改善卒中后失眠症状的文献，并追溯纳入文献的参考文献作为补充。中文检索词包含脑卒中、脑中风、脑血管意外、脑梗死、脑梗塞、脑出血、失眠、睡眠障碍、睡眠困难、不寐；英文检索词包含 stroke、cerebrovascular disease、cerebral infraction、cerebral hemorrhage、apoplexy、cerebrovascular attack、cerebrovascular accident、randomized control trial、randomised control trial、RCT、randomise*、randomize*、experimental 等。以 Pubmed 为例，具体检索策略见框 1。

1.3 文献筛选与资料提取

由两位具备循证医学知识的研究人员依照文献纳排标准独立进行文献筛选、提取资料并交叉核对，如有分歧则与第三位研究人员讨论解决。资料提取内容包括作者、研究发表年份、国家、样本量、年龄、干预措施、疾病病程、疗程和结局指标等。

1.4 文献质量评价

由两位研究者依照 Cochrane 图书馆推荐的

RCT 偏倚风险评估工具^[22]进行文献质量评价，评价内容包括随机序列产生方式、分配隐藏的措施、盲法的使用、数据报告是否完整、是否选择性报告研究结果及其他偏倚。每项评价可选择“不清楚”“低风险”和“高风险”；质量等级分为 A、B、C 三级，若全部符合评价标准，任何偏倚的可能性均较小，则为 A 级；若部分条目符合评价标准，偏倚可能性为中等，则评为 B 级；若完全不符合上述质量标准，偏倚风险可能性很高，则评为 C 级。若研究者各持不同意见，则咨询第三方协商解决。

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#1 insomnia [Mesh]
#2 "sleep disorder" [Title/Abstract] OR "sleep problem" [Title/Abstract] OR "sleep wake disorders" [Title/Abstract] OR sleep [Title/Abstract]
#3 #1 OR #2
#4 stroke [Mesh]
#5 "cerebrovascular disease" [Title/Abstract] OR "cerebral infraction" [Title/Abstract] OR "cerebral hemorrhage" [Title/Abstract] OR apoplexy [Title/Abstract] OR "cerebrovascular attack" [Title/Abstract] OR "cerebrovascular accident" [Title/Abstract]
#6 #4 OR #5
#7 "randomized control trial" [Mesh]
#8 "randomised control trial" [Title/Abstract] OR RCT [Title/Abstract] OR "randomise*" [Title/Abstract] OR "randomize*" [Title/Abstract] OR experimental [Title/Abstract]
#9 #7 OR #8
#10 #3 AND #6 AND #9
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框1 PubMed检索策略

Box 1. Search strategy in PudMed

1.5 统计分析

采用 Stata 15.0 软件中 mvmeta 安装包及相关代码命令进行网状 Meta 分析，首先对研究进行不一致性检验，若证据网络图存在闭环，则采用节点切割法进行不一致性检验， $P > 0.05$ 提示直接比较与间接比较之间无明显不一致，采用一致性模型进行网状 Meta 分析。若研究结局指标为分类变量时，采用比值比（odds ratio, OR）表示；若为连续性变量，则采用加权均方差（mean difference, MD）及其 95% 置信区间（confidence

interval, CI) 表示。采用累积概率排序概率图下面积 (surface under cumulative ranking area, SUCRA) 反映各干预措施成为最佳的可能性。绘制漏斗图进行发表偏倚检验。以 $P < 0.05$ 为差异具有统计学意义。

2 结果

2.1 文献筛选流程及结果

检索数据库后共获得文献 4 912 篇, 经逐层筛选, 最终纳入 42 篇文献, 文献筛选流程见图 1。

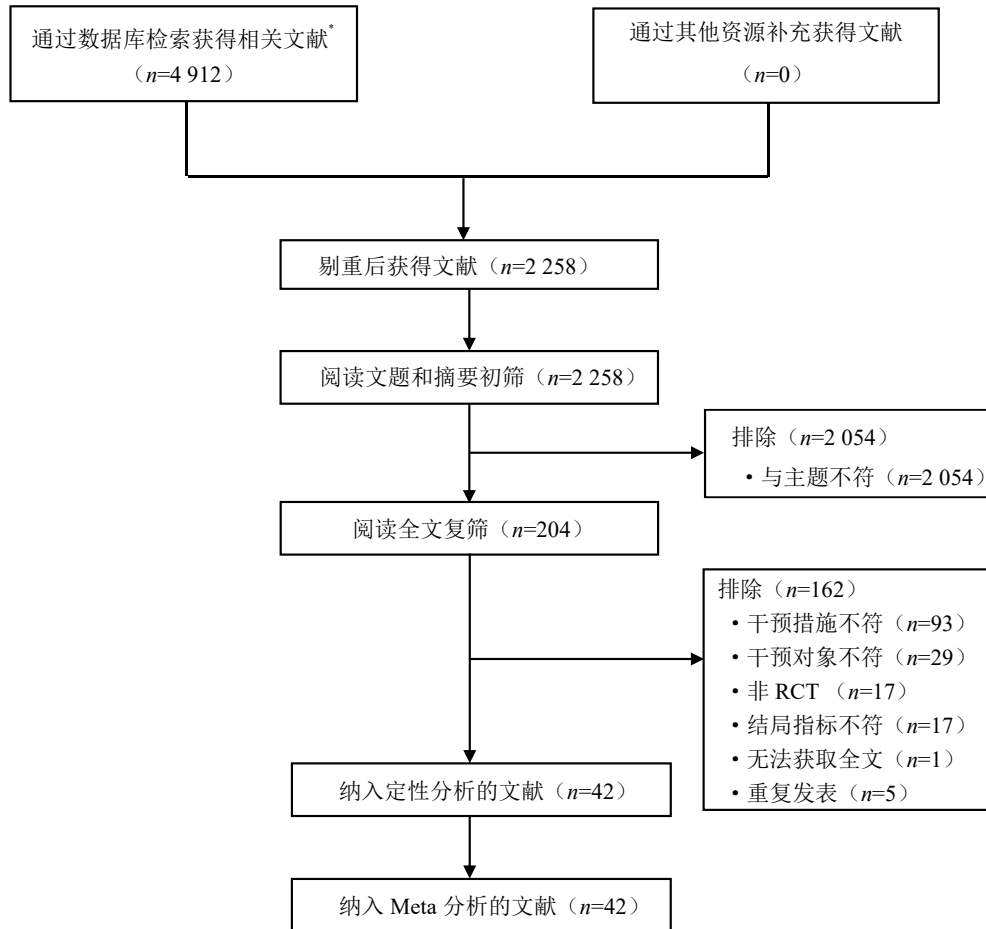


图1 文献筛选流程图

Figure 1. Flowchart of literature screening

注: *检索的数据库及具体文献检出数为中国知网 ($n=1\ 392$)、万方 ($n=275$)、维普 ($n=193$)、CBM ($n=42$)、PubMed ($n=1\ 425$)、Embase ($n=559$)、The Cochrane Library ($n=373$)、Web of Science ($n=653$)。

2.2 纳入文献基本特征

共纳入 42 篇文献^[23-64], 其中中文文献 41 篇、英文文献 1 篇, 包括 2 945 例患者, 涉及 9 种非药物干预措施, 分别为耳穴贴压、高压氧疗法、重复经颅磁刺激、穴位贴敷、中药浴足、针刺疗法、电针、五音疗法、艾灸。纳入文献基本特征见表 1。

2.3 纳入文献的偏倚风险评价结果

21 项研究^[24, 29-30, 32-34, 36-37, 39, 41, 44-45, 47-49, 52, 54, 60-62, 64]采用随机数字表法或通过计算机软件生成的随机数进行随机分组, 1 项研究^[55]采用区组随机进行

分组, 1 项研究^[50]采用掷骰子法进行随机分组, 3 项研究^[23, 43, 58]采用就诊顺序进行分组, 16 项研究^[25-28, 31, 35, 38, 40, 42, 46, 51, 53, 55, 57, 59, 63]仅提及随机字样, 其具体随机方式未予以详细说明; 因随机对照干预试验及其部分非药物干预措施的特殊性, 在临床中盲法难以实现, 仅 7 项研究^[37-39, 41, 60-62]提及盲法的实施, 4 项研究^[39, 41, 61-62]提及分配隐藏, 2 项研究^[39, 41]存在研究病例脱落情况, 但均报告了脱落的组别及其具体的脱落原因, 其余研究病例分组资料均完整。最终纳入文献级别均为 B 级, 偏倚风险评价结果见图 2 和图 3。

表1 纳入文献基本特征
Table 1. Basic characteristics of the included literature

纳入研究	国家	样本量(例)		平均年龄(岁)		病程		干预措施		疗程	结局指标
		T/C		T	C	T	C	T	C		
吴雪兰等 2012 ^[23]	中国	40/40	67.60 ± 10.40	66.20 ± 9.60	-	-	-	-	耳穴贴压	2周	①
邢雨胜 2014 ^[24]	中国	32/32	55.40 ± 6.40	54.80 ± 7.20	18.70 ± 7.90 ^b	17.80 ± 7.30 ^b	-	-	耳穴贴压	2周	①②
王子豪等 2020 ^[25]	中国	25/25	60.64 ± 10.82	59.28 ± 9.04	77.56 ± 45.49 ^c	76.00 ± 37.64 ^c	-	-	耳穴贴压	3周	①②
吴国英等 2012 ^[26]	中国	30/30	-	-	-	-	-	-	耳穴贴压	4周	②
钱铃铃 2016 ^[27]	中国	20/20	58.06 ± 11.60	59.32 ± 11.10	-	-	-	-	耳穴贴压	2周	②
梁秀莉 2016 ^[28]	中国	60/60	48.00 ± 7.50	48.20 ± 6.70	4.50 ± 0.70 ^a	4.70 ± 0.60 ^a	-	-	耳穴贴压	3周	①
张华军等 2022 ^[29]	中国	50/47	67.38 ± 2.98	67.62 ± 3.60	3.7 ± 0.88 ^b	3.78 ± 0.92 ^b	-	-	耳穴贴压	4周	①
孟庆涛 2020 ^[30]	中国	49/49	58.61 ± 5.30	57.56 ± 5.41	-	-	-	-	高压氧疗	4周	①
华美香等 2016 ^[31]	中国	30/30	-	-	-	-	-	-	高压氧疗	2周	①②③
徐丹等 2021 ^[32]	中国	30/28	65.70 ± 6.10	64.20 ± 5.90	39.40 ± 3.50 ^c	37.60 ± 3.20 ^c	-	-	rTMS	4周	①③
黄丹霞 2022 ^[33]	中国	45/45	61.06 ± 4.65	61.20 ± 4.69	-	-	-	-	rTMS	2周	①
陈鹏等 2018 ^[34]	中国	32/32	64.20 ± 6.90	66.50 ± 6.90	37.20 ± 5.40 ^c	39.80 ± 7.20 ^c	-	-	rTMS	4周	①②
Armalia等 2021 ^[35]	印度尼西亚	24/24	-	-	-	-	-	-	rTMS	-	①
齐文耀等 2022 ^[36]	中国	46/45	63.12 ± 6.07	63.75 ± 5.92	6.44 ± 1.13 ^b	6.37 ± 1.09 ^b	-	-	rTMS	4周	①③
陈曦光 2014 ^[37]	中国	30/30	65.96 ± 10.15	66.46 ± 11.91	-	-	-	-	穴位贴敷	2周	①②
许幸仪等 2013 ^[38]	中国	30/30	-	-	-	-	-	-	穴位贴敷	2周	①②
郝文文 2016 ^[39]	中国	27/29	65.79 ± 13.28	64.56 ± 15.47	9.20 ± 2.69 ^c	10.50 ± 3.78 ^c	-	-	中药浴足	1周	①③
陈惠玲等 2016 ^[40]	中国	32/32	72.20 ± 18.10	70.40 ± 17.60	29.20 ± 7.20 ^c	30.20 ± 5.90 ^c	-	-	中药浴足	1周	①②
蔡淑满 2020 ^[41]	中国	43/43	63.37 ± 10.42	64.77 ± 9.63	-	-	-	-	针刺	8周	③
贾瑞芝 2010 ^[42]	中国	30/30	62.50 ± 6.40	63.10 ± 7.00	31.20 ± 6.60 ^c	36.50 ± 8.10 ^c	-	-	针刺	4周	①②
叶翠河等 2013 ^[43]	中国	43/42	62.80 ± 7.20	67.30 ± 8.30	21.30 ± 7.40 ^c	24.60 ± 6.90 ^c	-	-	针刺	4周	①②
李泰标 2007 ^[44]	中国	32/32	69.80 ± 7.10	67.30 ± 8.30	48.00 ± 4.60 ^c	46.00 ± 5.30 ^c	-	-	针刺	4周	①②
刘健红等 2006 ^[45]	中国	32/30	69.90 ± 6.90	67.50 ± 8.20	34.40 ± 7.20 ^c	33.10 ± 8.30 ^c	-	-	针刺	4周	①②
朱晨 2014 ^[46]	中国	52/44	75.20 ± 1.30	74.30 ± 2.90	8.50 ± 1.50 ^c	8.70 ± 1.60 ^c	-	-	针刺	4周	①②
靳发万 2016 ^[47]	中国	28/25	-	-	-	-	-	-	针刺	4周	②
谢晓娟 2018 ^[48]	中国	43/40	56.94 ± 9.83	58.15 ± 12.20	39.43 ± 13.41 ^c	37.57 ± 14.92 ^c	-	-	针刺	4周	①②③
王建玲 2020 ^[49]	中国	50/48	57.82 ± 6.16	56.98 ± 1.22	38.82 ± 7.26 ^c	39.22 ± 7.14 ^c	-	-	针刺	4周	①②③

续表1

纳入研究	国家	样本量(例)		平均年龄(岁)		病程		干预措施		疗程	结局指标
		T/C		T	C	T	C	T	C		
陈源 2021 ^[50]	中国	41/41	60.24 ± 1.09	60.15 ± 1.12	3.45 ± 0.29 ^b	3.32 ± 0.34 ^b	针刺	镇静安眠西药	4周	①②	
李梦雪等 2020 ^[51]	中国	50/50	62.35 ± 11.82	61.90 ± 10.23	4.62 ± 1.35 ^b	4.70 ± 1.42 ^b	针刺	镇静安眠西药	4周	①②③	
刘军兴 2017 ^[52]	中国	35/35	62.08 ± 7.82	63.02 ± 7.79	2.59 ± 0.24 ^b	2.74 ± 0.25 ^b	针刺	镇静安眠西药	4周	①②③	
徐丰 2016 ^[53]	中国	20/20	56.26 ± 4.29	56.55 ± 4.36	20.94 ± 5.21 ^c	20.51 ± 5.31 ^c	针刺	镇静安眠西药	4周	①②	
高宇飞等 2009 ^[54]	中国	28/26	64.60 ± 6.20	63.40 ± 7.50	31.60 ± 6.80 ^c	31.10 ± 7.10 ^c	针刺	镇静安眠西药	4周	①②	
米建平等 2009 ^[55]	中国	40/40	65.28 ± 10.55	63.11 ± 11.96	26.41 ± 3.52 ^c	25.97 ± 2.70 ^c	针刺	镇静安眠西药	4周	①②	
汤宇等 2015 ^[56]	中国	34/31	58.25 ± 9.31	59.68 ± 8.73	28.64 ± 10.36 ^c	30.18 ± 8.55 ^c	针刺	镇静安眠西药	4周	①②	
郑杰等 2020 ^[57]	中国	40/40	65.60 ± 10.80	64.30 ± 10.90	-	-	针刺	镇静安眠西药	4周	①③	
王贯民等 2012 ^[58]	中国	32/30	68.70 ± 7.60	66.20 ± 6.90	33.50 ± 7.80 ^c	31.70 ± 7.30 ^c	针刺	镇静安眠西药	4周	②	
刘勇等 2021 ^[59]	中国	30/30	62.83 ± 7.48	62.60 ± 7.04	8.90 ± 3.06 ^b	8.63 ± 3.17 ^b	电针	针刺	2周	①②	
梁芳妮 2020 ^[60]	中国	35/35	55.31 ± 6.89	54.74 ± 7.35	56.71 ± 15.83 ^c	53.11 ± 11.72 ^c	电针	针刺	2周	①②	
陈晨友 2022 ^[61]	中国	33/34	62.76 ± 7.74	62.82 ± 8.70	8.45 ± 3.38 ^b	8.71 ± 3.04 ^b	电针	针刺	2周	②	
姜媛媛 2018 ^[62]	中国	30/28	54.77 ± 9.25	56.57 ± 9.09	64.07 ± 19.12 ^c	60.11 ± 23.91 ^c	电针	镇静安眠西药	3周	①②	
贾晓鑫 2021 ^[63]	中国	25/25	57.12 ± 1.98	56.77 ± 2.12	-	-	五音疗法	镇静安眠西药	2周	①②③	
杨坤等 2018 ^[64]	中国	30/30	70.09 ± 12.90	67.50 ± 11.57	16.69 ± 3.71 ^c	17.24 ± 2.77 ^c	艾灸	镇静安眠西药	2周	①②	

注: T: 试验组; C: 对照组; ①PSQI评分; ②总有效率; ③不良反应; ^a以年为单位; ^b以月为单位; ^c以天为单位; ^d以天为单位; ^e以天为单位; rTMS: 重复经颅磁刺激; -: 无数据。



图2 偏倚风险评估图

Figure 2. Risk of bias assessment

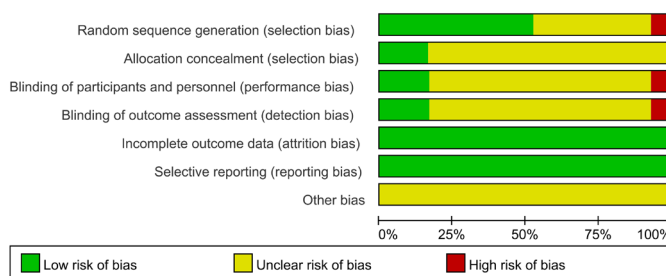


图3 纳入文献产生偏倚风险的项目所占比例

Figure 3. Proportion of items with risk of bias in the included literature

2.4 网状关系分析结果

2.4.1 PSQI评分

网状关系图显示，针刺疗法与镇静安眠西药比较的研究最多，其次为重复经颅磁刺激和耳穴贴压与镇静安眠西药的比较，针刺疗法、电针与镇静安眠西药形成 1 个闭合环，说明其既有直接比较，又有间接比较，其余非药物干预措施间尚无直接比较的证据，见图 4。

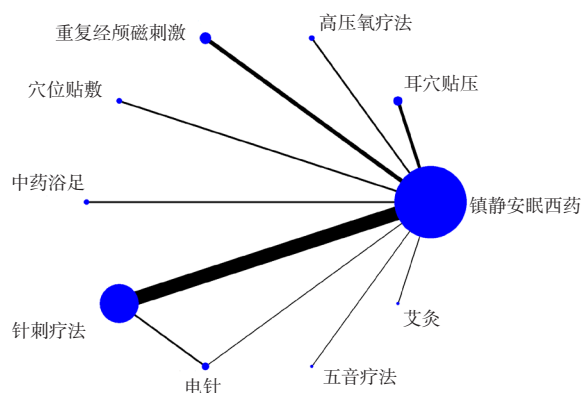


图4 PSQI的网络关系图

Figure 4. Network diagram of PSQI

2.4.2 总有效率

网状关系图显示，针刺疗法与镇静安眠西药比较的研究最多，耳穴贴压、穴位贴敷及高压氧疗法与镇静安眠西药的比较相对较多，针刺疗法、电针与镇静安眠西药形成 1 个闭合环，其余干预措施并无直接比较的证据，见图 5。

2.5 网状Meta分析结果

2.5.1 不一致性检验

节点切割法分析模型结果显示 $P > 0.05$ ，说明直接比较与间接比较结果一致，采用一致性模型进行网状 Meta 分析。

2.5.2 PSQI评分

36 项研究^[24-25, 28-46, 48-57, 59-60, 62-64]报告了

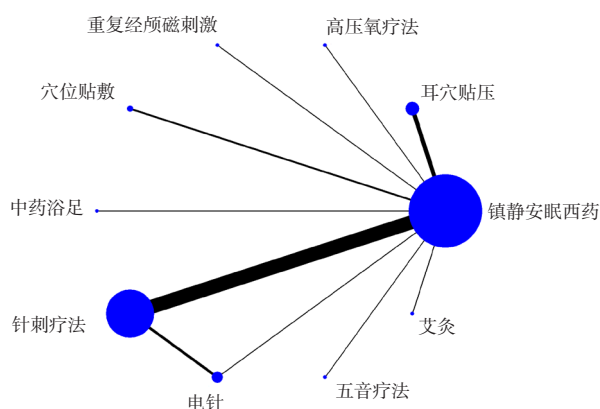


图5 总有效率的网络关系图

Figure 5. Network diagram of total efficiency

PSQI 评分。网状 Meta 分析结果显示，中药浴足 [MD=-3.70, 95%CI (-6.04, -1.36)]、电针 [MD=-3.50, 95%CI (-5.36, -1.64)]、重复经颅磁刺激 [MD=-3.33, 95%CI (-4.70, -1.95)]、针刺疗法 [MD=-2.95, 95%CI (-3.72, -2.19)]、耳穴贴压 [MD=-2.93, 95%CI (-4.38, -1.47)] 的 PSQI 评分优于镇静安眠西药 ($P < 0.05$)。最佳概率累积排序结果值从高到低依次为：中药浴足 (78%) > 电针 (74.3%) > 重复经颅磁刺激 (72%) > 针刺疗法 (61.1%) > 耳穴贴压 (60.4%) > 艾灸 (48.7%) > 高压氧疗法 (48.5%) > 五音疗法 (30.2%) > 穴位贴敷 (21.8%) > 镇静安眠西药 (4.9%)，见表 2 和图 6。

2.5.3 总有效率

32 项研究^[23-27, 31, 34, 37-38, 40, 42-56, 58-64]报告了总有效率。网状 Meta 分析结果显示，电针 [OR=6.32, 95%CI (2.97, 13.47)]、针刺疗法 [OR=4.41, 95%CI (3.01, 6.48)]、耳穴贴压 [OR=3.63, 95%CI (1.91, 6.87)] 的总有效率优于镇静安眠西药 ($P < 0.05$)。最佳概率累积排序结果值从高到低分别为：电针 (80.5%) > 五音疗法

表2 PSQI评分的网状Meta分析结果[MD (95%CI)]
Table 2. Results of network Meta-analysis of PSQI score [MD (95%CI)]

干预措施	镇静安眠西药	穴位贴敷	五音疗法	高压氧疗法	艾灸	耳穴贴压	针刺疗法	重复经颅磁刺激	电针
穴位贴敷	-1.05 (-3.18, 1.08)								
五音疗法	-1.37 (-4.36, 1.62)	-0.32 (-3.99, 3.35)							
高压氧疗法	-2.41 (-4.55, -0.28)	-1.36 (-4.38, 1.65)	-1.04 (-4.72, 2.63)						
艾灸	-2.38 (-5.58, 0.82)	-1.33 (-5.17, 2.52)	-1.01 (-5.39, 3.37)	0.03 (-3.81, 3.88)					
耳穴贴压	-2.93 (-4.38, -1.47)*	-1.87 (-4.46, 0.71)	-1.56 (-4.88, 1.77)	-0.51 (-3.10, 2.08)	-0.55 (-4.06, 2.97)				
针刺疗法	-2.95 (-3.72, -2.19)*	-1.90 (-4.17, 0.36)	-1.58 (-4.67, 1.50)	-0.54 (-2.80, 1.72)	-0.57 (-3.86, 2.72)	-0.03 (-1.68, 1.62)			
重复经颅磁刺激	-3.33 (-4.70, -1.95)*	-2.28 (-4.81, 0.26)	-1.96 (-5.25, 1.33)	-0.91 (-3.45, 1.62)	-0.95 (-4.43, 2.53)	-0.40 (-2.41, 1.60)	-0.37 (-1.95, 1.20)		
电针	-3.50 (-5.36, -1.64)*	-2.44 (-5.27, 0.38)	-2.13 (-5.65, 1.39)	-1.08 (-3.91, 1.74)	-1.12 (-4.82, 2.58)	-0.57 (-2.94, 1.79)	-0.54 (-2.35, 1.26)	-0.17 (-2.48, 2.14)	
中药浴足	-3.70 (-6.04, -1.36)*	-2.65 (-5.82, 0.52)	-2.33 (-6.13, 1.47)	-1.29 (-4.46, 1.88)	-1.32 (-5.29, 2.64)	-0.78 (-3.54, 1.98)	-0.75 (-3.21, 1.72)	-0.37 (-3.09, 2.34)	-0.20 (-3.20, 2.79)

注: * $P < 0.05$ 。

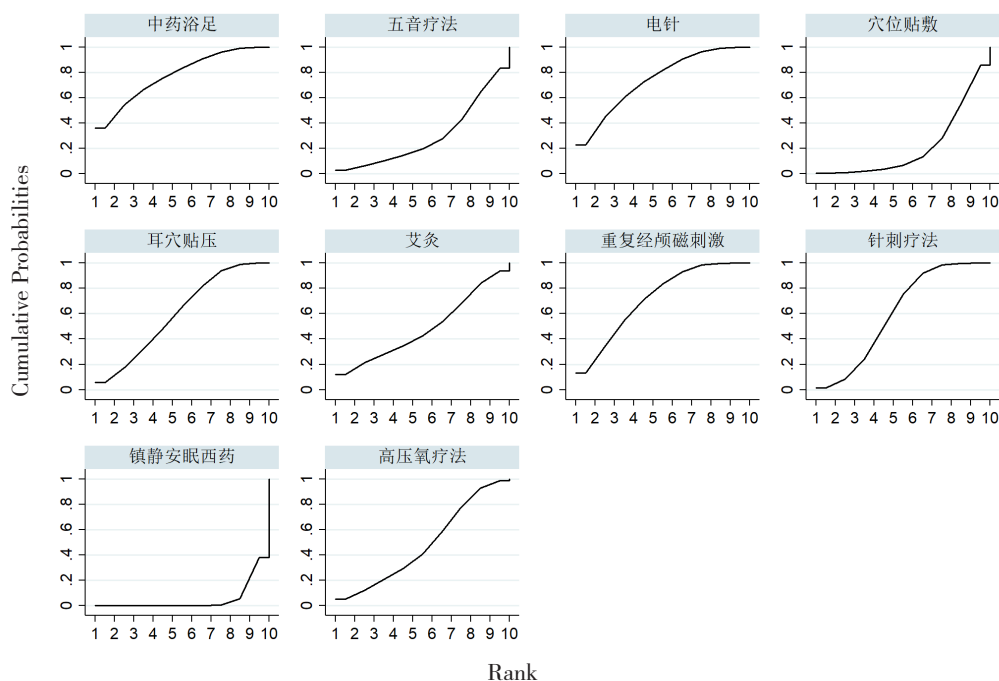


图6 PSQI评分的累积概率排序图

Figure 6. Cumulative probability ranking plot of PSQI scores

(75.6%) > 艾灸 (67.3%) > 针刺疗法 (64.4%) > 重复经颅磁刺激 (59.9%) > 耳穴贴压 (55.1%) > 穴位贴敷 (36.3%) > 中药浴足 (29.6%) > 高压氧疗法 (22.9%) > 镇静安眠西药 (8.4%)，见图 7 和表 3。

2.6 发表偏倚检验

对 PSQI 评分和总有效率两项结局指标绘制漏斗图，不同颜色代表不同的干预措施。漏斗图显示各散点不完全对称，说明可能存在发表偏倚或小样本效应，见图 8。

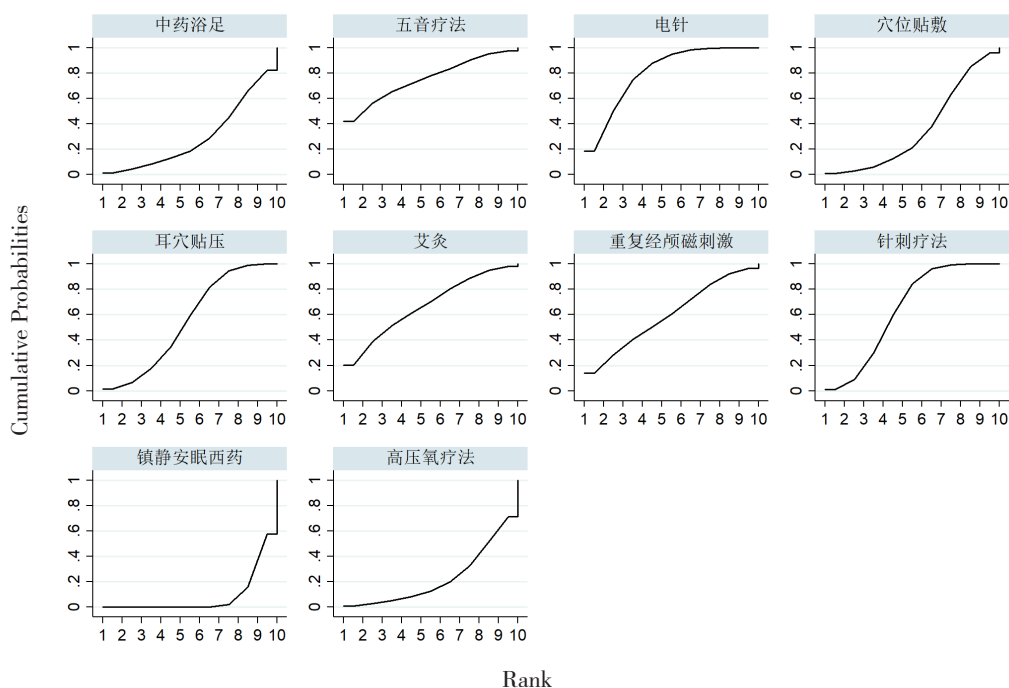


图7 总有效率的累积概率排序图

Figure 7. Cumulative probability ranking plot of total effective rates

表3 总有效率的网状Meta分析结果[OR (95%CI)]
Table 3. Results of network Meta-analysis of total effective rate [OR (95%CI)]

干预措施	镇静安眠西药	高压氧疗法	中药浴足	穴位贴敷	耳穴贴压	重复经颅磁刺激	针刺疗法	艾灸	五音疗法
高压氧疗法		1.38 (0.28, 6.80)							
中药浴足		1.79 (0.39, 8.22)	1.29 (0.14, 11.71)						
穴位贴敷		2.24 (0.78, 6.46)	1.62 (0.24, 10.94)	1.25 (0.20, 8.01)					
耳穴贴压		3.63 (1.91, 6.87)*	2.62 (0.47, 14.55)	2.03 (0.39, 10.58)	1.62 (0.47, 5.57)				
重复经颅磁刺激		4.20 (0.80, 22.06)	3.03 (0.30, 30.20)	2.35 (0.25, 22.32)	1.87 (0.26, 13.39)	1.16 (0.20, 6.85)			
针刺疗法		4.41 (3.01, 6.48)*	3.19 (0.62, 16.38)	2.47 (0.51, 11.87)	1.97 (0.64, 6.06)	1.22 (0.58, 2.56)	1.05 (0.19, 5.77)		
艾灸		5.09 (0.98, 26.43)	3.68 (0.37, 36.30)	2.84 (0.30, 26.82)	2.27 (0.32, 16.08)	1.40 (0.24, 8.21)	1.21 (0.12, 12.55)	1.15 (0.21, 6.26)	
五音疗法		7.58 (0.84, 68.46)	5.47 (0.36, 82.73)	4.23 (0.29, 61.58)	3.38 (0.29, 38.85)	2.09 (0.21, 20.67)	1.80 (0.11, 28.40)	1.72 (0.18, 16.03)	1.49 (0.10, 23.26)
电针		6.32 (2.97, 13.47)*	4.57 (0.78, 26.58)	3.53 (0.64, 19.36)	2.82 (0.77, 10.35)	1.74 (0.65, 4.69)	1.51 (0.24, 9.32)	1.43 (0.71, 2.87)	0.83 (0.20, 7.61)

注: * $P < 0.05$ 。

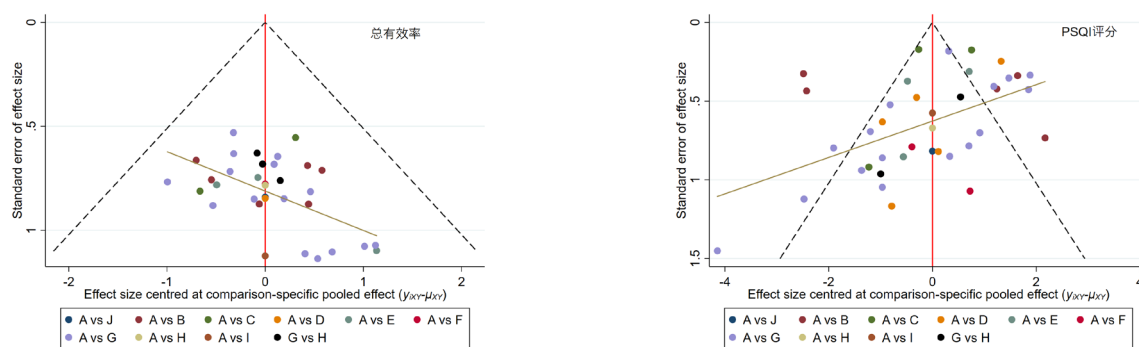


图8 PSQI评分和总有效率的漏斗图

Figure 8. Funnel plot of PSQI scores and total effective rates

注：A. 镇静安眠西药；B. 耳穴贴压；C. 高压氧疗法；D. 重复经颅磁刺激；E. 穴位贴敷；F. 中药浴足；G. 针刺疗法；H. 电针；I. 五音疗法；J. 艾灸。

3 讨论

脑卒中后失眠是卒中后患者常见的后遗症，长期睡眠障碍既是脑卒中发生的危险因素，又会对脑卒中患者后期康复产生不利影响。由于药物干预措施存在耐药及成瘾性，近年来非药物干预措施改善脑卒中后失眠得到了广泛关注。本研究通过检索各大数据库，对改善脑卒中后失眠的非药物干预措施进行网状 Meta 分析，结果显示，在改善脑卒中后睡眠质量的 PSQI 评分方面，中药浴足、电针、重复经颅磁刺激、针刺、耳穴贴压优于镇静安眠西药，其中中药浴足的效果最好。中医学认为，卒中后失眠为继发性失眠的一种，属“不寐”范畴，其病位在心，与肝、脾、肾均密切相关，根本病因在于阴阳不交。《黄帝内经》记载：“百病始于脚，人老脚先衰，养生先养脚，护足不畏老”。中药浴足法以传统中医脏腑经络理论为基础，结合脏象学说和西医的皮肤黏膜吸收与物理刺激原理，选用由一种或多种中药组成的方剂包进行足部熏洗、浸泡，在热温、热力的作用下药物中的有效成分可通过足部丰富的穴位与五脏六腑相连，并刺激穴位，以发挥疏通经络、调节脏腑阴阳平衡的作用，进而达到改善卒中后失眠症状的功效^[65]，这与相关研究结论一致^[66-67]。中药浴足法操作简单方便、普适性强、安全性高且具有良好的经济效益，但在临床上需根据患者的失眠证型开具浴足方剂，做到因人而异、辨证施方。

在改善脑卒中后失眠症状的总有效率方面，电针、针刺疗法、耳穴贴压优于镇静安眠西药，

电针的干预效果最好。目前针刺疗法作为一种疗效确切、操作简便、无不良反应及成瘾性的传统疗法，在卒中后失眠的治疗中占有重要地位^[68-69]。电针疗法结合了毫针的针刺作用与电刺激的生理效应，低频脉冲电刺激通过毫针刺刺激腧穴，可产生镇静、止痛、促进气血循环、调整肌张力等作用，兼具针刺与电刺激的双重刺激效果，能有效延长睡眠时间、减少觉醒次数，改善脑卒中后患者的睡眠问题，并提高其认知功能，作用机制可能是通过降低大脑皮质对视觉信号的处理水平，从而改善睡眠质量^[70]。也有相关研究指出，电针改善老年失眠症患者睡眠质量及认知功能的机制可能与调节老年人体内的血清褪黑素及多巴胺水平相关^[71]。相关动物实验表明，电针可显著改善失眠大鼠睡眠-觉醒及相关激素水平的昼夜节律紊乱，其调控机制可能与其对血清褪黑素水平及节律的调节有关，从而改善卒中后睡眠障碍^[72]。

本研究存在一定局限性：一是部分文献未说明盲法及分配隐藏方案，可能存在一定的实施、测量偏倚；二是部分文献样本量较小，可能导致结果的统计学效能降低；三是受地区、医院医疗水平及干预疗程的影响，可能导致结果存在一定偏倚；四是仅以 PSQI 评分及总有效率作为结局指标，可能会对结论产生一定影响。

综上所述，现有证据表明，中药浴足在改善脑卒中后睡眠质量的 PSQI 评分方面，电针在改善脑卒中后失眠症状的总有效率方面具有一定优势，但受限于纳入研究的质量及样本量，上述结论仍需更多多中心、大样本的高质量 RCT 加以验证。

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收稿日期: 2023 年 04 月 08 日 修回日期: 2023 年 05 月 20 日
本文编辑: 张 苗 黄 笛

引用本文: 曾友, 袁敏, 明晶, 等. 非药物干预改善脑卒中后失眠症状疗效的网状 Meta 分析 [J]. 数理医药学杂志, 2024, 37(7): 509–525. DOI: [10.12173/j.issn.1004-4337.202404043](https://doi.org/10.12173/j.issn.1004-4337.202404043).
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