

· 文献研究 ·

传统功法治疗膝骨关节炎临床随机对照试验的现状分析

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摘要 目的:分析传统功法治疗膝骨关节炎(knee osteoarthritis, KOA)临床随机对照试验(randomized controlled trial, RCT)的现状。方法:计算机检索中国知网、万方数据库、维普网、中国生物医学文献服务系统、PubMed、Embase、Web of Science、Cochrane Library 中传统功法治疗 KOA 的 RCT 文献,检索时限为各数据库建库至 2025 年 2 月。对检索所得的文献进行筛选后,提取文献中 RCT 研究的基本特征信息和结局指标信息,并对提取的信息进行分析。结果:①文献检索及筛选结果。初步检索出相关文章 2412 篇,经逐层筛选后最终纳入文献 67 篇,包括中文文献 25 篇、英文文献 42 篇。②纳入研究的基本特征分析结果。纳入的 67 项研究的发表时间集中在 2003—2024 年;样本量 <60 例 21 项,60~99 例 29 项,100~200 例 12 项,>200 例 5 项;均报告了疾病的西医诊断标准,其中有 5 项研究报告了中医证型诊断标准;41 项研究的试验组干预措施为单纯传统功法治疗,26 项研究的试验组干预措施为传统功法联合其他疗法;共出现 5 种传统功法,出现频次由高至低依次为太极拳、八段锦、易筋经、气功、五禽戏;干预疗程和随访时间均以 12 周居多。③纳入研究的结局指标分析结果。45 项研究的结局指标评价时间点为干预前和干预结束后 2 个时间点,21 项研究的结局指标评价时间点为干预前、干预过程中和干预结束后 3 个时间点。26 项研究区分了主、次要结局指标,采用行业现有评价标准,其中 1 项研究对主、次要结局指标采用了不同的评价时间点;41 项未区分主、次要结局指标,均采用自定义评价标准。每项研究选取的结局指标数为 1~13 个。共涉及结局指标 86 项,可划分为 7 个指标域,包括症状/体征指标 28 项、生活质量指标 20 项、理化指标 15 项、影像和生物力学指标 12 项、其他指标 6 项、安全性指标 4 项和远期疗效指标 1 项;出现频次较高的结局指标由高至低依次为西安大略和麦克马斯特大学骨关节炎指数疼痛评分(47 次)、功能评分(46 次)、僵硬评分(43 次),以及平衡能力/本体感觉测试(33 次)和疼痛视觉模拟量表评分(22 次)。结论:目前,传统功法治疗 KOA 的 RCT 研究中,所用的功法以太极拳、八段锦、易筋经居多。这些研究的中医辨证诊断不规范,缺乏长期随访,样本量差异较大,干预疗程不一;所选取的结局指标以症状/体征指标和生活质量指标居多,结局指标的选取存在未区分主次、数量差异大、替代指标针对性不强,以及客观性、安全性、远期疗效指标应用不足和对跌倒风险关注度较低等问题。

关键词 骨关节炎,膝;随机对照试验专题;结果评价,卫生保健;太极拳;八段锦;易筋经;五禽戏;气功(中医)

Current status of clinical RCTs on traditional Chinese exercises for treatment of knee osteoarthritis

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ABSTRACT **Objective:**To analyze the current status of clinical randomized controlled trials(RCTs)on traditional Chinese exercises for treatment of knee osteoarthritis(KOA). **Methods:**All the RCTs about traditional Chinese exercises for treatment of KOA included from database's inception to February 2025 were retrieved from the China National Knowledge Infrastructure, Wanfang Database, Vip Database, Chinese Biomedical Literature Service System, PubMed, Embase, Web of Science, and Cochrane Library through computer. The pertinent articles were screened, and the information, including the basic characteristics and outcome measures of the included RCTs, was extracted and analyzed. **Results:**①Literature search and screening results. Two thousand four hundred and twelve articles were searched out. After screening, 67 articles were included in the final analysis, including 25 Chinese articles and 42 English articles. ②Basic characteristics of the included RCTs. The included 67 studies were published between 2003 and 2024, the sample size was less than 60 participants in 21 studies, 60-99 participants in 29 studies, 100-200 participants in 12 studies, over 200 participants in 5 studies. The western medical diagnostic criteria for KOA was reported in all 67 studies, with 5 ones additionally reporting the TCM syndrome differentiation criteria. The intervention in the experimental group was traditional Chinese exercises alone in 41 studies and combined traditional Chinese exercises with other therapies in 26 studies. Five distinct traditional Chinese exercises were identified in the 67 studies, ranked in a descending order by the

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occurrence frequency as follows: shadow boxing, eight-sectioned exercise, Yi Jin Jing(易筋经), qigong(TCM), five mimic animal boxing, furthermore, a 12-week duration was predominant for both intervention period and follow-up time in the 67 studies. ③Outcome measures in the included RCTs. Among the 67 studies, the outcome measures were assessed at two time points(pre- and post-intervention) in 45 studies, and at three time points(pre-, during, and post-intervention) in 21 studies. Moreover, 26 studies explicitly distinguished between primary and secondary outcome measures, employing existing industry-standard assessment criteria, notably, one study utilized different assessment time points for primary and secondary outcome measures, and 41 studies did not differentiate primary and secondary outcome measures, exclusively relied on custom assessment criteria. Each study encompassed 1 – 13 outcome measures. Besides, 86 distinct outcome measures were identified in the 67 studies and were taxonomized into 7 domains, including symptoms & signs(28), quality of life(20), physicochemical measures(15), imaging & biomechanical measures(12), other measures(6), safety measures(4) and long-term efficacy measures(1), respectively. In addition, the outcome measures were ranked in a descending order by the occurrence frequency, and the top 5 were Western Ontario and McMaster Universities osteoarthritis index(WOMAC) pain score(47 times), WOMAC function score(46 times), WOMAC stiffness score(43 times), balance & proprioception test(33 times), and visual analogue scale(VAS) pain score(22 times). **Conclusion:** Current RCTs on traditional Chinese exercises for KOA primarily focus on shadow boxing, eight-sectioned exercise, and Yi Jin Jing(易筋经). These studies exhibit critical methodological limitations such as non-standardized TCM syndrome differentiation, lack of long-term follow-up, substantial variation in sample size, and heterogeneous intervention durations, apart from that, the selected outcome measures predominantly focus on symptoms & signs, and quality of life, with the key issues such as failure to distinguish primary and secondary outcome measures, substantial variation in the number of measures, weak relevance of surrogate measures, insufficient application of objective, safety, and long-term efficacy measures, and lack of attention to fall risk assessment.

Keywords osteoarthritis, knee; randomized controlled trials as topic; outcome assessment, health care; Shadow Boxing; Eight-Sectioned Exercise; Yi Jin Jing; Five Mimic Animal Boxing; Qigong(TCM)

膝关节炎(knee osteoarthritis, KOA)是一种关节软骨退行性疾病,属中医“骨痹”“痹证”范畴,以膝关节软骨退行性变、软骨下骨质反应性改变、关节边缘骨赘形成、滑膜病变、韧带松弛或挛缩、关节囊挛缩、肌肉萎软无力等为特征^[1]。KOA主要表现为膝关节慢性疼痛和功能障碍,可极大影响患者的生活质量,给家庭和社会造成沉重的经济负担^[2]。KOA的治疗包括药物治疗、非药物治疗,必要时可采用手术治疗^[1]。非甾体抗炎药是目前最常用的一类控制KOA症状的药物,但有胃肠道症状、肝肾功能损害等不良反应,且有增加心血管不良事件的风险^[3-4]。中医药治疗KOA不仅可以缓解患者的症状,还有利于恢复膝关节功能^[5]。太极拳、五禽戏、八段锦、易筋经等传统功法具有低风险、低成本、易操作等优势,是治疗KOA的重要措施^[6-7]。临床试验发现传统功法在缓解KOA症状和延缓病情进展方面具有良好疗效^[8-9]。

临床随机对照试验(randomized controlled trial, RCT)是医学研究中推断治疗效果的金标准^[10]。结局指标是反映待研究效应量的重要因素,高质量的结局指标有助于提高RCT研究的合理性和研究价值,并降低不同研究方法和结果的异质性^[11-13]。当前关于传统功法治疗KOA的高质量RCT较为缺乏,现有

研究的疗效评价标准也不统一,结局指标种类繁多且使用较为混乱,导致部分RCT结果可信度不高^[14]。为给开展高质量RCT提供支持,我们检索相关文献,对传统功法治疗KOA的RCT的基本特征和结局指标现状进行了分析,现报告如下。

1 资料与方法

1.1 文献检索

计算机检索中国知网、万方数据库、维普网、中国生物医学文献服务系统、PubMed、Embase、Web of Science、Cochrane Library。中文检索词:膝关节炎、膝骨性关节炎、膝关节炎、膝关节炎性骨性关节炎、老年性关节炎、骨痹、膝痹、传统功法、传统运动疗法、太极拳、气功、五禽戏、八段锦、易筋经等。英文检索词:osteoarthritis knee、knee osteoarthritis、knee osteoarthritides、osteoarthritis of the knee、osteoarthritis of knee、traditional Chinese exercise、Tai Chi、Tai Ji、Qigong、Wuqinxi、Baduanjin、Yijinjing。根据各数据库的特点,采用主题词结合自由词的方式进行检索。检索时限为各数据库建库至2025年2月。

1.2 文献筛选

由2位研究者对检索到的文献进行筛选,如遇分歧则请第3位研究者协助裁定。

1.2.1 纳入标准 ①报告语种为中、英文;②研究类型为 RCT;③研究对象为被明确诊断为 KOA 的患者;④对照组干预措施不限,试验组干预措施为单纯应用传统功法(太极拳、八段锦、易筋经、气功等),或在对照组常干预措施的基础上联合应用传统功法;⑤至少有 1 项明确的结局指标,如疼痛评价量表、运动功能量表/测试、睡眠质量评分、心理测试量表、理化指标、生活质量量表、安全性指标等。

1.2.2 排除标准 ①重复的文献;②数据不全的文献;③研究对象合并类风湿关节炎,或接受过人工全膝关节置换术的文献;④Meta 分析文献;⑤会议论文、学位论文文献;⑥生物力学作用机制研究文献。

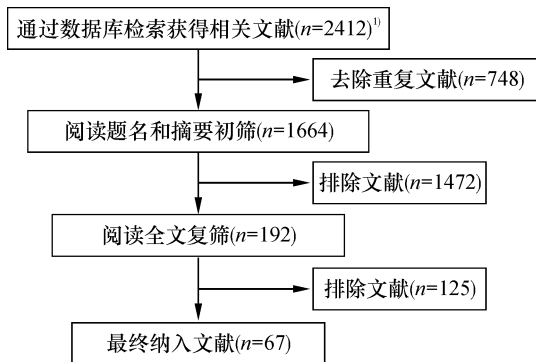
1.3 信息提取和分析

提取纳入研究的信息并导入 Microsoft Excel 软件。信息提取内容包括:题名、发表时间、样本量、诊断标准、干预措施、干预疗程、随访时间,以及结局指标名称、评价时间点等。参照有效性试验核心结局指标测量工作组推荐的方法^[15],将各项结局指标规范化、标准化处理后划分指标域。

2 结果

2.1 文献检索及筛选结果

初步检索出相关文献 2412 篇,经逐层筛选后最终纳入文献 67 篇,包括中文 25 篇^[16-40]、英文 42 篇^[41-82]。文献筛选流程见图 1。



1) 2412 项研究分别来源于中国知网($n = 244$)、万方数据库($n = 950$)、维普网($n = 143$)、中国生物医学文献服务系统($n = 183$)、PubMed($n = 218$)、Embase($n = 281$)、Web of Science($n = 215$)、Cochrane Library($n = 178$)。

图 1 文献筛选流程图

2.2 纳入研究的基本特征分析结果

2.2.1 发表时间 纳入的 67 项研究,发表时间集中在 2003—2024 年,其中 2020、2022 年发表数量最多,

均为 10 篇(图 2)。

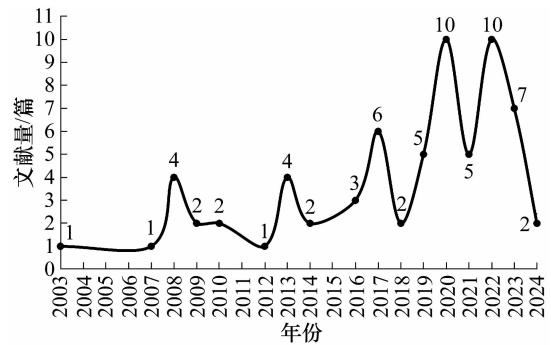


图 2 67 项传统功法治疗膝骨关节炎临床随机对照研究发表年份分布图

2.2.2 样本量 纳入的 67 项研究中,样本量 < 60 例 21 项,60 ~ 99 例 29 项,100 ~ 200 例 12 项, > 200 例 5 项^[46,48,54,67,76]。

2.2.3 诊断标准 纳入的 67 项研究均报告了疾病的西医诊断标准,其中应用最多的是美国风湿病学会膝骨关节炎诊断标准,其次是中华医学会颁布的骨关节炎相关诊疗指南中的诊断标准。此外,有 5 项研究^[16,20,27,29-30]报告了中医证型诊断标准,其中 4 项^[16,27,29-30]参考了《中医病证诊断疗效标准》中的相关证型诊断标准,1 项^[20]参考了《中药新药临床研究指导原则(试行)》中的相关证型诊断标准。

2.2.4 干预措施 41 项研究的试验组干预措施为单纯传统功法治疗,其中 1 项^[76]为 2 种传统功法联合;26 项研究的试验组干预措施为传统功法联合其他疗法,其中 1 项研究^[49]为 2 种传统功法联合其他疗法,1 项研究^[46]为在 3 种传统功法基础上创立的功法联合其他疗法。共出现 5 种传统功法,出现频次由高至低依次为太极拳、八段锦、易筋经、气功、五禽戏。见图 3。

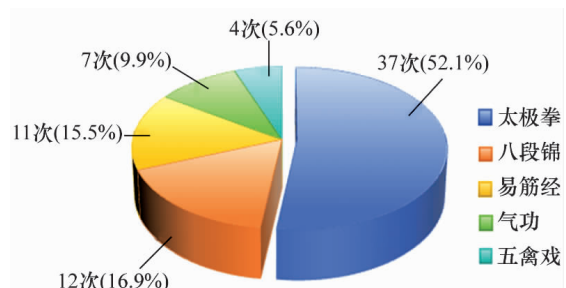


图 3 67 项传统功法治疗膝骨关节炎临床随机对照研究中所用功法分布图

2.2.5 干预疗程与随访时间 纳入的 67 项研究,均报告了干预疗程,干预疗程 2 ~ 36 周,出现频次前 3 位为 12 周(31 次)、4 周(9 次)、24 周(8 次);31 项研究报告了随访时间(1 ~ 53 周),随访时间出现频次

前 3 位为 12 周(9 次)、24 周(6 次)、48 周(5 次)。

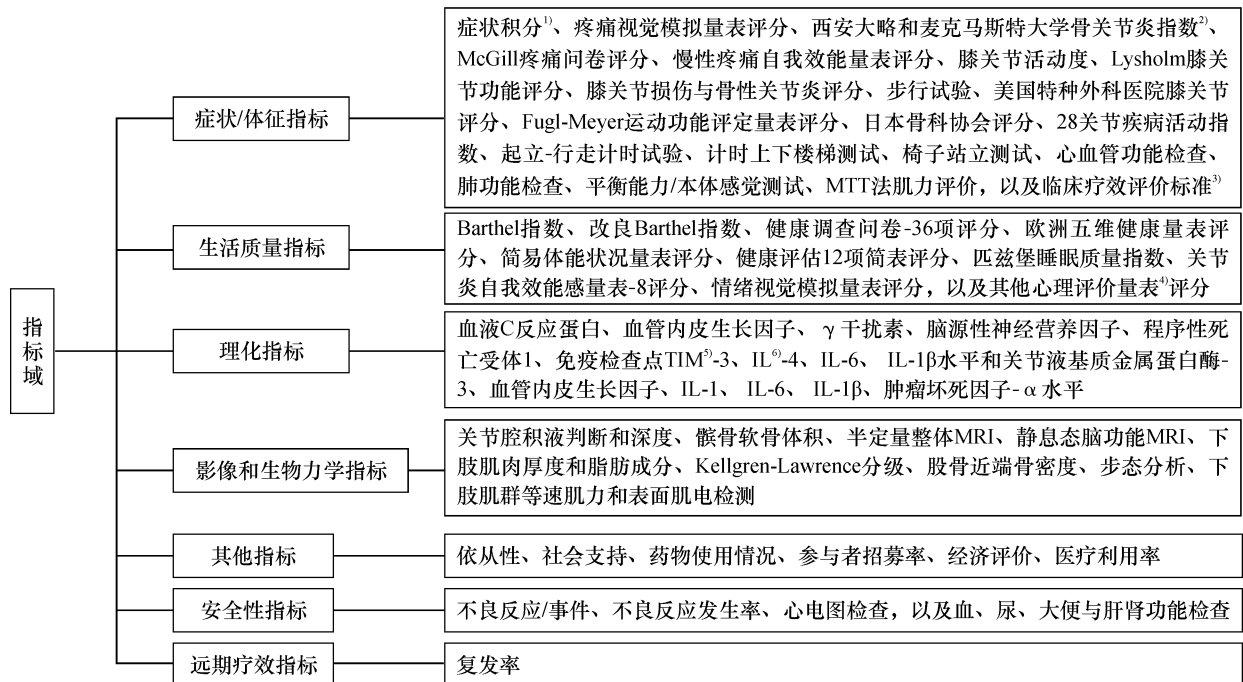
2.3 纳入研究的结局指标分析结果

2.3.1 评价时间点 45 项研究的结局指标评价时间点为干预前和干预结束后 2 个时间点,21 项研究的结局指标评价时间点为干预前、干预过程中和干预结束后。

2.3.2 结局指标构成 26 项研究区分了主、次要结局指标,采用行业现有评价标准,其中 1 项研究^[51]对主、次要结局指标采用了不同的评价时间点;41 项研究未区分主、次要结局指标,均采用自定义评价标准。

2.3.3 结局指标分类 每项研究的结局指标数为 1~13 个。共涉及结局指标 86 项,可划分为 7 个指标域,包括症状/体征指标 28 项、生活质量指标 20 项、理化指标 15 项、影像和生物力学指标 12 项、其他指标 6 项、安全性指标 4 项和远期疗效指标 1 项(图 4)。

2.3.4 高频结局指标 86 项结局指标中,出现频次较高的结局指标由高至低依次为西安大略和麦克马斯特大学骨关节炎指数疼痛评分、功能评分、僵硬评分,以及平衡能力/本体感觉测试和疼痛视觉模拟量表评分。见表 1。



1)中包括症状总积分、疼痛积分、功能积分和肿胀积分,2)中包括疼痛评分、功能评分和僵硬评分,3)中包括《中医病证诊断疗效标准》、《中药新药临床研究指导原则(试行)》、《骨关节炎诊断及治疗指南》中相关疗效评价标准,4)中包括特定活动平衡信心量表、贝克抑郁自评量表、运动恐惧症量表、一般自我效能感量表、五因素正念度量表、流调用抑郁自评量表、感知压力量表、社会排斥量表、国际积极消极情感量表-简表、状态-特质焦虑问卷、体育活动愉悦感量表,5)为 T 细胞免疫蛋白黏蛋白,6)为白细胞介素。

图 4 67 项传统功法治疗膝骨关节炎临床随机对照研究中结局指标分类图

表 1 67 项传统功法治疗膝骨关节炎临床随机对照研究中出现频次较高的结局指标

序号	结局指标	频次	序号	结局指标	频次
1	WOMAC ¹⁾ 疼痛评分	47	10	Kellgren-Lawrence 分级	12
2	WOMAC 功能评分	46	11	膝关节活动度	11
3	WOMAC 僵硬评分	43	12	下肢肌群等速肌力检测	11
4	平衡能力/本体感觉测试	33	13	步态分析	9
5	疼痛视觉模拟量表评分	22	14	MTT 法肌力评价	8
6	步行试验	17	15	Lysholm 膝关节功能评分	7
7	健康调查问卷-36 项评分	17	16	下肢肌群表面肌电检测	7
8	不良反应/事件	16	17	贝克抑郁自评量表评分	6
9	起立-行走计时试验	12			

注:1)西安大略和麦克马斯特大学骨关节炎指数。

3 讨论

充足的样本量可更敏感地识别组间差异,提升 RCT 研究结论的可靠性。目前,传统功法治疗 KOA 的 RCT 各项研究间样本量差别较大,存在样本量估算缺失的问题,这可能会降低统计结果的准确性^[83]。

规范化选取结局指标的种类和数量是提高临床结论准确性的关键,有助于提高卫生经济学效应^[84]。目前,传统功法治疗 KOA 的 RCT 所选取的结局指标中,主、次要结局指标不明确的问题普遍存在,这可能会导致研究的核心问题不清晰,降低结果的可靠性。未来研究应合理选择并区分主、次要结局指标,以降低研究的复杂性和偏倚风险^[85]。关于 KOA 的临床试验,随访时间 < 12 周时应重点关注症状/体征指标, > 48 周时应更注重膝关节功能和结构的变化^[86]。但本研究纳入的 RCT 结局指标的评价时间点缺乏对研究周期的考虑。替代指标是特定干预措施与临床终点之间因果关系链上的中间影响因素,既能间接反映疗效,又能弥补终点指标观察周期长、经济成本高的缺陷^[86]。本研究纳入的 RCT 中,各项研究间结局指标的种类和数量差异较大,替代指标选择跨度大、针对性不强,导致研究结果难以比较和合并,增加了开展循证医学研究的难度。且所选结局指标以评价症状/体征和生活质量的主观性指标居多,客观评价指标较少,这降低了试验结果的可信度。在以后的研究中还需增加客观指标的应用,但客观指标的检测应严格遵循医学伦理要求^[87]。

KOA 多发于中老年群体,患者在传统功法的锻炼过程中可能会出现心慌、呼吸不畅、头晕目眩、肢体疼痛麻木等不良反应,以及跌倒、运动损伤等不良事件,甚至会诱发心脑血管疾病。因此,安全性评价在传统功法治疗 KOA 的临床研究中具有重要价值。但本研究纳入的 RCT 中,仅 1 项研究报告了患者的心电图变化,其余研究均未对不良反应/事件进行详细描述。而完善的不良反应/事件报告应包括不良事件严重程度、发生频率和时间,以及预防和处理措施等^[88]。远期疗效指标包括复发率、症状或体征消失率/复常率等^[89]。现有研究普遍缺乏长期随访,仅 1 项研究报告了复发率,无法充分体现传统功法治疗 KOA 的长期疗效。此外,中老年 KOA 患者跌倒的发生率较高,而良好的本体感觉、平衡能力及下肢肌肉力量是预防跌倒的关键^[90]。目前的研究虽关注到跌

倒风险,但关注度不高,且各项研究选择的评价指标差异较大,可能导致对试验结果的解释不准确。

本研究的局限性:文献检索限定了检索时间、文献类型和语种等,且检索的数据库可能存在阳性结果较阴性结果更容易发表的现象^[91-92],检索结果可能存在发表偏倚。

目前,传统功法治疗 KOA 的 RCT 研究中,所用的功法以太极拳、八段锦、易筋经居多。这些研究的中医辨证诊断不规范,缺乏长期随访,样本量差异较大,干预疗程不一;所选取的结局指标以症状/体征指标和生活质量指标居多,结局指标的选取存在未区分主次、数量差异大、替代指标针对性不强,以及客观性、安全性、远期疗效指标应用不足和对跌倒风险关注度较低等问题。针对传统功法治疗 KOA 的 RCT 中存在的问题,未来的研究应规范估算样本量,注重中医的辨证治疗,增加随访时间,且应及早建立传统功法治疗 KOA 的核心结局指标集,规范结局指标的选取,不断提高相关临床试验的证据等级。

参考文献

- [1] 中华中医药学会. 膝关节炎中西医结合诊疗指南(2023 年版)[J]. 中医正骨, 2023, 35(6): 1-10.
- [2] 中国骨关节炎诊疗指南专家组, 中国老年保健协会疼痛病学分会, 黄东, 等. 中国骨关节炎诊疗指南(2024 版)[J]. 中华疼痛学杂志, 2024, 20(3): 323-338.
- [3] HUANG H, LUO M, LIANG H, et al. Meta-analysis comparing celecoxib with diclofenac sodium in patients with knee osteoarthritis[J]. Pain Med, 2021, 22(2): 352-362.
- [4] GREGORI D, GIACOVELLI G, MINTO C, et al. Association of pharmacological treatments with long-term pain control in patients with knee osteoarthritis: a systematic review and meta-analysis[J]. JAMA, 2018, 320(24): 2564-2579.
- [5] 中国中医药研究促进会骨伤科分会. 膝关节炎中医诊疗指南(2020 年版)[J]. 中医正骨, 2020, 32(10): 1-14.
- [6] 王诗恒, 童元元, 高曼, 等. 中国传统功法治疗膝关节炎的网状 Meta 分析[J]. 世界中医药, 2024, 19(10): 1428-1434.
- [7] 马健文, 岳虹好, 谢超群, 等. 传统功法干预膝关节炎的临床应用及效应机制研究进展[J]. 上海中医药杂志, 2023, 57(12): 96-100.
- [8] 曾令烽, 杨伟毅, 郭达, 等. 传统运动疗法干预对膝关节炎患者疼痛改善及关节功能影响的系统评价[J]. 中华中医药杂志, 2018, 33(5): 2132-2139.
- [9] LI R, CHEN H, FENG J, et al. Effectiveness of traditional

- Chinese exercise for symptoms of knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials[J]. *Int J Environ Res Public Health*, 2020, 17(21): 7873.
- [10] HARITON E, LOCASCIO J J. Randomised controlled trials—the gold standard for effectiveness research; study design: randomised controlled trials [J]. *BJOG*, 2018, 125(13): 1716.
- [11] KIRKHAM J J, GARGON E, CLARKE M, et al. Can a core outcome set improve the quality of systematic reviews? — a survey of the co-ordinating editors of cochrane review groups[J]. *Trials*, 2013, 14: 21.
- [12] WILLIAMSON P R, DE ÁVILA OLIVEIRA R, CLARKE M, et al. Assessing the relevance and uptake of core outcome sets (an agreed minimum collection of outcomes to measure in research studies) in Cochrane systematic reviews: a review[J]. *BMJ Open*, 2020, 10(9): e036562.
- [13] 邢冬梅, 张俊华, 张伯礼. 中医临床研究核心结局指标集形成路径[J]. *中华中医药杂志*, 2014, 29(5): 1352 – 1355.
- [14] MANDELL L A, WUNDERINK R G, ANZUETO A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults [J]. *Clin Infect Dis*, 2007, 44 Suppl 2(Suppl 2): S27 – S72.
- [15] WILLIAMSON P R, ALTMAN D G, BAGLEY H, et al. The COMET Handbook; version 1.0[J]. *Trials*, 2017, 18(Suppl 3): 280.
- [16] 陈长贤, 仲卫红, 赖传仕, 等. 针刀松解术联合南少林站桩功锻炼治疗早期膝骨关节炎的临床研究[J]. *中医正骨*, 2022, 34(2): 19 – 23.
- [17] 许明, 李亚, 秦爽, 等. 易筋经康复训练联合干扰电疗法对膝骨关节炎患者的影响[J]. *康复学报*, 2023, 33(6): 535 – 541.
- [18] 张帅攀, 朱清广, 程艳彬, 等. 易筋经功法干预膝骨关节炎患者步态生物力学的随机对照试验[J]. *中华中医药杂志*, 2023, 38(10): 5081 – 5086.
- [19] 李宇涛, 叶银燕, 牛晓敏, 等. 易筋经功法对膝骨关节炎患者下肢肌群协调激活能力的影响[J]. *中华中医药杂志*, 2022, 37(4): 2380 – 2385.
- [20] 高超, 石志敏, 李雪青. 穴位按摩联合八段锦锻炼在肝肾不足、瘀血内阻型膝骨关节炎中的应用效果[J]. *中国医药导报*, 2022, 19(7): 181 – 185.
- [21] 杨毅峰, 黄健, 邸申, 等. 膝骨关节炎患者应用体外冲击波联合站桩训练的效果及炎症水平分析[J]. *中国医学创新*, 2023, 20(10): 116 – 119.
- [22] 吴红飞, 叶超, 亓建, 等. 五禽戏联合膝关节镜手术治疗膝骨关节炎疗效观察[J]. *现代中西医结合杂志*, 2022, 31(8): 1072 – 1075.
- [23] 李建华, 龚利, 胡伟民, 等. 推拿加易筋经治疗膝骨性关节炎的临床研究[J]. *辽宁中医杂志*, 2010, 37(9): 1793 – 1795.
- [24] 蒋黎明, 于小明, 丁余武, 等. 体外冲击波疗法联合站桩训练治疗膝骨关节炎的临床疗效[J]. *广西医学*, 2022, 44(16): 1847 – 1850.
- [25] 李静雅, 程亮. 太极拳和抗阻训练对膝关节骨性关节炎老人症状及运动能力的影响[J]. *中国康复医学杂志*, 2019, 34(11): 1304 – 1309.
- [26] 张琥, 张旻, 龚幼波, 等. 太极拳对早期膝骨关节炎患者步态影响的研究[J]. *中医正骨*, 2018, 30(9): 34 – 38.
- [27] 朱智, 李恩慧, 朱清广. 太极拳锻炼结合针刺干预膝骨关节炎的临床观察[J]. *上海中医药杂志*, 2017, 51(3): 54 – 56.
- [28] 宋国红, 张娜, 张斌. 塞来昔布联合太极拳对膝骨关节炎患者平衡功能的影响[J]. *现代消化及介入诊疗*, 2019(A02): 2340 – 2341.
- [29] 仲卫红, 洪昆达, 李天骄, 等. 经筋推拿配合易筋经训练治疗膝骨性关节炎的临床研究[J]. *中华中医药杂志*, 2019, 34(8): 3861 – 3863.
- [30] 郑美艺, 刘洪波, 向雪情, 等. 健身气功五禽戏联合非甾体抗炎药治疗膝关节炎的临床疗效观察[J]. *中医学*, 2020, 9(3): 256 – 261.
- [31] 宋九龙, 李雪萍, 程凯, 等. 改良太极运动对老年女性膝 OA 患者下肢肌力与心肺耐力的影响[J]. *中国康复*, 2022, 37(3): 153 – 156.
- [32] 张爱民, 孙胜林, 鲍启忠, 等. 低位站桩结合手法推拿治疗膝关节炎的临床观察[J]. *河北中医*, 2009, 31(7): 994 – 995.
- [33] 陈琦, 孟晓耘, 邓华萍, 等. 导引功法治疗膝骨关节炎的效果观察[J]. *现代临床护理*, 2014, 13(10): 43 – 46.
- [34] 彭键勇, 唐剑邦. 补肾祛痰方联合太极拳锻炼对肾虚痰浊型膝骨关节炎的临床疗效观察[J]. *天津中医药大学学报*, 2021, 40(3): 336 – 341.
- [35] 段娜, 熊朝军, 邵黎云, 等. 八段锦联合自我管理的社区干预模式对膝骨关节炎临床疗效评价[J]. *中医学*, 2020, 9(5): 435 – 440.
- [36] 于倩, 徐俐, 林颖, 等. 八段锦导引功法对中老年膝骨关节炎患者疼痛的效果研究[J/OL]. *中文科技期刊数据库(全文版)医药卫生*, 2022(2) [2025 – 02 – 16]. <https://www.cqvip.com/doc/journal/2010228888476353536>.
- [37] 徐璐, 唐霞珠. 24 式简化太极拳对老年膝骨性关节炎患者关节功能的影响[J]. *护理学报*, 2016, 23(11):

51 - 53.

- [38] 江岩, 来章琦, 范恺怡, 等. 12 周健身气功八段锦对膝骨关节炎患者下肢体成分及肌肉厚度影响[J]. 辽宁中医药大学学报, 2020, 22(8): 90 - 93.
- [39] 陈凤娜, 吴为明, 乐益鸣. 八段锦功能锻炼对老年慢性膝骨关节炎患者运动能力、自我管理效能的影响[J]. 中华健康管理学杂志, 2020, 14(6): 556 - 559.
- [40] 田野, 王强, 路怀民, 等. 八段锦运动联合玻璃酸钠关节腔注射治疗膝骨性关节炎的疗效观察[J]. 中华物理医学与康复杂志, 2022, 44(12): 1104 - 1107.
- [41] FAN Y Z, WU Y C, WANG J X, et al. Effect of Tuina exercise on quadriceps femoris muscle strength of patients with knee osteoarthritis[J]. J Acupunct Tuina Sci, 2012, 10(5): 321 - 328.
- [42] AREEUDOMWONG P. Comparison of the results between Baduanjin dance and Muay Thai dance on parameter-related pain and physical performance in knee osteoarthritis patients [DB/OL]. Cochrane Library, 2021 [2025 - 02 - 16]. <https://trialssearch.who.int/Trial2.aspx?TrialID=TC-TR20210123001>.
- [43] BENNELL K. Effects of a self-directed online Tai Chi program in people with knee osteoarthritis: randomised controlled trial (The RETREAT Trial) [DB/OL]. Cochrane Library, 2023 [2025 - 02 - 16]. <https://trialssearch.who.int/Trial2.aspx?TrialID=ACTRN12623000780651>.
- [44] WANG C, IVERSEN M D, MCALINDON T, et al. Assessing the comparative effectiveness of Tai Chi versus physical therapy for knee osteoarthritis: design and rationale for a randomized trial[J]. BMC Complement Altern Med, 2014, 14: 333.
- [45] AN B, DAI K, ZHU Z, et al. Baduanjin alleviates the symptoms of knee osteoarthritis[J]. J Altern Complement Med, 2008, 14(2): 167 - 174.
- [46] GUO J M, XIAO Y, CAI T Y, et al. Chinese medicine involving triple rehabilitation therapy for knee osteoarthritis in 696 outpatients: a multi-center, randomized controlled trial[J]. Chin J Integr Med, 2021, 27(10): 729 - 736.
- [47] DING J Y, JU Z Y, ZHU Y J, et al. Clinical observation on electroacupuncture plus Yi Jin Jing (Sinew-transforming Qigong Exercises) for knee osteoarthritis[J]. J Acupunct Tuina Sci, 2020, 18(5): 396 - 402.
- [48] WANG C, SCHMID C H, IVERSEN M D, et al. Comparative effectiveness of Tai Chi versus physical therapy for knee osteoarthritis: a randomized trial[J]. Ann Intern Med, 2016, 165(2): 77 - 86.
- [49] LIU J, CHEN L, TU Y, et al. Different exercise modalities relieve pain syndrome in patients with knee osteoarthritis and modulate the dorsolateral prefrontal cortex: a multiple mode MRI study[J]. Brain Behav Immun, 2019, 82: 253 - 263.
- [50] ZHENG H, ZHANG D, ZHU Y, et al. Effect of Tai Chi exercise on lower limb function and balance ability in patients with knee osteoarthritis: a protocol of a randomized controlled trial[J]. Medicine, 2021, 100(46): e27647.
- [51] YUE H, LI Y, MA J, et al. Effect of Tai Chi on knee pain and muscle strength in middle-aged and older adults with knee osteoarthritis: a randomized controlled trial protocol[J]. BMC Complement Med Ther, 2023, 23(1): 256.
- [52] ZHANG Z, HUANG L, LIU Y, et al. Effect of Tai Chi training on plantar loads during walking in individuals with knee osteoarthritis[J]. Biomed Res Int, 2020, 2020: 3096237.
- [53] LÜ J, HUANG L, WU X, et al. Effect of Tai Ji Quan training on self-reported sleep quality in elderly Chinese women with knee osteoarthritis: a randomized controlled trial[J]. Sleep medicine, 2017, 33: 70 - 75.
- [54] XIAO Z, LI G. The effect of Wuqinxi exercises on the balance function and subjective quality of life in elderly, female knee osteoarthritis patients [J]. Am J Transl Res, 2021, 13(6): 6710 - 6716.
- [55] ZHANG S, GUO G, LI X, et al. The Effectiveness of traditional Chinese Yijinjing Qigong exercise for the patients with knee osteoarthritis on the pain, dysfunction, and mood disorder: a pilot randomized controlled trial[J]. Front Med (Lausanne), 2022, 8: 792436.
- [56] GUO G, WANG Y, XU X, et al. Effectiveness of Yijinjing exercise in the treatment of early-stage knee osteoarthritis: a randomized controlled trial protocol[J]. BMJ Open, 2024, 14(3): e074508.
- [57] YE J, SIMPSON M W, LIU Y, et al. The effects of Baduanjin Qigong on postural stability, proprioception, and symptoms of patients with knee osteoarthritis: a randomized controlled trial[J]. Front Med (Lausanne), 2020, 6: 307.
- [58] CHEN K W, PERLMAN A, LIAO J G, et al. Effects of external Qigong therapy on osteoarthritis of the knee. A randomized controlled trial[J]. Clin Rheumatol, 2008, 27(12): 1497 - 1505.
- [59] WORTLEY M, ZHANG S N, PAQUETTE M, et al. Effects of resistance and Tai training on mobility and symptoms in knee osteoarthritis patients[J]. Journal of Sport and Health Science, 2013, 2(4): 209 - 214.
- [60] SONG R, LEE E O, LAM P, et al. Effects of Tai Chi exercise on pain, balance, muscle strength, and perceived diffi-

- culties in physical functioning in older women with osteoarthritis: a randomized clinical trial [J]. *J Rheumatol*, 2003, 30(9):2039–2044.
- [61] SHEN C L, JAMES C R, CHYU M C, et al. Effects of Tai Chi on gait kinematics, physical function, and pain in elderly with knee osteoarthritis—a pilot study [J]. *Am J Chin Med*, 2008, 36(2):219–232.
- [62] WANG X, HOU M, CHEN S, et al. Effects of Tai Chi on postural control during dual-task stair negotiation in knee osteoarthritis: a randomised controlled trial protocol [J]. *BMJ Open*, 2020, 10(1):e033230.
- [63] WANG X Q, HUANG L Y, LIU Y, et al. Effects of Tai Chi program on neuromuscular function for patients with knee osteoarthritis: study protocol for a randomized controlled trial [J]. *Trials*, 2013, 14:375.
- [64] LEE A C, HARVEY W F, WONG J B, et al. Effects of Tai Chi versus physical therapy on mindfulness in knee osteoarthritis [J]. *Mindfulness*, 2017, 8(5):1195–1205.
- [65] ZHU Q, HUANG L, WU X, et al. Effects of Tai Ji Quan training on gait kinematics in older Chinese women with knee osteoarthritis: a randomized controlled trial [J]. *J Sport Health Sci*, 2016, 5(3):297–303.
- [66] XIAO C, ZHUANG Y, KANG Y. Effects of WuQinXi Qigong exercise on physical functioning in elderly people with knee osteoarthritis: a randomized controlled trial [J]. *Geriatrics & gerontology international*, 2020, 20(10):899–903.
- [67] YANG K, DING Y, XU H, et al. Efficacy and safety of platelet-rich plasma combined with Tai Chi for knee osteoarthritis: study protocol for a placebo-controlled randomized trial [J]. *J Orthop Surg Res*, 2023, 18(1):885.
- [68] KANG N, WANG Y, CHEN G, et al. Functional outcomes of Tai Chi exercise prescription in women with knee osteoarthritis [J]. *Sports Med Health Sci*, 2022, 4(4):239–244.
- [69] BRISMÉE J M, PAIGE R L, CHYU M C, et al. Group and home-based Tai Chi in elderly subjects with knee osteoarthritis: a randomized controlled trial [J]. *Clin Rehabil*, 2007, 21(2):99–111.
- [70] CHEN P Y, SONG C Y, YEN H Y, et al. Impacts of Tai Chi exercise on functional fitness in community-dwelling older adults with mild degenerative knee osteoarthritis: a randomized controlled clinical trial [J]. *BMC Geriatr*, 2021, 21(1):449.
- [71] SCHMID A, MCALINDON T, SCHMID C H, et al. The influence of Tai Chi exercise on proprioception in patients with knee osteoarthritis: results from a pilot randomized controlled trial [J]. *Int J Integr Med*, 2013, 1:37.
- [72] YE J, ZHENG Q, ZOU L, et al. Mindful exercise (Baduanjin) as an adjuvant treatment for older adults (60 years old and over) of knee osteoarthritis: a randomized controlled trial [J]. *Evid Based Complement Alternat Med*, 2020, 2020:9869161.
- [73] LEE A C, HARVEY W F, PRICE L L, et al. Mindfulness is associated with treatment response from nonpharmacologic exercise interventions in knee osteoarthritis [J]. *Arch Phys Med Rehabil*, 2017, 98(11):2265–2273.
- [74] LEE A C, HARVEY W F, HAN X, et al. Pain and functional trajectories in symptomatic knee osteoarthritis over up to 12 weeks of exercise exposure [J]. *Osteoarthritis Cartilage*, 2018, 26(4):501–512.
- [75] SONG R, ROBERTS B L, LEE E O, et al. A randomized study of the effects of tai chi on muscle strength, bone mineral density, and fear of falling in women with osteoarthritis [J]. *J Altern Complement Med*, 2010, 16(3):227–233.
- [76] YAN H, SU Y, CHEN L, et al. Rehabilitation for the management of knee osteoarthritis using comprehensive traditional Chinese medicine in community health centers: study protocol for a randomized controlled trial [J]. *Trials*, 2013, 14:367.
- [77] WANG C, SCHMID C H, HIBBERD P L, et al. Tai Chi for treating knee osteoarthritis: designing a long-term follow up randomized controlled trial [J]. *BMC Musculoskelet Disord*, 2008, 9:108.
- [78] WANG C, SCHMID C H, HIBBERD P L, et al. Tai Chi is effective in treating knee osteoarthritis: a randomized controlled trial [J]. *Arthritis Rheum*, 2009, 61(11):1545–1553.
- [79] ARIAYI E, SARCHAHI A, JAVAHERI S A A H. Comparative study of the effect of Tai Chi and isometric exercises on the severity of pain and balance in patients with knee osteoarthritis [J]. *Journal of Kerman University of Medical Sciences*, 2017, 24(4):268–277.
- [80] XU Y, XIE X, YE F, et al. The therapeutic effects of internet-based Tai Chi on knee osteoarthritis in chinese athletes: a randomized controlled trial protocol [J]. *Rev Int Med Cienc Act Fís Deporte*, 2023, 23(93):256–277.
- [81] ZHU Q, HUANG L, WU X, et al. Effect of Taijiquan practice versus wellness education on knee proprioception in patients with knee osteoarthritis: a randomized controlled trial [J]. *J Tradit Chin Med*, 2017, 37(6):774–781.

- [44] 张程,包丽荣,杨于桃,等. M2 巨噬细胞外泌体对高糖高胰岛素条件下小鼠骨髓间充质干细胞成骨分化的影响[J]. 四川大学学报(医学版), 2022, 53(1): 63-70.
- [45] LIANG Y J, DUAN L, LU J P, et al. Engineering exosomes for targeted drug delivery [J]. *Theranostics*, 2021, 11(7): 3183-3195.
- [46] HOU C Y, ZHANG Y J, LV Z Y, et al. Macrophage exosomes modified by miR-365-2-5p promoted osteoblast osteogenic differentiation by targeting OLFML1 [J]. *Regen Biomater*, 2024, 11: rbae018.
- [47] REN J X, YU R C, XUE J Y, et al. How do extracellular vesicles play a key role in the maintenance of bone homeostasis and regeneration? A comprehensive review of literature [J]. *Int J Nanomedicine*, 2022, 17: 5375-5389.
- [48] YANG D B, ZHANG W H, ZHANG H Y, et al. Progress, opportunity, and perspective on exosome isolation-efforts for efficient exosome-based theranostics [J]. *Theranostics*, 2020, 10(8): 3684-3707.
- [49] PALAKURTHI S S, SHAH B, KAPRE S, et al. A comprehensive review of challenges and advances in exosome-based drug delivery systems [J]. *Nanoscale Adv*, 2024, 6(23): 5803-5826.
- [50] LU Y, MAI Z Z, CUI L, et al. Engineering exosomes and bio-material-assisted exosomes as therapeutic carriers for bone regeneration [J]. *Stem Cell Res Ther*, 2023, 14(1): 55.
- (收稿日期:2025-01-07 本文编辑:时红磊)

(上接第 48 页)

- [82] XU K, ZHANG J, MA W, et al. Home-based Shi's knee daoyin exercise for knee osteoarthritis: a randomized controlled pilot trial [J]. *J Pain Res*, 2024, 17: 2811-2822.
- [83] 曹文聪,邱幸莹,刘冰清,等. 针刺治疗卒中后吞咽困难随机对照试验结局及其测量工具现状分析[J]. *中国针灸*, 2023, 43(9): 1086-1093.
- [84] 秦元,肖凌勇,杨欢,等. 针刺治疗膝骨关节炎随机对照试验结局指标现状分析[J]. *中国全科医学*, 2024, 27(8): 995-1000.
- [85] 董斐,刘建平. 从“经验”到“证据”:循证医学促进中医药传承创新发展[J]. *南京中医药大学学报*, 2021, 37(5): 642-647.
- [86] 曹月龙. 骨关节炎临床研究中疗效评价指标的选择与方法学考虑——《膝骨关节炎中医诊疗指南(2020年版)》解读[J]. *中医正骨*, 2021, 33(11): 1-5.
- [87] 张艳宏,艾艳珂,杨金洪,等. 安慰剂效应及临床试验中针刺安慰效应的设计思路[J]. *中医杂志*, 2024, 65(9): 904-908.
- [88] 何森,蒋帅,刘玲玉,等. 医疗(不良)事件内部报告系统优化及流程再造的应用研究[J]. *中国医院管理*, 2023, 43(11): 58-61.
- [89] 李素丹. 温针灸结合康复训练治疗膝骨关节炎的远期疗效及对患者 VAS 评分的影响[J]. *中国医药科学*, 2019, 9(24): 52-54.
- [90] 潘玥,庞立佳,姚云霜,等. 老年膝骨关节炎患者跌倒发生情况及影响因素分析[J]. *中华现代护理杂志*, 2019, 25(26): 3417-3423.
- [91] SENN S. Misunderstanding publication bias: editors are not blameless after all [J]. *F1000Res*, 2012, 1: 59.
- [92] CHALMERS I, DICKERSIN K. Biased under-reporting of research reflects biased under-submission more than biased editorial rejection [J]. *F1000Res*, 2013, 2: 1.
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