国际中医临床实践指南
功能性消化不良

编制说明

立 项 单 位： 世界中医药学会联合会

项目承担单位：中国中医科学院望京医院

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《国际中医临床实践指南 功能性消化不良》项目组

二〇二五年 月

目　录

一、工作简况

（一）任务背景

功能性消化不良（functional dyspepsia，FD）是一组以持续性或反复性发作的上腹部疼痛、食后饱胀、腹胀、嗳气、早饱、厌食、恶心等上腹部不适为主要症状的临床症候群，属功能性胃肠病（FGIDs）范畴。FD 是世界范围内重要的健康问题，2021 年以色列内盖夫本古里安大学健康科学学院的一项研究通过匿名互联网调查与面对面家庭调查两种方法，调查了 6 大洲 33 个国家的 FGIDs 的流行率，在这项调查研究中发现，全球超过 40%的人患有 FGIDs。其中 FD 是最常见的胃十二指肠疾病，互联网和家庭调查的合并患病率分别为 7.2% （7.1%—7.4%）和 4.8%（4.5%—5.1%）。此外，调查结果显示各国 FD 的患病率差异很大，在互联网调查中，中国为 5.9%，日本为 2.2%，埃及为 12.3%；在家庭调查中，中国为 4.3%（3.6%﹣5.1%），印度为 0.7%（0.5%﹣1.0%），孟加拉国为 19.4%（17.7%﹣21.2%）。FD 会导致巨大的全球医疗成本，降低患者的生活质量；结果显示 53.8% 的 FGIDs 患者存在高医疗负担（即每年多次检查、多次就诊）。

FD 发病率高，治愈率低，疾病所致身心负担沉重，疗效欠佳，目前其病理生理机制尚不完全清楚，但罗马 IV 的定义认为其与脑肠互动异常有关，导致胃肠运动障碍、内脏超敏反应以及胃肠道微生物群、黏膜和免疫功能、中枢神经系统处理的改变。现代医学主要采用对症治疗的方法来治疗功能性消化不良，但其临床疗效有限，长期使用会产生多种副作用，并且停药后易于复发，治疗的局限性较大。相比之下，中医药治疗功能性消化不良具有一定的优势，中医药强调辨证论治和综合干预，可以同时改善患者的胃肠道和身心症状。此外，研究表明，传统治疗方法如中草药和针刺在减轻胃肠道疾病症状方面具有一定的疗效，辅助和替代医学在西方国家的普及率也逐渐上升。

目前国际临床上还没有针对功能性消化不良的中医临床实践指南标准，因此有必要制定功能性消化不良中医临床实践的国际指南，以便更好地推广和应用中医治疗功能性消化不良的有效方法。这将有助于提高功能性消化不良的治疗效果，减轻患者的身心负担，提高患者的生活质量。

（二）主要工作过程

2022 年 12 月底在国际中医临床实践指南-功能性消化不良专家指导组的指导下组建了工作组。

2023 年 1-2 月在国际中医临床实践指南-功能性消化不良专家指导组的指导下，填写了《国际中医临床实践指南-功能性消化不良》项目立项书及初版草案，报世界中医药学会联合会批准。

2023 年 3 月 9 日世界中医药学会联合会批准《国际中医临床实践指南 功能性消化不良》（SCMNP2023-0155）立项。

2023 年 4 月-2024 年 4 月，工作组完成了文献检索、证据筛选和资料提取及证据评价，形成了文献证据总结报告。

2024 年 4 月-8 月邀请了中医、西医、中西医结合、指南研究方法学等专家进行第一轮德尔菲问卷征求意见，8 月-12 月梳理专家意见并修订草案。

，2025 年 1 月邀请中医、西医、中西医结合、药学、护理学、指南研究方法学等专家对草稿进行第二轮德尔菲线上会议征求意见，梳理专家意见并修订草案后，进行草案专家评议，会后形成了《国际中医临床实践指南 功能性消化不良》草案。

2025 年 2 月，项目工作组形成了标准草案，经专家指导组审核后报送世界中医药学会联合会办公室网上发布，全国征求意见后再次修改，形成送审稿。本指南的编制过程见图 1。

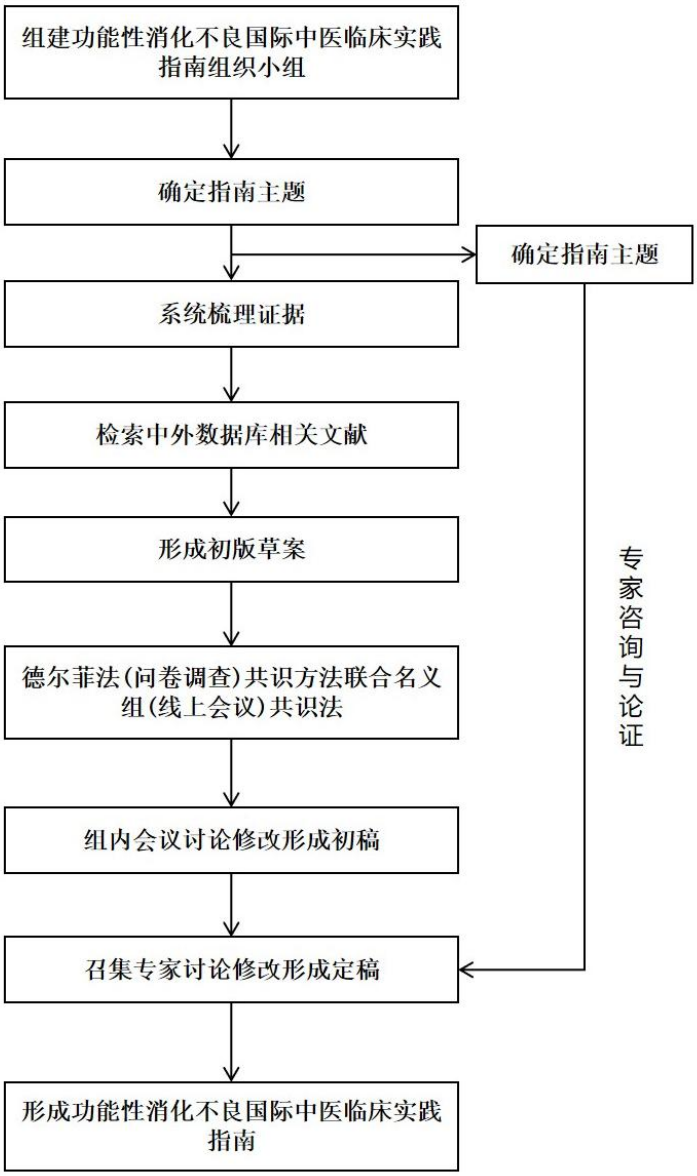


图 1 指南编制过程

（三）主要工作过程指南主要起草人及其所做工作

1.起草成员

姓名	单位	承担工作
魏　玮	中国中医科学院望京医院	项目负责人。组织申报、实施、总结
张声生	首都医科大学附属北京中医医院	参与指南申报、总结、起草、修改
Nicholas Talley	澳大利亚纽卡斯尔大学	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
Louis Liu	多伦多大学消化病学分部	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
Jiande Chen	美国密西根大学医学院	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
Gengqing Song	美国凯斯西储大学	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
柯美云	北京协和医院	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
段丽萍	北京大学第三医院	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
侯晓华	华中科技大学同济医学院附属协和医院	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
荣培晶	中国中医科学院针灸研究所	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
刘建平	北京中医药大学循证医学中心	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等
陈　薇	北京中医药大学循证医学中心	参与工作讨论、文献研究、专家咨询问卷等的整理工作，参与编写草案、编制说明等

2.参与专家

姓名	单位	承担工作

苏晓兰	中国中医科学院望京医院	专家调查问卷、意见征询
张学智	北京大学第一医院	专家调查问卷、意见征询
汪红兵	首都医科大学附属北京中医医院	专家调查问卷、意见征询
杜正光	首都医科大学附属北京中医医院	专家调查问卷
王彦刚	北京中医药大学第三附属医院	专家调查问卷
方继良	中国中医科学院广安门医院	专家调查问卷
刘凤斌	广州中医药大学第一附属医院	专家调查问卷
李培武	广州中医药大学第一附属医院	专家调查问卷
时昭红	武汉市第一医院	专家调查问卷
苏娟萍	山西省中医院	专家调查问卷
王垂杰	辽宁中医药大学附属医院	专家调查问卷
丁　霞	北京中医药大学东直门医院	专家调查问卷
迟莉丽	山东中医药大学附属医院	专家调查问卷
刘华一	天津市中医药研究院附属医院	专家调查问卷、意见征询
索　标	厦门市中医院	专家调查问卷
黄穗平	广东省中医院	专家调查问卷
刘启泉	河北省中医院	专家调查问卷
鱼　涛	陕西省中医医院	专家调查问卷
夏志伟	北京大学第三医院	专家调查问卷
杜时雨	中日友好医院	专家调查问卷
杨　倩	河北省中医院	专家调查问卷
张晓岚	河北医科大学第二医院	专家调查问卷
王邦茂	天津医科大学总医院	专家调查问卷
唐艳萍	天津市南开医院	专家调查问卷
肖小河	解放军 302 医院	专家调查问卷、意见征询
曹俊岭	北京中医药大学东方医院	专家调查问卷
王景红	中国中医科学院望京医院	专家调查问卷
曹艳霞	中国中医科学院望京医院	专家调查问卷
陈一秀	中国中医科学院望京医院	专家调查问卷
沈　洪	南京中医药大学附属医院	专家调查问卷
何　凌	江西中医药大学附属医院	专家调查问卷
蓝　宇	首都医科大学附属北京积水潭医院	专家调查问卷
胡运莲	湖北省中医院	专家调查问卷
王林恒	北京中医药大学东方医院	专家调查问卷
柯　晓	福建省第二人民医院	专家调查问卷
王化虹	北京大学第一医院	专家调查问卷
巩　阳	沈阳军区总医院	专家调查问卷

肖力文	中国科学院动物研究所	专家调查问卷
丁士刚	北京大学第三医院	专家调查问卷

二、标准编制原则和确定标准主要内容的依据

（一）指南编制原则

本指南编制遵循“科学性、实用性、规范性”原则，按照“能够为中医行业内实际应用，能被行业外广泛接受和认可，并与国际诊疗指南接轨”的要求，充分考虑起草过程中所涉及的有关问题，在相关法律法规和技术文件指导的框架下，前期已建立的中医临床研究数据及相关临床经验与共识，制定《国际中医临床实践指南 功能性消化不良》。

1.科学性

科学性是编制本指南的前提，也是保障指南质量的基础。本指南在编制过程中严格遵循科学性原则，团队广泛调查了国际形成循证指南证据的方法，选取具有中医药特色的“文献研究法”、“ 专家问卷调查法”、“ 专家会议法”三法合一的研究方法，保证了本指南研制的科学性。其中“文献检索”按国际通行要求方法进行，搜索功能性消化不良中医临床实践研究的相关文献，并提取包括证功能性消化不良中医临床实践研究的主要流程、主要内容、共性关键技术等内容，为开展专家问卷调查提供依据。专家问卷调查采用国际广泛应用的 Delphi 法为基础加以改良，结合中医药行业的具体情况，结合文献研究报告及工作组讨论形成专家问卷，筛选具有代表性、权威性、地域性的调查专家，回收问卷并进行统计分析，从而有效凝聚专家意见。按照“专家会议法”要求，项目组邀请了以功能性消化不良中医临床实践研究相关的专家为主，相关的中医内科学专家、中西医结合专家、西医内科学专家、药学专家、护理学专家与指南研究方法学等组成专家论证组并召开专家论证会，就项目通过文献研究、专家问卷调查初步形成的指南草稿，特别是其中存有争议、有待讨论、商榷的内容，请专家们给出较客观的和专业化的意见，形成本标准草稿。

2.实用性

本指南研制的目的主要是为了规范功能性消化不良国际中医临床实践标准，旨在为能性消化不良的诊断与治疗标准的研制提供指导，进而提高标准的准确性、权威性和代表性，进一步满足功能性消化不良实践标准在临床研究与基础研究等方面的实际需求。即本指南要求适用于功能性消化不良国际中医临床实践指南的研制，能在功能性消化不良相关的临床、教学、科学研究中得到广泛的实际应用。

在标准研制过程中，不仅查找了相关文献研究、学术著作与教材等，将相关研究要素组成调查问卷，调查了分布于全国各地区从事或了解功能性消化不良中医临床实践指南研制的专家，集中他们的意见，再经过专家论证和向行业专家广泛征求意见，综合反馈意见，形成最终的功能性消化不良中医临床实践指南，本标准从研制过程到结果保证实用性和可操作性。

3.规范性

本指南在研制过程中的标准编制遵循 GB/T 1.1-2020《标准化工作导则 第一部分：标准化文件的结构和起草规则》以及已经颁布的各项相关标准、指南，并在世界中医药学会联合会的指导下进行。所采用的方法，包括文献检索、专家问卷调查方法、专家论证会方法等，均按照国际比较公认的办法。保证了本指南的研制过程，包括技术方法及形成的指南规格体例、名词术语、语言文字等的规范性要求。

（二）确定标准主要内容的方法和论据

1. 标准的主要内容

（1）范围

（2）规范性引用文件

（3）术语和定义

（4）研制原则与方法

（5）研制流程

2.确定标准主要内容的方法

2.1专家访谈

2.1.1访谈方案确定过程及方法

被访谈专家是功能性消化不良的中医、西医临床专家，均为高级职称人员，从事功能性消化不良临床与科学研究多年。数量中医专家三人，中西医结合专家一人，西医专家三人。访谈提纲由起草组秘书张世翼、姜瀚起草，内容包括基于前期文献检索形成的临床问题和结局指标，逐个征求专家的意见，并由专家进行问题补充。

2.1.2受访专家名单

表2 受访专家基本信息

姓名	单位	职务/职称	专业
王化虹	北京大学第一医院	主任医师	西医内科学
段丽萍	北京大学第三医院	主任医师	西医内科学
侯晓华	华中科技大学同济医学院附属协和医院	主任医师	西医内科学
张学智	北京大学第一医院	主任医师	中西医结合内科学
魏玮	中国中医科学院望京医院	科主任	中医内科学
苏晓兰	中国中医科学院望京医院	主任医师	中医内科学
杨倩	河北省中医院	院长	中医内科学

2.1.3访谈提纲：

临床问题：

①如何结合现代医学检查结果来指导中医治疗功能性消化不良？

②中医经典方剂治疗 FD 寒热错杂证患者的疗效如何？

③中医经典方剂治疗 FD 脾虚气滞证患者的疗效如何？
④中成药治疗 FD 脾虚气滞证患者的疗效如何？
⑤中医经典方剂治疗 FD 肝胃不和证患者的疗效如何？
⑥中成药治疗 FD 肝胃不和证患者的疗效如何？
⑦中医经典方剂治疗 FD 脾胃湿热证患者的疗效如何？
⑧中医经典方剂治疗 FD 脾胃虚寒（弱）证患者的疗效如何？
⑨中成药治疗 FD 脾胃虚寒（弱）证患者的疗效如何？
⑩药膳干预 FD 的疗效如何？具体方法有哪些?
⑪体表医学干预 FD 的疗效如何？具体方法有哪些?
⑫功能性消化不良患者在进行中医治疗时，需要注意哪些事项？如何避免治疗过程中的不良反应？
⑬FD 患者是否应该配合生活指导/如何配合生活指导?
⑭FD 患者是否应该配合辅助心理治疗/如何配合辅助心理治疗?
⑮FD 患者的预后与转归如何?
结局指标：
①临床疗效（总有效率）
②临床复发率
③胃排空率（B 超实时检测、钡条法检测等）
④腹痛症状:疼痛强度评分（NRS）
⑤FD 中医证候积分
⑥FD 中医证候各项症状积分
⑦FD 单项症状量化分级表
⑧尼平消化不良症状指数（NDSI）
⑨尼平消化不良生活质量指数（NDLQI）
⑩功能性消化不良生存质量量表（FDDQL）
⑪健康调查简表（SF-36）
⑫汉密尔顿焦虑量表（HAMA）
⑬汉密尔顿抑郁量表（HAMD）
⑭焦虑自评量表（SAS）
⑮抑郁自评量表（SDS）
2.1.4 确定临床问题与结局指标
临床问题:
①中医经典方剂治疗 FD 寒热错杂证患者的疗效如何？
②中医经典方剂治疗 FD 脾虚气滞证患者的疗效如何？
③中成药治疗 FD 脾虚气滞证患者的疗效如何？
④中医经典方剂治疗 FD 肝胃不和证患者的疗效如何？
⑤中成药治疗 FD 肝胃不和证患者的疗效如何？
⑥中医经典方剂治疗 FD 脾胃湿热证患者的疗效如何？

⑦中医经典方剂治疗 FD 脾胃虚寒（弱）证患者的疗效如何？
⑧中成药治疗 FD 脾胃虚寒（弱）证患者的疗效如何？
⑨体表医学干预 FD 的疗效如何？具体方法有哪些?
⑩FD 患者是否应该配合生活指导/如何配合生活指导?
结局指标：
①临床疗效（总有效率）
②临床复发率
③胃排空率（B 超实时检测、钡条法检测等）
④腹痛症状:疼痛强度评分（NRS）
⑤FD 中医证候积分
⑥FD 中医证候各项症状积分
⑦FD 单项症状量化分级表
⑧尼平消化不良症状指数（NDSI）
⑨尼平消化不良生活质量指数（NDLQI）
⑩功能性消化不良生存质量量表（FDDQL）

根据以上临床问题与结局指标进行文献检索。

2.2 文献检索

计算机检索 CNKI 期刊全文数据库、万方数据知识服务平台、维普数据库、中国生物医学文献数据库、PubMed、Cochrane library 收录的相关文献。

2.2.1 检索词

2.2.1.1 中文检索词

西医病名：功能性消化不良/餐后不适综合征/上腹痛综合征

中医病名：胃痞/胃脘痛/脘痞/痞满

干预措施：

口服汤剂：柴胡疏肝散/柴芍六君子汤/香砂六君子汤/六君子汤/枳实消痞丸/四君子汤/越鞠方/补中益气汤/升阳益胃汤/半夏泻心汤/逍遥散/附子理中丸/柴胡达原饮/连朴饮/一贯煎/玉女煎/益胃汤/旋复代赭汤/左金丸/生姜泻心汤/柴枳实平肝汤/柴胡桂枝干姜汤/黄芪建中汤/六磨汤/枳术丸/安中汤/安胃汤/沙参麦冬汤/三仁汤

中成药：附子理中丸/参苓白术散/补中益气颗粒/气滞胃痛颗粒/香砂养胃颗粒/胃苏冲剂/荜铃胃痛颗粒/加味逍遥丸/枳术宽中胶囊/木香顺气丸/健胃消食片/保和丸/香砂六君子丸/补中益气丸

外治法：针刺/针灸/艾灸/电针/穴位埋线/经皮耳迷走神经刺激

全文：随机

2.2.1.2 英文检索词：

西医病名：Functional dyspepsia/postprandial distress syndrome/epigastric pain syndrome

中医病名：Gastric fullness/epigastric pain/ Stomach fullness /fullness sensation

干预手段：

Chaihu Shugan San / Chaihu Liu Jun Zi Tang / Xiang Sha Liu Jun Zi Tang / Liu Jun Zi Tang / Zhi Shi Xiao Pi Wan / Si Jun Zi Tang / Yue Ju Fang / Bu Zhong Yi Qi Tang / Sheng Yang Yi Wei Tang / Ban Xia Xie Xin Tang / Xiao Yao San / Fuzi Li Zhong Wan / Chaihu Da Yuan Yin / Lian Pao Yin / Yi Guan Jian / Yu Nu Jian / Yi Wei Tang / Xuan Fu Dai Zhe Tang / Zuo Jin Wan / Sheng Jiang Xie Xin Tang / Chai Zhi Shi Ping Gan Tang / Huang Qi Jian Zhong Tang / Liu Mo Tang / Zhi Shu Wan / An Zhong Tang / An Wei Tang / Sha Shen Mai Dong Tang / San Ren Tang / Fuzi Li Zhong Wan / Shen Ling Bai Zhu San / Bu Zhong Yi Qi Ke Li / Qi Zhi Wei Tong Ke Li / Xiang Sha Yang Wei Ke Li / Wei Su Chong Ji / Bi Ling Wei Tong Ke Li / Jia Wei Xiao Yao Wan / Zhi Shu Kuan Zhong Jiao Nang / Mu Xiang Shun Qi Wan / Jian Wei Xiao Shi Pian / Bao He Wan / Xiang Sha Liu Jun Zi Wan / Bu Zhong Yi Qi Wan / Acupuncture / Moxibustion / Electroacupuncture / Acupoint-embedding / Transcutaneous vagus nerve stimulation

全文：Randomized。

检索时间为数据库建立至 2023 年 6 月。

纳入标准：中医治疗功能性消化不良的随机对照试验和 Meta 分析，治疗方法包括中医经典方剂及加减、中成药、中医外治法。

排除标准：综述类、述评、理论探讨、动物实验、无中医药干预、中药自拟方、会议、科技成果以及信息不全的文献。

对于合格文献，由 2 名研究者提取纳入文献的题目、作者姓名、发表年份、结局指标（如有效率、总症状积分、单症状积分及其他评分），进行证据综合和质量评价撰写文献证据总结，详见附件 1。

2.2.2 检索式

2.2.2.1 中文检索式

以 CNKI 期刊全文数据库为例。SU 为主题检索，TKA 为篇关摘检索。主题检索是以知网标引的主题（机标关键词）为核心检索内容，同时涵盖所有内容相关字段，在检索过程中嵌入了专业词典、主题词表、中英对照词典、停用词表等工具，并采用关键词截断算法，将低相关或微相关文献进行截断。主题检索旨在提供一种能够涵盖文章所有主题特征并综合时间特征的检索手段，适用普通用户快速查询和调研。检索式为：

（SU=（功能性消化不良） OR SU=（餐后不适综合征） OR SU=（腹痛综合征） OR SU=（胃痞） OR SU=（胃脘痛） OR SU=（脘痞） OR SU=（痞满） OR TKA=（餐后不适综合征） OR TKA=（腹痛综合征） OR TKA=（胃痞） OR TKA=（胃脘痛） OR TKA=（脘痞） OR TKA=（痞满） ） AND （SU=（柴胡疏肝散） OR SU=（柴芍六君子汤） OR SU=（香砂六君子汤） OR SU=（六君子汤） OR SU=（枳实消痞丸） OR SU=（四君子汤） OR SU=（越鞠方） OR SU=（补中益气汤） OR SU=（升阳益胃汤） OR SU=（半夏泻心汤） OR SU=

（逍遥散） OR SU=（附子理中丸） OR SU=（柴胡达原饮） OR SU=（连朴饮） OR SU=（一贯煎） OR SU=（玉女煎） OR SU=（益胃汤） OR SU=（旋复代赭汤） OR SU=（左金丸） OR SU=（生姜泻心汤） OR SU=（柴枳实平肝汤） OR SU=（柴胡桂枝干姜汤） OR SU=（黄芪建中汤） OR SU=（六磨汤） OR SU=（枳术丸） OR SU=（安中汤） OR SU=（安胃汤） OR SU=（沙参麦冬汤） OR SU=（三仁汤） OR SU=（附子理中丸） OR SU=（参苓白术散） OR SU=（补中益气颗粒） OR SU=（气滞胃痛颗粒） OR SU=（香砂养胃颗粒） OR SU=（胃苏冲剂） OR SU=（荜铃胃痛颗粒） OR SU=（加味逍遥丸） OR SU=（枳术宽中胶囊） OR SU=（木香顺气丸） OR SU=（健胃消食片） OR SU=（保和丸） OR SU=（香砂六君子丸） OR SU=（补中益气丸） OR SU=（针刺） OR SU=（艾灸） OR SU=（针灸） OR SU=（电针） OR SU=（穴位埋线） OR SU=（经皮耳迷走神经刺激） OR TKA=（柴胡疏肝散） OR TKA=（柴芍六君子汤） OR TKA=（香砂六君子汤） OR TKA=（六君子汤） OR TKA=（枳实消痞丸） OR TKA=（四君子汤） OR TKA=（越鞠方） OR TKA=（补中益气汤） OR TKA=（升阳益胃汤） OR TKA=（半夏泻心汤） OR TKA=（逍遥散） OR TKA=（附子理中丸） OR TKA=（柴胡达原饮） OR TKA=（连朴饮） OR TKA=（一贯煎） OR TKA=（玉女煎） OR TKA=（益胃汤） OR TKA=（旋复代赭汤） OR TKA=（左金丸） OR TKA=（生姜泻心汤） OR TKA=（柴枳实平肝汤） OR TKA=（柴胡桂枝干姜汤） OR TKA=（黄芪建中汤） OR TKA=（六磨汤） OR TKA=（枳术丸） OR TKA=（安中汤） OR TKA=（安胃汤） OR TKA=（沙参麦冬汤） OR TKA=（三仁汤） OR TKA=（附子理中丸） OR TKA=（参苓白术散） OR TKA=（补中益气颗粒） OR TKA=（气滞胃痛颗粒） OR TKA=（香砂养胃颗粒） OR TKA=（胃苏冲剂） OR TKA=（荜铃胃痛颗粒） OR TKA=（加味逍遥丸） OR TKA=（枳术宽中胶囊） OR TKA=（木香顺气丸） OR TKA=（健胃消食片） OR TKA=（保和丸） OR TKA=（香砂六君子丸） OR TKA=（补中益气丸） OR TKA=（针刺） OR TKA=（艾灸） OR TKA=（针灸） OR TKA=（电针） OR TKA=（穴位埋线） OR TKA=（经皮耳迷走神经刺激））AND （FT=（随机） OR FT= （RCT））。

2.2.2.2 英文检索式

以 PubMed 为例。检索式为：

#1 ((((((Functional dyspepsia[Title/Abstract]) OR (postprandial distress syndrome[Title/Abstract])) OR (epigastric pain syndrome[Title/Abstract])) OR (Gastric fullness[Title/Abstract])) OR (epigastric pain[Title/Abstract])) OR (stomach fullness[Title/Abstract])) OR (fullness sensation[Title/Abstract])

#2 ”Functional dyspepsia”[Mesh Terms]

#3 ”Postprandial distress syndrome”[Mesh Terms]

#4 ”Epigastric pain syndrome”[Mesh Terms]

#5 #1 OR #2 OR #3 OR #4

#6 ((Chaihu Shugan San[Title/Abstract])

OR (Chaihu Liu Jun Zi Tang[Title/Abstract])) OR (Xiang Sha Liu Jun Zi Tang[Title/Abstract])) OR (Liu Jun Zi Tang[Title/Abstract])) OR (Zhi Shi Xiao Pi Wan[Title/Abstract])) OR (Si Jun Zi Tang[Title/Abstract])) OR (Yue Ju Fang[Title/Abstract])) OR (Bu Zhong Yi Qi Tang[Title/Abstract])) OR (Sheng Yang Yi Wei Tang[Title/Abstract])) OR (Ban Xia Xie Xin Tang[Title/Abstract])) OR (Xiao Yao San[Title/Abstract])) OR (Fuzi Li Zhong Wan[Title/Abstract])) OR (Chaihu Da Yuan Yin[Title/Abstract])) OR (Lian Pao Yin[Title/Abstract])) OR (Yi Guan Jian[Title/Abstract])) OR (Yu Nu Jian[Title/Abstract])) OR (Yi Wei Tang[Title/Abstract])) OR (Xuan Fu Dai Zhe Tang[Title/Abstract])) OR (Zuo Jin Wan[Title/Abstract])) OR (Sheng Jiang Xie Xin Tang[Title/Abstract])) OR (Chai Zhi Shi Ping Gan Tang[Title/Abstract])) OR (Huang Qi Jian Zhong Tang[Title/Abstract])) OR (Liu Mo Tang[Title/Abstract])) OR (Zhi Shu Wan[Title/Abstract])) OR (An Zhong Tang[Title/Abstract])) OR (An Wei Tang[Title/Abstract])) OR (Sha Shen Mai Dong Tang[Title/Abstract])) OR (San Ren Tang[Title/Abstract])) OR (Fuzi Li Zhong Wan[Title/Abstract])) OR (Shen Ling Bai Zhu San[Title/Abstract])) OR (Bu Zhong Yi Qi Ke Li[Title/Abstract])) OR (Qi Zhi Wei Tong Ke Li[Title/Abstract])) OR (Xiang Sha Yang Wei Ke Li[Title/Abstract])) OR (Wei Su Chong Ji[Title/Abstract])) OR (Bi Ling Wei Tong Ke Li[Title/Abstract])) OR (Jia Wei Xiao Yao Wan[Title/Abstract])) OR (Zhi Shu Kuan Zhong Jiao Nang[Title/Abstract])) OR (Mu Xiang Shun Qi Wan[Title/Abstract])) OR (Jian Wei Xiao Shi Pian[Title/Abstract])) OR (Bao He Wan[Title/Abstract])) OR (Xiang Sha Liu Jun Zi Wan[Title/Abstract])) OR (Bu Zhong Yi Qi Wan[Title/Abstract])) OR (Acupuncture[Title/Abstract])) OR (Moxibustion[Title/Abstract])) OR (Electroacupuncture[Title/Abstract])) OR (Acupoint-embedding[Title/Abstract])) OR (Transcutaneous vagus nerve stimulation[Title/Abstract])

#7 randomized[Text Word]

##5 AND #6 AND #7

2.3 专家问卷调查

项目组根据文献研究总结研讨后，采用德尔菲（Delphi）法，撰写专家调查问卷，按标准遴选出的专家进行两轮问卷调查。专家遴选的标准：具有副高级职称和临床工作经验、有兴趣和能够坚持完成数轮专家调查，遴选专家时同时考虑到专家分布的地域性。

对专家答卷的统计分析，第一轮调查问卷结果导入 Excel 软件，通过统计专家积极系数、专家权威系数和肯德尔协调系数（Kendall's W）进行评价。第二轮调查问卷采用 GRADE 网格计票法确定推荐强度。“推荐意见”除了“C”格以外的任何 1 格票数超过 50%，则达成共识，可直接确定推荐方向及强度，A 格为强推荐，B 格为弱推荐，C 格为不确定，D 格为弱不推荐，E 格为强不推荐；若无任何 1 格超过 50%，但“C”格某一侧两格总票数超过 70%，也算达成共识和

推荐方向，推荐强度为“弱”，被视为在本指南研制过程中需要整理的条目；排除以上条件则视为未达成共识。通过专家共识条目筛选所形成的初始条目由制订小组讨论整理后形成最终纳入的条目。按照数理统计结果分析汇总专家意见，由第一轮调查问卷形成第二轮调查问卷，再总结初步形成了《国际中医临床实践指南 功能性消化不良》草稿。详见附件 2、3。

2.4 专家论证会

2025 年 1 月在线上召开了《国际中医临床实践指南 功能性消化不良》（草稿）专家论证会。工作组汇报标准草案情况及需请专家组重点讨论的问题。会议对于《国际中医临床实践指南 功能性消化不良》（草稿）进行认真的论证。会议上专家们积极发言。他们总体上对项目组提交的草稿给予了肯定，认为草稿已比较成熟，可以作为此次标准制定文本的基础。对于草稿中的若干具体内容，专家们通过讨论基本上达成共识，提出了许多有价值的修改意见，详见附件 4。

三、与相关法律、法规和强制性标准的关系

本项目组研究形成的《国际中医临床实践指南 功能性消化不良》与现行法律、法规和强制性标准没有冲突，并且在编制过程中严格遵循已有的国际、国内标准，使文本内容符合规范，言之有据。

四、重大意见的处理经过和依据

本指南标准文献研究完成后，制订了专家调查问卷，采用两轮 Delphi 法专家问卷调查征求专家意见，两轮均收回 31 份专家反馈的答卷。专家们基本认可问卷中的内容，对一些具体问题提出了自己的意见。根据专家修改意见，项目组再查找文献，并结合相应领域专家意见，对文稿进行了修改，初步形成草稿。初步形成的指南草稿经专家论证会论证，针对专家提出的意见建议进行修改，形成的修改稿再送专家指导组论证，项目组将按照“循证”等原则，讨论了提出的所有意见，确定是否采纳及其理由，然后对初步形成的草稿进行修改，形成了指南草稿，将再开展指南方法学质量评价和同行评议，根据专家们提出的修改意见认真研讨，采纳，进一步修改完善本指南。

五、作为推荐性指南的建议

《国际中医临床实践指南 功能性消化不良》规范了规定了中医药治疗功能性消化不良的诊断标准、中医药治疗等。适用于各级中医院、综合医院、中西医结合医院、基层医院等医疗机构对功能性消化不良的诊断与治疗。旨在为能性消化不良的诊断与治疗标准的研制提供指导，进而提高标准的准确性、权威性和代表性，进一步满足功能性消化不良实践标准在临床研究与基础研究等方面的实际需求。即本指南要求适用于功能性消化不良国际中医临床实践指南的研制，能在功能性消化不良相关的临床、教学、科学研究中得到广泛的实际应用。

六、贯彻指南的要求和措施建议

本项目研究形成的《国际中医临床实践指南 功能性消化不良》经审查批准发布后，需要采用多种渠道宣传、贯彻、实施。

1.由世界中医药学会联合会统一组织行业内的推广和贯彻实施工作。

2.举办标准应用推广培训班、继续教育学习班，培训相关专业人员，促进指南的宣传、推广和应用。

3.利用世界中医药学会联合会肺康复专业委员会、中国民族医药学会肺病分会这两个学术平台，在其所开展的各种国内、国际学术活动中加以介绍，推广。

4.在学术杂志上发表指南及相关的学术论文，宣传、推广，并吸收进一步完善的意见。

七、应用时的促进和阻碍因素

无。

八、应当说明的其他事项

建议在本指南发布实施 3～5 年后，要依据临床研究的进展和技术方法的进步，对本标准进一步补充、修订、更新。

九、附件

附件 1 《国际中医临床实践指南 功能性消化不良》文献研究总结报告

附件 2 《国际中医临床实践指南 功能性消化不良》第一轮专家问卷调查工作报告

附件 3 《国际中医临床实践指南 功能性消化不良》第二轮专家问卷调查工作报告

附件 4 《国际中医临床实践指南 功能性消化不良》（草稿）专家论证会会议纪要

附件 1

文献证据总结报告

一、文献检索结果

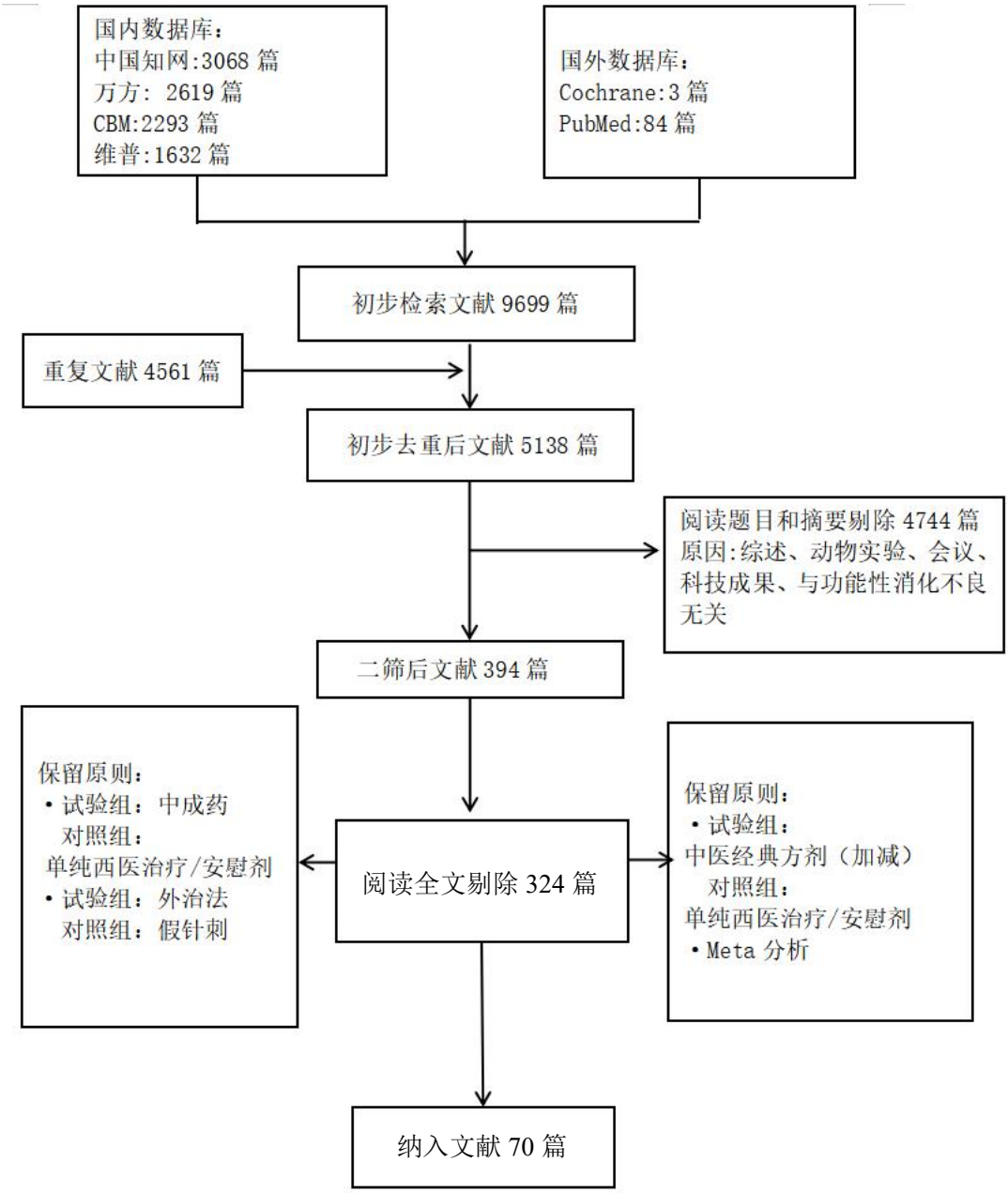
共检索到 9699 篇文献，其中 CNKI 数据库检索结果：共检索题录 3068 条；万方数据库检索结果：共检索题录 2619 条；维普数据库检索结果：共检索题录 1632 条；中国生物医学文献服务系统检索结果：共检索题录 2293 条；Pubmed 检索结果：共检索题录 84 条；Cochrane 检索结果：共检索题录 3 条。去除重复后共纳入 5138 篇文献。

二、纳入排除标准

纳入标准：①文献中明确诊断为功能性消化不良；②随机对照试验或 meta 分析；③干预措施必须满足：试验组：中医经典方剂及加减、中成药、中医外治法；对照组：单纯西医治疗或安慰剂或假针刺。

排除标准：①综述类、述评、理论探讨、动物实验、无中医药干预、中药自拟方、会议、科技成果；②结局指标无法与其他研究合并的文献；③纳入的研究均不符合纳入标准的 meta 分析；④非随机对照试验。

三、证据筛选流程及结果



四、证据评价

两位项目组成员参照《基于证据体的中医药临床证据分级标准建议》中 RCT 方法学质量评价标准，对纳入的 RCT 进行风险偏倚评估（随机序列的产生、随机化隐藏、盲法、不完整结局报告、选择性报告结局、样本量计算），如有分歧则通过协商或请第三方进行裁决。

五、证据分级方法

证据分级标准参考刘建平教授在《基于证据体的中医药临床证据分级标准建议》中提出的传统医学证据体的构成及证据分级的建议进行证据质量评价。

Ⅰ级 随机对照试验及其系统综述、N-of-1试验系统综述

Ⅱ级 非随机临床对照试验、队列研究、N-of-1试验

Ⅲ级 病例对照研究、前瞻性病例系列

Ⅳ级 规范化的专家共识、回顾性病例系列、历史性对照研究
Ⅴ级 非规范化专家共识、病例报告、经验总结

六、证据概要表

纳入文献证据概要表

研究对象（P）：FD 寒热错杂证

干预措施（I）：半夏泻心汤加减

对照措施（C）：西医治疗（吗丁啉）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床总有效率											
Hu XL 2006	RCT	2	0	0	1	1	0	30/30	30/30	RR=2.00，95%CI[1.69，2.31]，P＜0.00001	III级

研究对象（P）： FD 脾虚气滞证

干预措施（I）： 香砂六君子汤加味

对照措施（C）： 西医治疗（兰索拉唑+莫沙必利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Zeng ZS 2017；Zhou WB 2016	RCT	2	0	0	1	1	0	91/104	70/104	RR=1.30， 95% CI [1.12，1.51]，P=0.0007	III级

研究对象（P）：FD 脾虚气滞证

干预措施（I）：枳实消痞丸加减

对照措施（C）：西医治疗（莫沙必利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Wang D 2021	RCT	2	0	0	1	1	0	40/40	30/40	RR=1.33， 95%CI[1.11， 1.59]，P=0.002	Ⅲ级
症状积分											
Wang D 2021	RCT	2	0	0	1	1	0	40	40	MD $_{积分}$=4.08，95%CI[3.73，4.43]，P＜0.00001	Ⅲ级

研究对象（P）： FD 脾虚气滞证

干预措施（I）： 枳术宽中胶囊

对照措施（C）： 西医治疗（多潘立酮/西沙必利/枸橼酸莫沙必利分散片）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Zhu M 2011; Xu CP 2004; Xiao BF 2021	RCT	2	1	0	1	1	0	229/266	122/175	RR=1.26， 95% CI [1.04，1.51]， P=0.02	Ⅱ级

研究对象（P）：FD 肝胃不和证

干预措施（I）：柴胡疏肝散加减

对照措施（C）：西医治疗（多潘立酮）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Men CY 2012	RCT	2	0	0	1	1	0	25/28	15/28	RR=1.67，95% CI[1.15，2.41]，P=0.007	III级

研究对象（P）：FD 肝胃不和证

干预措施（I）：气滞胃痛颗粒

对照措施（C）：安慰剂

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Su Q 2018	RCT	2	1	2	1	1	1	66/85	17/80	RR=3.65，95%CI[2.36，5.66]，P < 0.00001	Ⅰ级

研究对象（P）： FD 肝胃不和证

干预措施（I）： 荜铃胃痛颗粒

对照措施（C）： 安慰剂

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Wen Y 2020	RCT	2	1	2	1	1	1	101/118	34/120	RR=3.02，95%CI[2.25，4.05]，P＜0.00001	Ⅰ级
生活质量评分											
Wen Y 2020	RCT	2	1	2	1	1	1	118	120	MD $_{积分}$=16.21， 95%CI[12.33，20.09]，P＜0.00001	Ⅰ级

研究对象（P）：FD 肝胃不和证

干预措施（I）：达立通颗粒

对照措施（C）：西医治疗（莫沙比利/多潘立酮/西沙比利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Sun XX 2016；Liu XJ 2013；Wu QB 2012；Li R 2013；Wang GY 2014；Hu K 2005；Wang L 2004；Zhu D 2005；Xu SQ 2009；Ji PZ 2010	RCT	2	0	0	1	1	0	919/1075	554/742	RR=1.33，95%CI[1.05，1.22]，P=0.002	III 级

研究对象（P）：FD 肝胃不和证

干预措施（I）：枳实总黄酮片

对照措施（C）：西医治疗（多潘立酮）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
治疗后症状消失率											
Wei M 2024	RCT	2	1	1	1	1	2	34/120	38/119	RR=0.90，95%CI[0.63，1.28]*，P=0.54	Ⅰ级
治疗 4 周后症状消失率											
Wei M 2024	RCT	2	1	1	1	1	2	25/120	5/119	RR=4.96，95%CI[1.96，12.52]，P=0.0007	III 级

研究对象（P）：FD 脾胃湿热证

干预措施（I）：加味连朴饮加减

对照措施（C）：西医治疗（多潘立酮）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Wen PY 2014	RCT	2	0	0	1	1	0	28/30	21/30	RR=1.33，95%CI[1.04，1.72]，P=0.03	III 级

研究对象（P）：FD 脾胃湿热证

干预措施（I）：柴胡达原饮加减

对照措施（C）：西医治疗（莫沙必利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床总有效率											
Zhang Y 2020	RCT	2	0	0	1	1	0	36/36	36/36	RR=2.38， 95%CI[171， 3.32]，P<0.00001	III 级
头身困重症状积分											
Zhang Y 2020	RCT	2	0	0	1	1	0	36	36	MD 积分=-0.8，95%CI[-1.2，-0.4]，P＜0.0001	III 级
口苦口黏症状积分											
Zhang Y 2020	RCT	2	0	0	1	1	0	36	36	MD 积分=-0.83，95%CI[-1.22，-0.44]，P＜0.0001	III 级
小便短黄症状积分											
Zhang Y 20207.	RCT	2	0	0	1	1	0	36	36	MD 积分=-0.93，95%CI[-1.39，-0.47]，P＜0.0001	III 级

研究对象（P）：FD 脾胃湿热证

干预措施（I）：三仁汤加减

对照措施（C）：西医治疗（莫沙必利/西沙必利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Gan DC 2016; Wang D 2017	RCT	2	0	0	1	1	0	90/97	79/97	RR=1.13，95%CI[1.01，1.27]，P =0.03	III 级

研究对象（P）： FD 脾胃虚寒证

干预措施（I）： 附子理中汤加减

对照措施（C）： 西医治疗（奥美拉唑）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies(研究数量)	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床疗效总有效率											
Miao XX 2018	RCT	2	0	0	1	1	0	45/46	37/46	RR=1.22，95%CI[1.05，1.41]，P=0.01	III 级
腹部疼痛症状积分											
Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD 积分=-0.36，95%CI[-0.44，-2.08]，P＜0.00001	III 级
腹部烧灼症状积分											
Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD 积分=-0.51，95%CI[-0.59，-0.43]，P＜0.00001	III 级
胃胀症状积分											
Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD 积分=-0.58，95%CI[-0.68，-0.48]，P＜0.00001	III 级
嗳气症状积分											

Miao XX 2018	RCT	2	0	0	1	1	0	46	46	$MD_{积分}$=-0.41，95%CI[-0.56，-0.37]，P＜0.00001	III 级

研究对象（P）： FD 脾胃虚弱证

干预措施（I）： 四君子汤加味

对照措施（C）： 西医治疗（多潘立酮）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
症状积分											
Li YH 2008	RCT	2	0	0	1	1	0	45	45	$MD_{积分}$=6.50，95%CI [6.32，6.68]，P＜0.00001	III 级

研究对象（P）：功能性消化不良患者

干预措施（I）：针刺疗法（针刺百会、中脘、气海、天枢、内关、足三里、公孙、膻中）

对照措施（C）：假针灸

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
4 周应答率											
Yang JW 2020	RCT	2	1	2	1	1	1	97/117	58/112	RR=1.60，95% CI[1.32，1.95]，P < 0.00001	Ⅰ级

研究对象（P）：功能性消化不良患者

干预措施（I）：针刺、电针疗法

对照措施（C）：西药（促胃动力药、抑酸药、促胃动力药与抑酸药联合）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床总有效率											
Chen GE，2000，Liu WQ，2001，Luo L，2002，LI HJ 2004，Zhou Y 2004，Zhang XJ 2004，Chen YJ 2004，Shi HJ 2009，Xu GX 2005，Tang SX 2006，Zhao YW 2009，Jin L 2013，Chen MH 2023，Zhou DQ 2019，Qiang LM 2018，Han J 2017，Liu X 2017，Du R 2016，Liu WR 2016，Xu Y 2015，Ren J 2015，Yuan XX 2015，Zhou L 2014，Zhang YP 2014，Yang M 2014	RCT	2	0	2	1	1	0	948/1030	754/981	RR=1.21，95%CI[1.16，1.25]，P＜0.00001	Ⅱ级

研究对象（P）：功能性消化不良患者

干预措施（I）：针刺、电针疗法

对照措施（C）：假针刺

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床总有效率											
Yang ZQ，2011，Zou X 2021，Hou YQ 2020，Chen P 2020，Chen P 2016，	RCT	2	1	2	1	1	0	193/223	90/200	RR=2.33，95%CI[1.99，2.74]，P < 0.00001	Ⅰ级

研究对象（P）：功能性消化不良患者

干预措施（I）：针刺、电针疗法

对照措施（C）：西药（促胃动力药、促胃动力药+抑酸药）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
NDSI											
Fan HZ，2012，Zhou L 2019，Dai M 2018，Li DD 2014，Sheng JW 2013	RCT	2	0	2	1	1	0	178	176	$MD_{评分}$=-7.44 分，95%CI[-9.79，-5.08]，P < 0.00001	Ⅱ级
NDLQI											
Fan HZ，2012，Zhou L 2019，Dai M 2018，Li DD 2014，Sheng JW 2013	RCT	2	0	2	1	1	0	178	176	$MD_{评分}$=5.71 分，95%CI[4.20，7.23]，P < 0.00001	Ⅱ级

研究对象（P）：功能性消化不良患者

干预措施（I）：针刺、电针疗法

对照措施（C）：假针刺

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
NDSI											
Yang ZQ，2011	RCT	0	0	2	1	1	0	30	28	$MD_{评分}$=MD=-9.94 分，95%CI[-16.33，-3.55]，P = 0.002	III级

研究对象（P）：功能性消化不良患者

干预措施（I）：经皮耳迷走神经刺激

对照措施（C）：假经皮耳迷走神经刺激

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
空腹正常胃慢波百分率											
Zhu Y 2021	RCT	2	1	2	1	1	1	36	39	MD $_{百分率}$=0.15，95%CI[0.13，0.17]，P＜0.00001	Ⅰ级
餐后正常胃慢波百分率											
Zhu Y 2021	RCT	2	1	2	1	1	1	36	39	MD $_{百分率}$=0.10，95%CI[0.08，0.13]，P＜0.00001	Ⅰ级
主要症状积分											
Wu D 2020	RCT	2	1	1	1	1	0	45	45	MD $_{积分}$=-5.02 分，95%CI[-6.34，-3.70]，P < 0.00001	Ⅰ级
生命质量指数（FDDQL）评分											
Wu D 2020	RCT	2	1	1	1	1	0	45	45	MD $_{评分}$=2.56，95%CI[0.91，4.21]，P= 0.002	Ⅰ级

研究对象（P）：功能性消化不良患者

干预措施（I）：耳穴疗法

对照措施（C）：西医治疗（枸橼酸莫沙必利分散片）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
尼平消化不良指数											
Wang D 2018	RCT	2	0	0	1	1	0	30	30	$MD_{评分}$=-4.94，95%CI[-9.32，-0.56]，P =0.03	III级
生活质量											
Wang D 2018	RCT	2	0	0	1	1	0	30	30	$MD_{评分}$=5.37，95%CI[2.95，7.79]，P ＜0.0001	III级

研究对象（P）：功能性消化不良患者

干预措施（I）：穴位埋线（中脘、天枢、肝俞、足三里、脾俞、胃俞埋线）

对照措施（C）：西医治疗（西沙比利）

结局指标（O）：

Certainty assessment（证据质量评价）								Summary of findings（结果总结）			
№ of studies（研究数量）	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
临床总有效率											
Jiao YX 2006	RCT	2	0	0	1	1	0	58/60	26/30	RR=1.12，95%CI[0.96，1.29]，P =0.15	III级

注：证据综合

将从纳入的研究中提取的数据导入Review Manager 5.3 软件计算效应值及可信区间。二分类变量用风险比 （Relative Risk，RR）的95% 置信区间（Confidence intervals ， CI）表示，连续变量则用均值差（mean difference ， MD） 的95% CI表示。

附件 2

《国际中医临床实践指南 功能性消化不良》第一轮专家问卷调查工作报告

《国际中医临床实践指南 功能性消化不良》第一轮专家调查问卷的设计，是依据循证医学原则和德尔菲法（Delphi）的要求，在文献研究的基础上，通过项目组认真讨论，针对本研究主题筛选出的相关条目，供各位专家对各项指标赋予分值，并用文字提出补充修改意见和建议。共收到 35 位专家的有效问卷，现将 35 份答卷总结分析如下：

1. 专家基本信息的统计分析和专家积极系数

1.1 专家基本信息的统计分析

性别		学位			工作年限（年）
男	女	学士	硕士	博士	平均年限
22（62.86%）	13（37.15%）	6（17.14%）	4（11.43%）	25（71.43%）	32±9.61
职称			-	-	-
主任医师	副主任医师	主治医师	-	-	-
34（97.14%）	1（2.86%）	0	-	-	-
职业					
中医医师	中西医结合医师	西医医师	针灸医师	科研人员	其他（护士）
14（40%）	8（22.86%）	8（22.86%）	1（2.86%）	2（5.71%）	2（5.71%）

备注：括号内为各项所占百分比。

1.2 专家积极系数

第一轮专家调查问卷共发出 38 份问卷，共收到 35 位专家回信，专家调查问卷回收率为 92.1％。

2.专家调查问卷的分析

2.1 专家调查问卷的组成和评价办法

《国际中医临床实践指南 功能性消化不良》第一轮专家调查问卷表主要分为 3 个部分：中医辨证、中医治疗、生活指导，并每一部分后都请专家用具体文字列出补充修改意见和建议。

2.1.2 评价方法

运用专家调查问卷的各项指标的评价统一采用：同意；同意，但有一定保留；同意，但有较大保留；不同意，但有保留；完全不同意；分别赋予 5 分、4 分、3 分、2 分和 1 分。

2.1.3 统计分析方法

其中同意率为专家问卷调查“同意”，“同意，但有一定保留”，“同意，但有较大保留所占比例”，记为共识度，当共识度＞ 70%，记为达成共识，共识度≤70%的条目，则需通过专家共识会议进一步讨论

2.1.3.1 主要流程

条目	一级指标	二级指标	同意率	是否达成共识
1	中医辨证	寒热错杂证	91.42%	是
2		肝郁脾虚证	65.71%	否
3		肝郁气滞证	62.85%	否
4		脾虚气滞证	85.71%	是
5		肝胃不和证	94.28%	是
6		脾胃湿热证	71.43%	是
7		湿热内蕴证	62.86%	否
8		脾胃虚寒（弱）证	91.42%	是
9		脾胃气虚证	60%	否
10		胃虚气逆痰阻证	34.29%	否
11	中医治疗	中医经典方剂	100%	是
12		中成药	100%	是
13		体表医学疗法	100%	是
14	生活指导	生活起居	100%	是
15		心理健康	100%	是
16		饮食调护	100%	是

附件 3

《国际中医临床实践指南 功能性消化不良》第二轮专家问卷调查工作报告

项目组在文献研究及第一轮专家问卷的基础上，已对中医辨证、中医治疗、生活指导的主要内容基本达成共识。但具体推荐意见需进一步探讨。在系统梳理常用方剂、中成药及体表疗法的基础上，第二轮专家咨询旨在进一步探讨具体内容。本轮专家咨询共收到 38 位专家的有效问卷星答卷，现将第二轮专家调查问卷 38 份问卷星答卷总结分析如下：

1.专家基本信息的统计分析和专家积极系数

1. 专家基本信息的统计分析和专家积极系数

1.1 专家基本信息的统计分析

性别		学位			工作年限（年）
男	女	学士	硕士	博士	平均年限
24（63.16%）	14（36.84%）	8（21.05%）	5（13.16%）	25（65.79%）	35±9.61
职称			-	-	-
主任医师	副主任医师	主治医师	其他	-	-
34（89.47%）	1（2.63%）	0	3（7.89%）	-	-
职业					
中医医师	中西医结合医师	西医医师	针灸医师	科研人员	其他
14（36.84%）	8（21.05%）	8（21.05%）	1（2.63%）	2（5.26%）	5（13.15%）

备注：括号内为各项所占百分比。

1.2 专家积极系数

第一轮专家调查问卷共发出 38 份问卷，共收到 38 位专家回信，专家调查问卷回收率为 100%。

2.专家调查问卷的分析

2.1 专家调查问卷及评价办法

《国际中医临床实践指南 功能性消化不良》第二轮专家调查问卷表主要为推荐意见的具体内容，并每一部分后都请专家用具体文字列出补充修改意见和建议。

2.1.2 评价方法

通过 GRADE 网格计票法确定推荐强度。“推荐意见”除了“C”格以外的任何 1 格票数超过 50%，则达成共识，可直接确定推荐方向及强度，A 格为强推荐，B 格为弱推荐，C 格为不确定，D 格为弱不推荐，E 格为强不推荐；若无任何 1 格超过 50%，但“C”格某一侧两格总票数超过 70%，也算达成共识和推荐方向，推荐强度为“弱”。

2.1.3.1 推荐意见投票结果

序号	推荐条目	推荐方向强度的票数					投票轮数	是否达成共识
		↑↑	↑	／	↓	↓↓		
1	针对寒热错杂证 FD 的患者，推荐使用中医经典方剂半夏泻心汤	30	7	0	0	1	1	是
2	针对脾虚气滞证 FD 的患者，推荐使用中医经典方剂香砂六君子汤	32	6	0	0	0	1	是
3	针对脾虚气滞证 FD 的患者，推荐使用中医经典方剂枳实消痞丸	28	10	0	0	0	1	是
4	针对脾虚气滞证 FD 患者，推荐使用中成药香砂六君丸	30	8	0	0	0	1	是
5	针对脾虚气滞证 FD 患者，推荐使用中成药枳术宽中胶囊	32	6	0	0	0	1	是
6	针对肝胃不和证 FD 患者，推荐使用中医经典方剂柴胡疏肝散	27	11	0	0	0	1	是
7	针对肝胃不和证 FD 患者，推荐使用中成药气滞胃痛颗粒（片）	34	4	0	0	0	1	是
8	针对肝胃不和证 FD 患者，推荐使用中成药荜铃胃痛颗粒	32	5	1	0	0	1	是
9	针对肝胃不和证 FD 患者，推荐使用中成药达立通颗粒	22	16	0	0	0	1	是
10	针对肝胃不和证 FD 患者，推荐使用中成药枳实总黄酮片	29	8	1	0	0	1	是
11	针对脾胃湿热证中湿热并重的 FD 患者，推荐使用中医经典方剂连朴饮	21	17	0	0	0	1	是
12	针对脾胃湿热证中湿重于热的 FD 患者，推荐使用中医经典方剂柴胡达原饮	25	11	1	1	0	1	是
13	针对脾胃湿热证湿热并重的 FD 患者，推荐使用中医经典方剂三仁汤	20	17	1	0	0	1	是

14	针对脾胃虚寒证 FD 患者，推荐使用中医经典方剂附子理中汤	28	9	1	0	0	1	是
15	针对脾胃虚弱证 FD 患者，推荐使用中医经典方剂四君子汤	28	10	0	0	0	1	是
16	针对脾胃虚寒证 FD 患者，推荐使用中成药附子理中丸	26	10	2	0	0	1	是
17	针对 FD 脾胃虚弱证的患者，推荐使用中成药参苓白术颗粒提高临床有效率	26	9	3	0	0	1	是
18	推荐使用针刺或电针疗法提高 FD 4 周应答率、临床有效率，改善尼平消化不良症状（NDSI）评分和生活质量评分（NDLQI）	28	10	0	0	0	1	是
19	推荐使用经皮耳迷走神经刺激改善 FD 症状及生活质量	23	14	1	0	0	1	是
20	推荐使用耳穴疗法改善 FD 症状及生活质量	15	22	1	0	0	1	是
21	推荐使用穴位埋线疗法改善 FD 临床有效率	14	22	2	0	0	1	是

附件 4

《国际中医临床实践指南 功能性消化不良》（草稿）专家论证会会议纪要

会议时间：2025 年 1 月 25 日

会议地点：线上腾讯会议

参会人员：魏玮、荣培晶、刘建平、陈薇、张学智、苏晓兰、汪红兵、杜正光、王彦刚、方继良、时昭红、苏娟萍、王垂杰、丁霞、迟莉丽、巩阳、刘华一、胡运莲、柯晓、沈洪、杨倩、黄穗平、刘启泉、鱼涛、李景南、王化虹、夏志伟、丁士刚、杜时雨、蓝宇、张晓岚、王邦茂、唐艳萍、肖小河、王林恒、何凌、索标、曹俊岭、刘建勋、孙晓波、曹艳霞、陈一秀

会议主持人：张世翼

会务组：张世翼、姜瀚、于凡雅、钱紫星、王纯

项目组秘书姜瀚向各位专家汇报了本工作组的工作情况：

《国际中医临床实践指南 功能性消化不良》研制工作自 2022 年 11 月正式启动。2022 年 12 月底国际中医临床实践指南-功能性消化不良专家指导组的指导下组建了工作组，工作组成立后，随即开展了文献研究工作，共检索到与功能性消化不良相关文献 9699 篇，经筛选后撰写了文献研究总结。项目组以文献研究为基础，讨论编制了专家调查问卷，邀请全国相关专家进行问卷调查，并于 2025 年 1 月底完成了两轮问卷调查，每轮问卷调查完成后均作了统计分析和问卷调查总结。经文献研究和专家问卷调查，项目工作组讨论形成了《国际中医临床实践指南 功能性消化不良》草稿，提请专家会议评审。

指南制定专家陈薇教授进行《专家共识方法介绍》：对常用专家共识形成方法进行介绍，主要有德尔菲法、名义群组法、共识形成会议法以及改良德尔菲法。并且对四种方法的优缺点、应用进行了详细阐述。

项目工作组秘书张世翼接着向各位专家汇报了《国际中医临床实践指南 功能性消化不良》草稿的内容，以及需提请专家组重点讨论的问题。

专家们会前已收到《国际中医临床实践指南 功能性消化不良》草稿的电子版，阅读了草稿。会议上专家们积极发言。对于草稿中的若干具体内容，专家们进行了认真的讨论，基本上达成共识，提出了修改意见，主要内容有：

（1）推荐意见中的描述修改为“针对 FD 某证的患者，推荐使用某药”，注意有效率或者总有效率的书写，按照文献中来。

（2）中医经典方剂应核对原方中药组成，并讨论修改各个方剂的加减情况。

（3）将用药建议修改为“每日 1 剂，水煎 2 次，取汁 300-400ml，分早晚 2 次饭前服用，每次 150-200ml，或遵医嘱。”

（4）增加疗程与增加安全性说明。

（5）中成药中，建议在脾虚气滞证中增加香砂六君丸，在肝胃不和证中增加枳实总黄酮片，在脾胃虚寒（弱）证中增加附子理中丸浓缩丸。

（6）修正耳穴疗法的操作方法及疗程。

专家们经认真评议，认为《国际中医临床实践指南 功能性消化不良》草稿已基本成形，项目工作组就以上问题认真讨论，少数欠妥当之处进行修改，可形成《国际中医临床实践指南 功能性消化不良》初稿，后需经专家指导组进一步论证。

《国际中医临床实践指南 功能性消化不良》项目工作组

2025 年 2 月 12 日

International Clinical Practice Guideline of Chinese Medicine Functional Dyspepsia

Compilation instructions

Sponsor: World Federation of Chinese Medicine Societies
Project Undertaker: Wangjing Hospital, China Academy of Chinese Medical Sciences
Project Leader: Wei Wei

Guideline Development Team: International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia
2025

Contents

I. Project Overview

(I) Task Background

Functional dyspepsia (FD) is a clinical syndrome primarily characterized by persistent or recurrent upper abdominal pain, postprandial fullness, bloating, belching, early satiety, anorexia, and nausea. It falls under the category of functional gastrointestinal disorders (FGIDs). FD is a significant global health issue. In 2021, a study from Ben - Gurion University of the Negev in Israel surveyed the prevalence of FGIDs across 33 countries in six continents using anonymous internet and face - to - face household surveys. The study found that over 40% of the global population suffers from FGIDs, with FD being the most common gastroduodenal disease. The pooled prevalence of FD was 7.2% (7.1%–7.4%) from internet surveys and 4.8% (4.5%–5.1%) from household surveys. There are substantial differences in FD prevalence across countries. For instance, in internet surveys, China had a prevalence of 5.9%, Japan 2.2%, and Egypt 12.3%; in household surveys, China was 4.3% (3.6%–5.1%), India 0.7% (0.5%–1.0%), and Bangladesh 19.4% (17.7%–21.2%). FD leads to high global medical costs and reduces patients' quality of life, with 53.8% of FGID patients experiencing a high medical burden (multiple annual check - ups and visits).

FD has a high incidence but a low cure rate, imposing a heavy physical and mental burden on patients and offering suboptimal treatment outcomes. Its pathophysiology is not fully understood, but the Rome IV criteria attribute it to abnormal brain - gut interaction, causing gastrointestinal motility disorders, visceral hypersensitivity, and alterations in gut microbiota, mucosa, immune function, and central nervous system processing. Modern medicine typically treats FD symptomatically, yet this approach has limited efficacy, can cause various side effects with long - term use, and is prone to relapse upon discontinuation, highlighting the limitations of current treatments.

In contrast, traditional Chinese medicine (TCM) has certain advantages in treating FD. TCM emphasizes syndrome differentiation and holistic treatment and holistic intervention, simultaneously improving gastrointestinal and psychosomatic symptoms. Studies indicate that traditional therapies like herbal medicine and acupuncture are effective in alleviating gastrointestinal symptoms, and the prevalence of complementary and alternative medicine is on the rise in Western countries.

Currently, there are no international TCM clinical practice guidelines for FD. Developing such guidelines is essential to promote and apply effective TCM treatments for FD. This will enhance FD treatment outcomes, reduce patients' burdens, and improve their quality of life.

(II) Major Project Process

At the end of December 2022, the project team was set up under the guidance of the expert steering group for the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”.

From January to February 2023, under the guidance of the expert steering group, the project team completed the application form and the first - draft of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”, which was then submitted to the World Federation of Chinese Medicine Societies (WFCMS) for approval.

On March 9, 2023, the WFCMS approved the project application for the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” (SCMNP2023 - 0155).

From April 2023 to April 2024, the team finished literature search, evidence screening, data extraction, and evidence evaluation, and compiled a literature evidence summary report.

Between April and August 2024, the first - round Delphi questionnaire was conducted among experts in traditional Chinese medicine, Western medicine, integrated traditional Chinese and Western medicine, and guideline research methodology to collect their opinions. From August to December 2024, expert opinions were consolidated, and the draft was revised.

In January 2025, the second-round Delphi online meeting was conducted for experts in traditional Chinese medicine (TCM), Western medicine, integrated TCM and Western medicine, pharmacy, nursing, and guideline research methodology to gather their feedback. After organizing expert opinions and revising the draft, an expert review of the document was performed, and the final draft of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” was finalized following the meeting. In February 2025, the project team finalized the standardized draft of the guidelines. Following a rigorous review by the expert steering group, the document was submitted to the World Federation of Chinese Medicine Societies (WFCMS) office for nationwide online public consultation. Subsequent revisions were implemented based on the comprehensive feedback received, culminating in the preparation of the final review draft. The entire development process of the guidelines is systematically outlined in Figure 1.

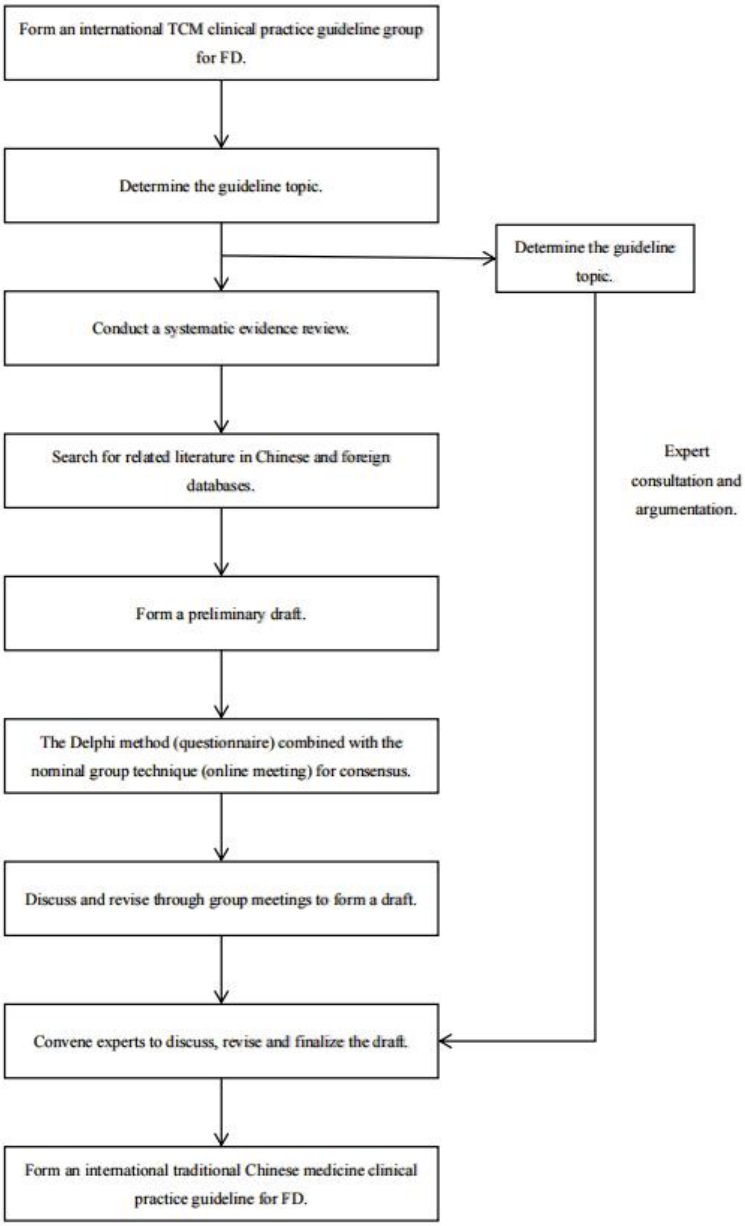


Figure 1: The process of developing the guidelines

(III) Main Drafters of the Guideline and Their Contributions

1. Drafting Members

Table 1 Drafting Members

Name	Organization	Contributions
Wei Wei	Wangjing Hospital, China Academy of Chinese Medical Sciences	Project leader. Organized project application, implementation, and summary.
Zhang Shengsheng	Beijing University of Chinese Medicine Affiliated to Capital Medical University	Participated in project application, summary, drafting, and revision.

Nicholas Talley	University of Newcastle, Australia	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Louis Liu	Gastroenterology Division, University of Toronto	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Jiande Chen	University of Michigan Medical School	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Gengqing Song	Case Western Reserve University, USA	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Ke Mei Yun	Peking Union Medical College Hospital	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Duan Liping	The Third Hospital of Peking University	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Hou Xiaohua	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Rong Peijing	China Academy of Chinese Medical Sciences Acupuncture Research Institute	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Liu Jianping	Evidence-Based Medicine Center, Beijing University of Chinese Medicine	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.
Chen Wei	Evidence-Based Medicine Center, Beijing University of Chinese Medicine	Participated in work discussions, literature research, and the organization of expert consultation questionnaires, and contributed to drafting and drafting explanations.

2. Participating Experts

Table 2 Participating Experts

Name	**Organization**	**Contributions**
Su Xiaolan	China Academy of Chinese Medical Sciences Wangjing Hospital	Expert questionnaires and opinion consultation.
Zhang Xuezhi	The First Hospital of Peking University	Expert questionnaires and opinion consultation.

Wang Hongbing	Beijing University of Chinese Medicine Affiliated to Capital Medical University	Expert questionnaires and opinion consultation.
Du Zhenguang	Beijing University of Chinese Medicine Affiliated to Capital Medical University	Expert questionnaires.
Wang Yangang	The Third Affiliated Hospital of Beijing University of Chinese Medicine	Expert questionnaires.
Fang Jiliang	Guang'anmen Hospital, China Academy of Chinese Medical Sciences	Expert questionnaires.
Liu Fengbin	The First Affiliated Hospital of Guangzhou University of Chinese Medicine	Expert questionnaires.
Li Peiwu	The First Affiliated Hospital of Guangzhou University of Chinese Medicine	Expert questionnaires.
Shi Zhaohong	Wuhan First Hospital	Expert questionnaires.
Su Juanping	Shanxi Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Wang Chuijie	The Affiliated Hospital of Liaoning University of Traditional Chinese Medicine	Expert questionnaires.
Ding Xia	Dongzhimen Hospital, Beijing University of Chinese Medicine	Expert questionnaires.
Chi Lili	The Affiliated Hospital of Shandong University of Traditional Chinese Medicine	Expert questionnaires.
Liu Huayi	The Affiliated Hospital of Tianjin Institute of Traditional Chinese Medicine Research	Expert questionnaires and opinion consultation.
Suiao	Xiamen Hospital of Traditional Chinese Medicine	Expert questionnaires.
Huang Suiping	Guangdong Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Liu Qi Quan	Hebei Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Yu Tao	Shaanxi Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Xia Zhiwei	The Third Hospital of Peking University	Expert questionnaires.
Du Shiyu	China-Japan Friendship Hospital	Expert questionnaires.
Yang Qian	Hebei Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Zhang Xiaolan	The Second Hospital of Hebei Medical University	Expert questionnaires.
Wang Bangmao	General Hospital of Tianjin Medical University	Expert questionnaires.

Tang Yanping	Tianjin Nankai Hospital	Expert questionnaires.
Xiao Xiaohuo	People's Liberation Army 302 Hospital	Expert questionnaires and opinion consultation.
Cao Junling	Dongfang Hospital, Beijing University of Chinese Medicine	Expert questionnaires.
Wang Jinghong	China Academy of Chinese Medical Sciences Wangjing Hospital	Expert questionnaires.
Cao Yanxia	China Academy of Chinese Medical Sciences Wangjing Hospital	Expert questionnaires.
Chen Yixiu	China Academy of Chinese Medical Sciences Wangjing Hospital	Expert questionnaires.
Shen Hong	The Affiliated Hospital of Nanjing University of Chinese Medicine	Expert questionnaires.
He Ling	The Affiliated Hospital of Jiangxi University of Chinese Medicine	Expert questionnaires.
Lan Yu	Beijing Jishuitan Hospital Affiliated to Capital Medical University	Expert questionnaires.
Hu Yunlian	Hubei Provincial Hospital of Traditional Chinese Medicine	Expert questionnaires.
Wang Linheng	Dongfang Hospital, Beijing University of Chinese Medicine	Expert questionnaires.
Ke Xiao	The Second People's Hospital of Fujian Province	Expert questionnaires.
Wang Huazhong	The First Hospital of Peking University	Expert questionnaires.
Gong Yang	General Hospital of Shenyang Military Region	Expert questionnaires.
Xiao Liwen	Institute of Zoology, Chinese Academy of Sciences	Expert questionnaires.
Ding Shigang	The Third Hospital of Peking University	Expert questionnaires.

II. Guideline Development Principles and Basis for Determining Main Content

(I) Guideline Development Principles

The development of these guidelines is based on the principles of "scientific validity, applicability, and standardization". The aim is to create guidelines that are practical for use within the TCM industry, widely acceptable and recognizable outside the industry, and aligned with international diagnostic and treatment guidelines. During the development process, all relevant issues were fully considered within the framework of relevant laws, regulations, and technical documents. The existing TCM clinical research data and relevant clinical experience and consensus were also taken into account in formulating the "International Clinical Practice Guideline of Chinese

Medicine for Functional Dyspepsia".

1. Scientific Validity

Scientific validity is essential for guideline development and ensures the quality of the guidelines. The team strictly adhered to this principle by conducting extensive research on international evidence - based guideline development methods. A combination of three research methods with TCM characteristics was selected: "literature research, Delphi surveys, and expert meetings", ensuring the scientific validity of the guidelines.

Literature Research: In line with international standards, literature related to TCM clinical practice for functional dyspepsia was searched. Key information such as major processes, main content, and common key technologies was extracted to provide a basis for the expert questionnaire survey.

Expert Questionnaire Survey: Based on the internationally recognized Delphi method and adapted to the TCM industry's specific circumstances, expert questionnaires were developed using literature research and group discussions. Experts with representatives, authority, and geographic diversity were selected. Questionnaires were collected and statistically analyzed to effectively consolidate expert opinions.

Expert Panel Meeting: The project team formed an expert panel comprising experts in TCM clinical practice for functional dyspepsia, TCM internal medicine, integrated traditional Chinese and Western medicine, Western internal medicine, pharmacy, nursing, and guideline research methodology. An expert meeting was held to review the guideline draft, especially contentious or discussion - worthy parts. Experts provided objective and professional feedback, shaping the guideline draft.

2. Applicability

The primary goal of developing these guidelines is to establish international TCM clinical practice standards for functional dyspepsia. This aims to guide the development of diagnostic and treatment standards for functional dyspepsia, enhance the accuracy, authority, and representatives of these standards, and meet the practical needs of functional dyspepsia - related clinical and basic research.

Targeted Application: The guidelines are designed for the development of international TCM clinical practice standards for functional dyspepsia and are applicable in clinical, teaching, and research settings related to functional dyspepsia.

Practical Development Process: In addition to reviewing relevant literature, academic works, and textbooks, a questionnaire was developed to survey experts nationwide involved in or familiar with the development of TCM clinical practice guidelines for functional dyspepsia. Their opinions were consolidated, and after expert review and broad consultation with industry experts, the final TCM clinical practice guidelines for functional dyspepsia were formed, ensuring practicality and

operability.

3. Standardization

During the development process, the guidelines followed GB/T 1.1 - 2020 ("Standardization Work Guidelines - Part 1: Structure and Drafting Rules for Standardization Documents") and other relevant standards and guidelines, under the guidance of the World Federation of Chinese Medicine Societies.

Standardized Methods: Methods such as literature search, expert questionnaires, and expert meetings followed internationally recognized approaches.

Standardized Format and Terminology: The guideline's format, terminology, and language met standardized requirements, ensuring consistency and professionalism.

(II) Methods and Evidence for Determining Main Content

1. Main Content of the Guideline

(1) Scope

(2) Normative Reference Documents

(3) Terms and Definitions

(4) Development Principles and Methods

(5) Development Process

2. Methods for Determining Main Content

2.1 Expert Interviews

2.1.1 Interview Plan Development

The interviewees were TCM and Western medicine clinical experts in functional dyspepsia, all holding senior titles and with years of clinical and research experience. Three were TCM experts, one integrated traditional Chinese and Western medicine expert, and three Western medicine experts. The interview outline, drafted by the secretaries of the drafting group, Zhang Shiwei and Jiang Han, covered clinical questions and outcome indicators based on prior literature search. Experts were asked for their opinions and any additional questions.

2.1.2 List of Interviewed Experts

Table 3 Basic information of the interviewed experts

Name	Hospital	Position/Title	Specialty
Wang Huahong	The First Hospital of Peking University	Chief Physician	Western Internal Medicine
Duan Liping	The Third Hospital of Peking University	Chief Physician	Western Internal Medicine
Hou Xiaohua	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology	Chief Physician	Western Internal Medicine

Zhang Xuezhi	The First Hospital of Peking University	Chief Physician	Integrated Traditional Chinese and Western Internal Medicine
Wei Wei	Wangjing Hospital, China Academy of Chinese Medical Sciences	Department Head	Traditional Chinese Internal Medicine
Su Xiaolan	Wangjing Hospital, China Academy of Chinese Medical Sciences	Chief Physician	Traditional Chinese Internal Medicine
Yang Qian	Hebei Provincial Hospital of Traditional Chinese Medicine	President	Traditional Chinese Internal Medicine

2.1.3 Interview Outline:

Clinical Questions: ① How to guide TCM treatment of functional dyspepsia with modern medical test results? ② How effective are classical TCM formulas for FD patients with syndrome of intermingled heat and cold? ③ How effective are classical TCM formulas for FD patients with syndrome of spleen deficiency and qi stagnation? ④ How effective are Chinese patent medicines for FD patients with syndrome of spleen deficiency and qi stagnation? ⑤ How effective are classical TCM formulas for FD patients with syndrome of incoordination between liver and stomach? ⑥ How effective are Chinese patent medicines for FD patients with syndrome of incoordination between liver and stomach? ⑦ How effective are classical TCM formulas for FD patients with Syndrome of dampness-heat of spleen and stomach? ⑧ How effective are classical TCM formulas for FD patients with syndrome of deficient cold (weakness) of spleen and stomach? ⑨ How effective are Chinese patent medicines for FD patients with syndrome of deficient cold (weakness) of spleen and stomach? ⑩ How effective is food therapy for FD? What are the specific methods? ⑪ How effective is body - surface medical intervention for FD? What are the specific methods? ⑫ What precautions should FD patients take during TCM treatment? How to avoid adverse reactions? ⑬ Should FD patients follow lifestyle guidance? How to follow it? ⑭ Should FD patients receive adjunctive psychological therapy? How to receive it? ⑮ What is the prognosis of FD patients?

Outcome Indicators: ① Clinical efficacy (total effectiveness rate) ② Clinical recurrence rate ③ Gastric emptying rate (real - time ultrasound, barium meal method, etc.) ④ Abdominal pain: Numerical Rating Scale (NRS) score ⑤ TCM syndrome score for FD ⑥ Scores for each symptom of TCM syndrome in FD ⑦ FD single - symptom quantification and grading ⑧ Nepean Dyspepsia Symptom Index (NDSI)

⑨ Nepean Dyspepsia Quality of Life Index (NDLQI) ⑩ Functional Dyspepsia Quality of Life Scale (FDDQL) ⑪ Short - Form Health Survey (SF - 36) ⑫ Hamilton Anxiety Scale (HAMA) ⑬ Hamilton Depression Scale (HAMD) ⑭ Self - Rating Anxiety Scale (SAS) ⑮ Self - Rating Depression Scale (SDS)

2.1.4 Determination of Clinical Questions and Outcome Indicators:

Clinical Questions: ① How effective are classical TCM formulas for FD patients with syndrome of intermingled heat and cold? ② How effective are classical TCM formulas for FD patients with syndrome of spleen deficiency and qi stagnation? ③ How effective are Chinese patent medicines for FD patients with syndrome of spleen deficiency and qi stagnation? ④ How effective are classical TCM formulas for FD patients with syndrome of incoordination between liver and stomach? ⑤ How effective are Chinese patent medicines for FD patients with syndrome of incoordination between liver and stomach? ⑥ How effective are classical TCM formulas for FD patients with Syndrome of dampness-heat of spleen and stomach? ⑦ How effective are classical TCM formulas for FD patients with syndrome of deficient cold (weakness) of spleen and stomach? ⑧ How effective are Chinese patent medicines for FD patients with syndrome of deficient cold (weakness) of spleen and stomach? ⑨ How effective is body - surface medical intervention for FD? What are the specific methods? ⑩ Should FD patients follow lifestyle guidance? How to follow it?

Outcome Indicators: ① Clinical efficacy (total effectiveness rate) ② Clinical recurrence rate ③ Gastric emptying rate (real - time ultrasound, barium meal method, etc.) ④ Abdominal pain: Numerical Rating Scale (NRS) score ⑤ TCM syndrome score for FD ⑥ Scores for each symptom of TCM syndrome in FD ⑦ FD single - symptom quantification and grading ⑧ Nepean Dyspepsia Symptom Index (NDSI) ⑨ Nepean Dyspepsia Quality of Life Index (NDLQI) ⑩ Functional Dyspepsia Quality of Life Scale (FDDQL) ⑪ Short - Form Health Survey (SF - 36)

Literature search was conducted based on the above clinical questions and outcome indicators.

2.2 Literature Search

A computer-based literature search was conducted on databases including CNKI, Wanfang Data, VIP Database, CBM, PubMed, and Cochrane Library.

2.2.1 Search Terms

2.2.1.1 Chinese Search Terms

Western Medicine Disease Names: 功能性消化不良/餐后不适综合征/上腹痛综合征

TCM Disease Names: 胃痞/胃脘痛/脘痞/痞满

Interventions:

Oral Decoctions:

柴胡疏肝散/柴芍六君子汤/香砂六君子汤/六君子汤/枳实消痞丸/四君子汤/越鞠方/补中益气汤/升阳益胃汤/半夏泻心汤/逍遥散/附子理中丸/柴胡达原饮/连朴饮/一贯煎/玉女煎/益胃汤/旋复代赭汤/左金丸/生姜泻心汤/柴枳实平肝汤/柴胡桂枝干姜汤/黄芪建中汤/六磨汤/枳术丸/安中汤/安胃汤/沙参麦冬汤/三仁汤

Chinese Patent Medicines:

附子理中丸/参苓白术散/补中益气颗粒/气滞胃痛颗粒/香砂养胃颗粒/胃苏冲剂/荜铃胃痛颗粒/加味逍遥丸/枳术宽中胶囊/木香顺气丸/健胃消食片/保和丸/香砂六君子丸/补中益气丸

External Treatments:针刺/针灸/艾灸/电针/穴位埋线/经皮耳迷走神经刺激

Full - text:随机

2.2.1.2 English search terms:

Western Medicine Disease Names: Functional dyspepsia/postprandial distress syndrome/epigastric pain syndrome

TCM Disease Names: Gastric fullness/epigastric pain/ Stomach fullness /fullness sensation

Interventions: Chaihu Shugan San / Chaihu Liu Jun Zi Tang / Xiang Sha Liu Jun Zi Tang / Liu Jun Zi Tang / Zhi Shi Xiao Pi Wan / Si Jun Zi Tang / Yue Ju Fang / Bu Zhong Yi Qi Tang / Sheng Yang Yi Wei Tang / Ban Xia Xie Xin Tang / Xiao Yao San / Fuzi Li Zhong Wan / Chaihu Da Yuan Yin / Lian Pao Yin / Yi Guan Jian / Yu Nu Jian / Yi Wei Tang / Xuan Fu Dai Zhe Tang / Zuo Jin Wan / Sheng Jiang Xie Xin Tang / Chai Zhi Shi Ping Gan Tang / Huang Qi Jian Zhong Tang / Liu Mo Tang / Zhi Shu Wan / An Zhong Tang / An Wei Tang / Sha Shen Mai Dong Tang / San Ren Tang / Fuzi Li Zhong Wan / Shen Ling Bai Zhu San / Bu Zhong Yi Qi Ke Li / Qi Zhi Wei Tong Ke Li / Xiang Sha Yang Wei Ke Li / Wei Su Chong Ji / Bi Ling Wei Tong Ke Li / Jia Wei Xiao Yao Wan / Zhi Shu Kuan Zhong Jiao Nang / Mu Xiang Shun Qi Wan / Jian Wei Xiao Shi Pian / Bao He Wan / Xiang Sha Liu Jun Zi Wan / Bu Zhong Yi Qi Wan / Acupuncture / Moxibustion / Electroacupuncture / Acupoint-embedding / Transcutaneous vagus nerve stimulation

Full - text:Randomized。

2.2 Literature Search

The literature search was conducted from the database establishment date to June 2023.

Inclusion Criteria:

Randomized controlled trials and Meta - analyses on TCM treatment of functional dyspepsia, covering classical TCM formulas (with or without modifications), Chinese patent medicines, and TCM external therapies.

Exclusion Criteria:

Reviews, commentaries, theoretical discussions, animal experiments, non - TCM interventions, self - developed Chinese formulas, conference papers, scientific

achievements, and incomplete 文献.

For eligible literature, two researchers extracted the title, authors, publication year, and outcome indicators (e.g., effectiveness rate, total symptom scores, single - symptom scores, and other ratings) to conduct evidence synthesis and quality evaluation. A detailed evidence summary is in Annex 1.

2.2.2 Search Strategies

2.2.2.1 Chinese Search Strategy

Taking the CNKI database as an example:

SU represents subject search, which focuses on the subject terms (machine - indexed keywords) and covers all content - related fields. During the search, tools like professional dictionaries, subject thesauri, Chinese - English dictionaries, and stop - word lists were used. A keyword truncation algorithm was applied to filter out less or slightly relevant literature. This method aims to capture all thematic features of an article and is suitable for quick queries and research by general users.

TKA represents search of title, keywords, and abstract. The search strategy is as follows:（SU=（功能性消化不良） OR SU=（餐后不适综合征） OR SU=（腹痛综合征） OR SU=（胃痞） OR SU=（胃脘痛） OR SU=（脘痞） OR SU=（痞满） OR TKA=（餐后不适综合征） OR TKA=（腹痛综合征） OR TKA=（胃痞） OR TKA=（胃脘痛） OR TKA=（脘痞） OR TKA=（痞满） ） AND （SU=（柴胡疏肝散） OR SU=（柴芍六君子汤） OR SU=（香砂六君子汤） OR SU=（六君子汤） OR SU=（枳实消痞丸） OR SU=（四君子汤） OR SU=（越鞠方） OR SU=（补中益气汤） OR SU=（升阳益胃汤） OR SU=（半夏泻心汤） OR SU=（逍遥散） OR SU=（附子理中丸） OR SU=（柴胡达原饮） OR SU=（连朴饮） OR SU=（一贯煎） OR SU=（玉女煎） OR SU=（益胃汤） OR SU=（旋复代赭汤） OR SU=（左金丸） OR SU=（生姜泻心汤） OR SU=（柴枳实平肝汤） OR SU=（柴胡桂枝干姜汤） OR SU=（黄芪建中汤） OR SU=（六磨汤） OR SU=（枳术丸） OR SU=（安中汤） OR SU=（安胃汤） OR SU=（沙参麦冬汤） OR SU=（三仁汤） OR SU=（附子理中丸） OR SU=（参苓白术散） OR SU=（补中益气颗粒） OR SU=（气滞胃痛颗粒） OR SU=（香砂养胃颗粒） OR SU=（胃苏冲剂） OR SU=（荜铃胃痛颗粒） OR SU=（加味逍遥丸） OR SU=（枳术宽中胶囊） OR SU=（木香顺气丸） OR SU=（健胃消食片） OR SU=（保和丸） OR SU=（香砂六君子丸） OR SU=（补中益气丸） OR SU=（针刺） OR SU=（艾灸） OR SU=（针灸） OR SU=（电针） OR SU=（穴位埋线） OR SU=（经皮耳迷走神经刺激） OR TKA=（柴胡疏肝散） OR TKA=（柴芍六君子汤） OR TKA=（香砂六君子汤） OR TKA=（六君子汤） OR TKA=（枳实消痞丸） OR TKA=（四君子汤） OR TKA=（越鞠方） OR TKA=（补中益气汤） OR TKA=（升阳益胃汤） OR TKA=（半夏泻心汤） OR TKA=（逍遥散） OR TKA=（附子理中丸） OR TKA=（柴胡达原饮） OR TKA=（连朴饮） OR TKA=（一贯

煎） OR TKA=（玉女煎） OR TKA=（益胃汤） OR TKA=（旋复代赭汤） OR TKA=（左金丸）OR TKA=（生姜泻心汤）OR TKA=（柴枳实平肝汤）OR TKA=（柴胡桂枝干姜汤） OR TKA=（黄芪建中汤） OR TKA=（六磨汤） OR TKA=（枳术丸） OR TKA=（安中汤） OR TKA=（安胃汤） OR TKA=（沙参麦冬汤） OR TKA=（三仁汤） OR TKA=（附子理中丸） OR TKA=（参苓白术散）OR TKA=（补中益气颗粒） OR TKA=（气滞胃痛颗粒） OR TKA=（香砂养胃颗粒） OR TKA=（胃苏冲剂） OR TKA=（荜铃胃痛颗粒） OR TKA=（加味逍遥丸） OR TKA=（枳术宽中胶囊） OR TKA=（木香顺气丸） OR TKA=（健胃消食片） OR TKA=（保和丸） OR TKA=（香砂六君子丸） OR TKA=（补中益气丸） OR TKA=（针刺） OR TKA=（艾灸） OR TKA=（针灸） OR TKA=（电针）OR TKA=（穴位埋线）OR TKA=（经皮耳迷走神经刺激））AND （FT=（随机） OR FT= （RCT））。

2.2.2.2 English search formula

PubMed as an example. The search formula is:

#1 ((((((Functional dyspepsia[Title/Abstract]) OR (postprandial distress syndrome[Title/Abstract])) OR (epigastric pain syndrome[Title/Abstract])) OR (Gastric fullness[Title/Abstract])) OR (epigastric pain[Title/Abstract])) OR (stomach fullness[Title/Abstract])) OR (fullness sensation[Title/Abstract])

#2 ”Functional dyspepsia”[Mesh Terms]

#3 ”Postprandial distress syndrome”[Mesh Terms]

#4 ”Epigastric pain syndrome”[Mesh Terms]

#5 #1 OR #2 OR #3 OR #4

#6 ((Chaihu Shugan San[Title/Abstract]) OR (Chaihu Liu Jun Zi Tang[Title/Abstract])) OR (Xiang Sha Liu Jun Zi Tang[Title/Abstract])) OR (Liu Jun Zi Tang[Title/Abstract])) OR (Zhi Shi Xiao Pi Wan[Title/Abstract])) OR (Si Jun Zi Tang[Title/Abstract])) OR (Yue Ju Fang[Title/Abstract])) OR (Bu Zhong Yi Qi Tang[Title/Abstract])) OR (Sheng Yang Yi Wei Tang[Title/Abstract])) OR (Ban Xia Xie Xin Tang[Title/Abstract])) OR (Xiao Yao San[Title/Abstract])) OR (Fuzi Li Zhong Wan[Title/Abstract])) OR (Chaihu Da Yuan Yin[Title/Abstract])) OR (Lian Pao Yin[Title/Abstract])) OR (Yi Guan Jian[Title/Abstract])) OR (Yu Nu Jian[Title/Abstract])) OR (Yi Wei Tang[Title/Abstract])) OR (Xuan Fu Dai Zhe Tang[Title/Abstract])) OR (Zuo Jin Wan[Title/Abstract])) OR (Sheng Jiang Xie Xin Tang[Title/Abstract])) OR (Chai Zhi Shi Ping Gan Tang[Title/Abstract])) OR (Huang Qi Jian Zhong Tang[Title/Abstract])) OR (Liu Mo Tang[Title/Abstract])) OR (Zhi Shu Wan[Title/Abstract])) OR (An Zhong Tang[Title/Abstract])) OR (An Wei Tang[Title/Abstract])) OR (Sha Shen Mai Dong Tang[Title/Abstract])) OR (San Ren Tang[Title/Abstract])) OR (Fuzi Li Zhong Wan[Title/Abstract])) OR (Shen Ling Bai Zhu San[Title/Abstract])) OR (Bu Zhong Yi Qi Ke Li[Title/Abstract])) OR (Qi Zhi Wei Tong Ke Li[Title/Abstract])) OR (Xiang

Sha Yang Wei Ke Li[Title/Abstract])) OR (Wei Su Chong Ji[Title/Abstract])) OR (Bi Ling Wei Tong Ke Li[Title/Abstract])) OR (Jia Wei Xiao Yao Wan[Title/Abstract])) OR (Zhi Shu Kuan Zhong Jiao Nang[Title/Abstract])) OR (Mu Xiang Shun Qi Wan[Title/Abstract])) OR (Jian Wei Xiao Shi Pian[Title/Abstract])) OR (Bao He Wan[Title/Abstract])) OR (Xiang Sha Liu Jun Zi Wan[Title/Abstract])) OR (Bu Zhong Yi Qi Wan[Title/Abstract])) OR (Acupuncture[Title/Abstract])) OR (Moxibustion[Title/Abstract])) OR (Electroacupuncture[Title/Abstract])) OR (Acupoint-embedding[Title/Abstract])) OR (Transcutaneous vagus nerve stimulation[Title/Abstract])

#7 randomized[Text Word]

##5 AND #6 AND #7

2.3 Expert questionnaire survey

After summarizing and critically analyzing the relevant literature, the project team employed the Delphi method to develop an expert questionnaire. Subsequently, the selected experts participated in two rounds of questionnaire surveys based on predefined criteria. The criteria for expert selection included holding an associate senior professional title with substantial clinical experience, demonstrating interest and commitment to completing multiple rounds of expert consultations, and ensuring regional diversity in the distribution of experts during the selection process.

A comprehensive statistical analysis was performed on the experts' responses. The results of the first-round questionnaires were imported into Excel software for evaluation, utilizing statistical measures such as the experts' positive coefficient, authority coefficient, and Kendall's W. In the second round of questionnaires, the GRADE grid counting method was employed to assess the strength of recommendations. If the proportion of votes for any option under "recommendations," excluding "C," exceeds 50%, a consensus is deemed to have been reached, allowing for the direct determination of the direction and intensity of the recommendation. A indicates a strong recommendation, B indicates a weak recommendation, C indicates uncertainty, D indicates a weak non-recommendation, and E indicates a strong non-recommendation. If none of the squares exceeds 50%, but the cumulative percentage of votes on one side of the "C" square exceeds 70%, it is also considered a consensus with a direction of recommendation. In this case, the recommendation intensity is classified as "weak," and the item is regarded as requiring further clarification during the development of this guideline. Any scenario not meeting the aforementioned conditions will be deemed as no consensus. The preliminary entries derived from the expert consensus screening process will be reviewed and refined by the formulation panel to determine the final included entries. Based on the analysis and synthesis of expert opinions using mathematical statistics, the first-round questionnaires were revised into the second-round questionnaires, which subsequently

led to the initial drafting of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”. See Annex 2 and 3.

2.4 Expert review meeting

An expert review meeting regarding the draft of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” was conducted online in January 2025. The working group presented the draft standard and highlighted the key issues requiring attention from the expert panel. The meeting meticulously evaluated the draft of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”. Experts actively participated in discussions, expressing general approval of the draft submitted by the project team, deeming it sufficiently mature to serve as the foundational text for this standard. Through deliberation on several specific aspects of the draft, the experts reached a consensus and provided numerous constructive suggestions for revision, which are detailed in Annex 4.

3. Relationship with relevant laws, regulations and mandatory standards

The “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” developed by our project team is fully aligned with current laws, regulations, and mandatory standards. During the compilation process, strict adherence to both international and domestic standards was maintained, ensuring that the content of the text is not only compliant but also well-supported.

4. The process and basis for handling major opinions

After completing the research on the standard literature for this guideline, an expert questionnaire was developed. Two rounds of Delphi-method-based expert questionnaires were conducted to gather expert opinions, with 31 expert feedback responses collected in each round. The experts generally endorsed the questionnaire content and provided specific comments on certain issues. Based on the experts' revision suggestions, the project team conducted a secondary literature search and integrated field-specific expert opinions to revise the manuscript, thereby forming an initial draft. Following the review of the initial draft by the expert review meeting and incorporating the experts' feedback, the revised draft was submitted to the expert guidance group for further evaluation. The project team comprehensively analyzed all suggestions according to the "evidence-based" principle, determined their applicability along with corresponding reasons, and subsequently revised the initial draft to produce the final guideline draft. A methodological quality assessment and peer review of the guidelines will be carried out, with expert recommendations carefully considered and adopted to further refine and enhance the guidelines.

5. Suggestions as a recommended guideline

The “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” delineates the diagnostic criteria and traditional Chinese medicine (TCM) treatment protocols for functional dyspepsia. This guideline is applicable to the

diagnosis and treatment of functional dyspepsia across various medical institutions, including TCM hospitals, general hospitals, integrated TCM-Western medicine hospitals, primary care facilities, and other healthcare organizations. Its purpose is to provide a framework for the development of standardized diagnostic and therapeutic protocols for functional dyspepsia, enhancing the accuracy, authority, and representativeness of these standards. Furthermore, it aims to meet the practical requirements of functional dyspepsia practice standards in both clinical and basic research. Specifically, the recommendations within this guideline are designed to inform the development of "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia" and can be broadly applied in clinical practice, education, and scientific research related to this condition.

6. Implement the requirements and measures of the guideline

The "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia" developed by this project, after being reviewed and officially approved for release, should be promoted, implemented, and disseminated through multiple channels.

1.Industry-wide promotion and implementation will be uniformly organized by the World Federation of Chinese Medicine Societies.

2.Training courses and continuing education programs focused on the application and dissemination of these standards will be organized to train relevant professionals and enhance the promotion and application of the guidelines.

3.The two academic platforms, namely the Pulmonary Rehabilitation Professional Committee of the World Federation of Chinese Medicine Societies and the Lung Disease Branch of the Chinese Society of Ethnic Medicine, will be utilized to introduce and promote the guidelines in various domestic and international academic activities.

4.The guidelines and related academic papers will be published in reputable academic journals to further promote their adoption and incorporate feedback for continuous improvement.

7. Facilitators and hindrances in application

None.

8. Other matters that should be explained

It is recommended that this guideline be further supplemented, revised, and updated three to five years after its release and implementation, in accordance with advancements in clinical research and technical methodologies.

9. Annex

Annex 1 Summary report of literature evidence on "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia"

Annex 2 Work Report on the First Round of Expert Questionnaire Survey of

“International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”

Annex 3 Work Report on the Second Round of Expert Questionnaire Survey of “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”

Annex 4 “ International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” (Draft) Minutes of the expert argumentation meeting

Annex 1

Summary report of literature evidence

1. Literature search results

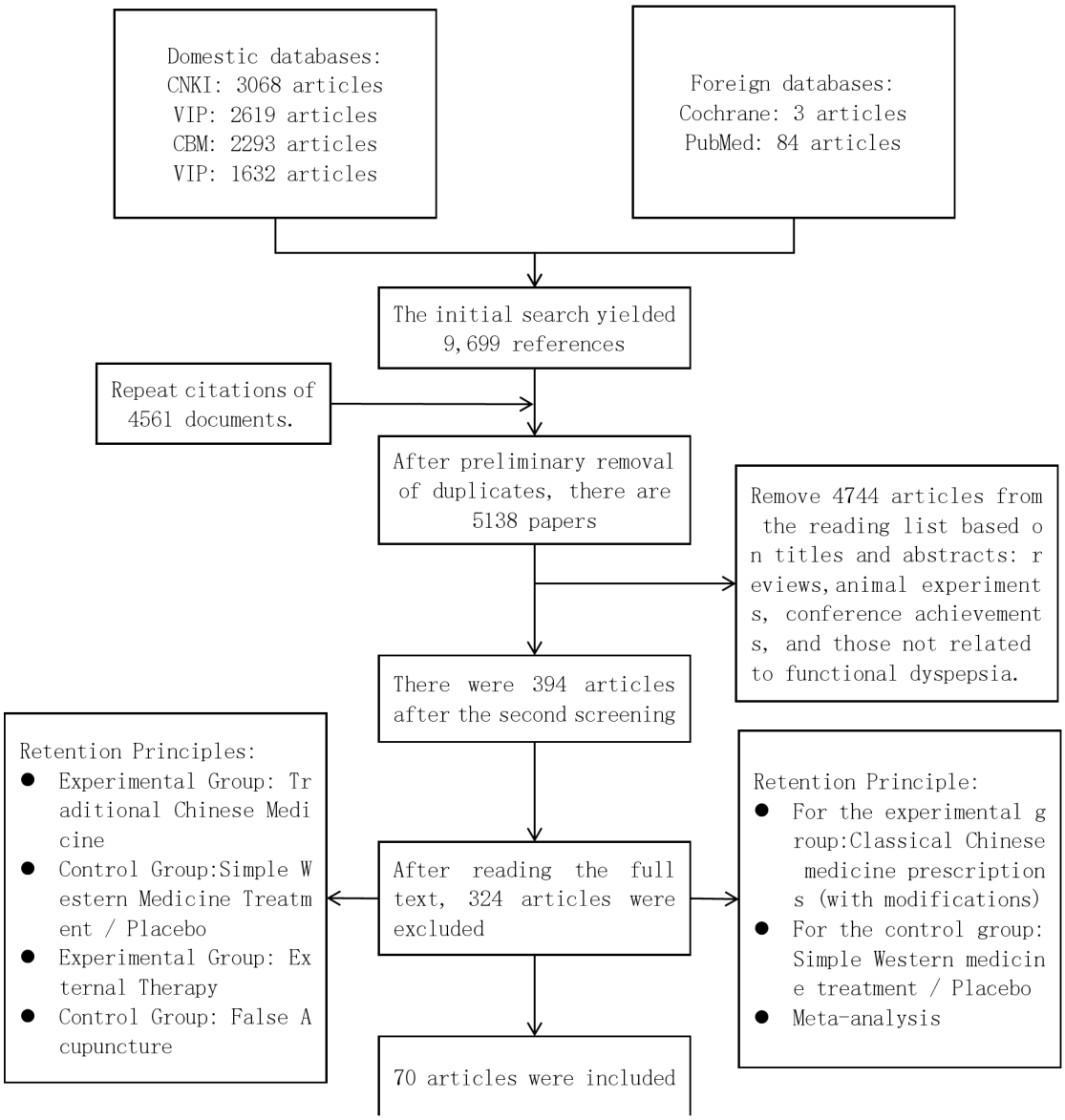
A total of 9,699 documents were retrieved. Among them, CNKI database retrieval results: a total of 3,068 bibliographies were retrieved; Wanfang database search results: A total of 2,619 entries were retrieved; VIP database search results: A total of 1,632 search entries; China Biomedical Literature Service System search results: A total of 2,293 search entries; Pubmed search results: 84 entries; Cochrane search results: A total of 3 search entries. After removing duplicates, a total of 5,138 articles were included.

2. Inclusion and exclusion criteria

Inclusion criteria: ① A clear diagnosis of functional dyspepsia in the literature; ② Randomized controlled trials or meta-analysis; ③ The intervention must meet the following requirements: Experimental group: classic prescriptions of traditional Chinese medicine and their additions and subtractions, Chinese patent medicines, and external treatment methods of traditional Chinese medicine; Control group: Western medical treatment alone or placebo or sham acupuncture.

Exclusion criteria: ① Review type, review, theoretical discussion, animal experiment, no intervention of traditional Chinese medicine, self-proposed traditional Chinese medicine prescription, conference, scientific and technological achievements; ② Literature with outcome indicators that cannot be combined with other studies; ③ Meta-analysis where none of the included studies met the inclusion criteria; ④ Non-randomized controlled trials.

3. Evidence screening process and results



4. Evidence evaluation

Two project team members conducted risk bias assessment on the included RCTS (generation of random sequences, randomization hiding, blinding, incomplete outcome reporting, selective outcome reporting, sample size calculation) in accordance with the RCT methodological quality evaluation standards in the "Suggestions on the Grading Standards of Clinical Evidence in Traditional Chinese Medicine Based on Evidence Body". If there were any differences, they would be judged through consultation or by a third party.

5. Method of evidence grading

The criteria for evidence grading are based on the suggestions made by Professor Liu Jianping in his "Suggestions on the Criteria for Grading Clinical Evidence of

Traditional Chinese Medicine Based on Evidence Body" for evaluating the quality of evidence in traditional medicine.

Level I: Randomized controlled trials (RCTs) and their systematic reviews, N-of-1 trial systematic reviews

Level II: Non-randomized controlled clinical trials, cohort studies, N-of-1 trials

Level III: Case-control studies, prospective case series

Level IV: Standardized expert consensus[1], retrospective case series, historical control studies

Level V: Non-Standardized Expert Consensus, Case Reports, Experience Summaries

6. Summary Table of Evidence

Summary table of evidence from included literature

Population(P): FD with syndrome of intermingled heat and cold

Intervention(I): Modified Banxia Xiexin Decoction

Comparator(C): Western medical treatment (domperidone)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Hu XL 2006	RCT	2	0	0	1	1	0	30/30	30/30	RR=2.00 , 95%CI[1.69 , 2.31] , P ＜ 0.00001	III

Population(P): FD with syndrome of spleen deficiency and qi stagnation

Intervention(I): Modified Xiangsha Liujunzi Decoction

Comparator(C): Western medical treatment (Lansoprazole+Mosapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Zeng ZS 2017; Zhou WB 2016	RCT	2	0	0	1	1	0	91/104	70/104	RR=1.30，95% CI [1.12，1.51]，P=0.0007	III

Population(P): FD with syndrome of spleen deficiency and qi stagnation

Intervention(I): Modified Zhi Shi Xiaopi Wan

Comparator(C): Western medical treatment (Mosapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Wang D 2021	RCT	2	0	0	1	1	0	40/40	30/40	RR=1.33，95%CI[1.11，1.59]，P=0.002	III
Symptom score											
Wang D 2021	RCT	2	0	0	1	1	0	40	40	MD_{score}=4.08，95%CI[3.73，4.43]，P＜0.00001	III

Population(P): FD with syndrome of spleen deficiency and qi stagnation

Intervention(I): Zhizhu Kuanzhong Capsules

Comparator(C): Western medical treatment (Domperidone/Itopride/Mosapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Zhu M 2011; Xu CP 2004; Xiao BF 2021	RCT	2	1	0	1	1	0	229/266	122/175	RR=1.26， 95% CI [1.04，1.51]，P=0.02	II

Population(P): FD with syndrome of incoordination between liver and stomach

Intervention(I): Modified Chaihu Shugan Powder

Comparator(C): Western medical treatment (Domperidone)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Men CY 2012	RCT	2	0	0	1	1	0	25/28	15/28	RR=1.67，95% CI[1.15，2.41]，P=0.007	III

Population(P): FD with syndrome of incoordination between liver and stomach

Intervention(I): Qizhi Weitong Keli

Comparator(C): Placebo

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Su Q 2018	RCT	2	1	2	1	1	1	66/85	17/80	RR=3.65，95%CI[2.36，5.66]，P < 0.00001	I

Population(P): FD with syndrome of incoordination between liver and stomach

Intervention(I): Biling Weitong Keli

Comparator(C): Placebo

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Wen Y 2020	RCT	2	1	2	1	1	1	101/118	34/120	RR=3.02，95%CI[2.25，4.05]，P＜0.00001	I
Quality of life score											
Wen Y 2020	RCT	2	1	2	1	1	1	118	120	MD_{score}=16.21，95%CI[12.33，20.09]，P＜0.00001	I

Population(P): FD with syndrome of incoordination between liver and stomach

Intervention(I): Dalitong Keli

Comparator(C): Western medical treatment (Mosapride/Domperidone/Itopride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Sun XX 2016; Liu XJ 2013; Wu QB 2012; Li R 2013; Wang GY 2014; Hu K 2005; Wang L 2004; Zhu D 2005; Xu SQ 2009; Ji PZ 2010	RCT	2	0	0	1	1	0	919/1075	554/742	RR=1.33 , 95%CI[1.05 , 1.22], P=0.002	III

Population(P): FD with syndrome of incoordination between liver and stomach

Intervention(I): Aurantii Fructus Immaturus flavonoid Tablets

Comparator(C): Western medical treatment (Domperidone)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Symptom Disappearance Rate After Treatment											
Wei M 2024	RCT	2	1	1	1	1	2	34/120	38/119	RR=0.90 ， 95%CI[0.63 ， 1.28]*， P=0.54	I
Symptom Disappearance Rate at Week 4 of Treatment											
Wei M 2024	RCT	2	1	1	1	1	2	25/120	5/119	RR=4.96 ， 95%CI[1.96 ， 12.52]， P=0.0007	III

Population(P): FD with syndrome of dampness-heat of spleen and stomach

Intervention(I): Modified Jiawei Lianpu Drink

Comparator(C): Western medical treatment (Domperidone)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Wen PY 2014	RCT	2	0	0	1	1	0	28/30	21/30	RR=1.33 , 95%CI[1.04 , 1.72], P=0.03	III

Population(P): FD with syndrome of dampness-heat of spleen and stomach

Intervention(I): Modified Chaihu Dayuan Drink

Comparator(C): Western medical treatment (Mosapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Zhang Y 2020	RCT	2	0	0	1	1	0	36/36	36/36	RR=2.38，95%CI[171，3.32]，P<0.00001	III
Heavy Sensation in Head and Body Symptom score											
Zhang Y 2020	RCT	2	0	0	1	1	0	36	36	MD_{score}=-0.8 ， 95%CI[-1.2 ，-0.4]，P＜0.0001	III
Bitter Taste and Sticky Mouth Symptom score											
Zhang Y 2020	RCT	2	0	0	1	1	0	36	36	MD_{score}=-0.83， 95%CI[-1.22，-0.44]，P＜0.0001	III 级
Scanty and Dark Urination Symptom score											
Zhang	RCT	2	0	0	1	1	0	36	36	MD_{score}=-0.93， 95%CI[-1.39，	III 级

Y 20207.										-0.47]，P＜0.0001	

Population(P): FD with syndrome of dampness-heat of spleen and stomach

Intervention(I): Modified Sanren Decoction

Comparator(C): Western medical treatment (Mosapride / Cisapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Gan DC 2016; Wang D 2017	RCT	2	0	0	1	1	0	90/97	79/97	RR=1.13，95%CI[1.01，1.27]，P =0.03	III

Population(P): FD with syndrome of deficient cold of spleen and stomach

Intervention(I): Modified Fuzi Lizhong Decoction

Comparator(C): Western medical treatment (Omeprazole)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Miao XX 2018	RCT	2	0	0	1	1	0	45/46	37/46	RR=1.22，95%CI[1.05，1.41]，P=0.01	III
Abdominal Pain Symptom score											
Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD_{score}=-0.36， 95%CI[-0.44，-2.08]，P＜0.00001	III
Abdominal Burning Sensation Symptom score											
Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD_{score}=-0.51， 95%CI[-0.59，-0.43]，P＜0.00001	III
Gastric Distention Symptom score											
Miao	RCT	2	0	0	1	1	0	46	46	MD_{score}=-0.58， 95%CI[-0.68，	III

XX 2018										-0.48]，P＜0.00001	

Belching Symptom score

Miao XX 2018	RCT	2	0	0	1	1	0	46	46	MD_{score}=-0.41， 95%CI[-0.56，-0.37]，P＜0.00001	III

Population(P): FD with syndrome of deficient weakness of spleen and stomach

Intervention(I): Modified Sijunzi Decoction

Comparator(C): Western medical treatment (Domperidone)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Symptom score											
Li YH 2008	RCT	2	0	0	1	1	0	45	45	MD_{score}=6.50 ， 95%CI [6.32，6.68]， P＜0.00001	III

Population(P): FD patients

Intervention(I): Acupuncture (Acupuncture at Baihui (GV20), Zhongwan (CV12), Qihai (CV6), Tianshu (ST25), Neiguan (PC6), Zusanli (ST36), Gongsun (SP4), and Tanzhong (CV17))

Comparator(C): Sham acupuncture

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
4-Week Response Rate											
Yang JW 2020	RCT	2	1	2	1	1	1	97/117	58/112	RR=1.60， 95% CI[1.32，1.95]，P < 0.00001	I

Population(P): FD patients

Intervention(I): Acupuncture, electroacupuncture

Comparator(C): Western Medicine (Prokinetic Agents, Acid Suppressants, or Combination Therapy)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Chen GE，2000，Liu WQ，2001，Luo L，2002，LI HJ 2004，Zhou Y 2004，Zhang XJ 2004，Chen YJ 2004，Shi HJ 2009，Xu GX 2005，Tang SX 2006，Zhao YW 2009，Jin L 2013，Chen MH 2023，Zhou DQ 2019，Qiang LM 2018，	RCT	2	0	2	1	1	0	948/1030	754/981	RR=1.21，95%CI[1.16，1.25]，P < 0.00001	II

Han J 2017，Liu X 2017，Du R 2016，Liu WR 2016，Xu Y 2015，Ren J 2015，Yuan XX 2015，Zhou L 2014，Zhang YP 2014，Yang M 2014											

Population(P): FD patients

Intervention(I): Acupuncture, electroacupuncture

Comparator(C): Sham acupuncture

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Clinical total efficacy rate											
Yang ZQ，2011，Zou X 2021，Hou YQ 2020，Chen P 2020，Chen P 2016，	RCT	2	1	2	1	1	0	193/223	90/200	RR=2.33，95%CI[1.99，2.74]，P < 0.00001	I

Population(P): FD patients

Intervention(I): Acupuncture, electroacupuncture

Comparator(C): Western Medicine (Prokinetics +/- acid suppressants)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
NDSI											
Fan HZ, 2012, Zhou L 2019, Dai M 2018, Li DD 2014, Sheng JW 2013	RCT	2	0	2	1	1	0	178	176	MD_{score}=-7.44 , 95%CI[-9.79，-5.08]，P < 0.00001	II
NDLQI											
Fan HZ, 2012, Zhou L 2019, Dai M 2018, Li DD 2014, Sheng JW 2013	RCT	2	0	2	1	1	0	178	176	MD_{score}=5.71 , 95%CI[4.20，7.23]，P < 0.00001	II

Population(P): FD patients

Intervention(I): Acupuncture, electroacupuncture

Comparator(C): Sham acupuncture

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
NDSI											
Yang ZQ，2011	RCT	0	0	2	1	1	0	30	28	MD_{score}=MD=-9.94，95%CI[-16.33，-3.55]，P = 0.002	III

Population(P): FD patients

Intervention(I): Transcutaneous auricular vagus nerve stimulation

Comparator(C): Sham transcutaneous auricular vagus nerve stimulation

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
The percentage of normal gastric slow waves on an empty stomach											
Zhu Y 2021	RCT	2	1	2	1	1	1	36	39	MD=0.15，95%CI[0.13，0.17]，P＜0.00001	I
The percentage of normal gastric slow waves after a meal											
Zhu Y 2021	RCT	2	1	2	1	1	1	36	39	MD=0.10，95%CI[0.08，0.13]，P＜0.00001	I
Main symptom score											
Wu D 2020	RCT	2	1	1	1	1	0	45	45	MD_{score}=-5.02， 95%CI[-6.34，-3.70]， P < 0.00001	I
FDDQL											
Wu D 2020	RCT	2	1	1	1	1	0	45	45	MD_{score}=2.56， 95%CI[0.91，4.21]， P= 0.002	I

Population(P): FD patients

Intervention(I): Auricular therapy

Comparator(C): Western medical treatment (Mosapride Citrate Dispersible Tablets)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design	Random sequence generation	Randomization concealment	Blind method	Incomplete outcome report	Selective reporting outcome	Sample size	№ of patients		Effect	Control group
								Intervention group	Control group		
Nipine dyspepsia index											
Wang D 2018	RCT	2	0	0	1	1	0	30	30	MD_{score}=-4.94， 95%CI[-9.32，-0.56]， P =0.03	III
Quality of life score											
Wang D 2018	RCT	2	0	0	1	1	0	30	30	MD_{score}=5.37， 95%CI[2.95，7.79]， P ＜0.0001	III

Population(P): FD patients

Intervention(I): Acupoint thread embedding (Zhongwan, Tianshu, Gan Shu, Zusanli, PI Shu, Wei Shu thread embedding)

Comparator(C): Western medical treatment (Cisapride)

Outcome(O):

Certainty assessment								Summary of findings			
№ of studies	Study design（研究类型）	随机序列的产生	随机化隐藏	盲法	不完整结局报告	选择性报告结局	样本含量	№ of patients（人数）		Effect（效应值）	证据等级
								试验组	对照组		
Clinical total efficacy rate											
Jiao YX 2006	RCT	2	0	0	1	1	0	58/60	26/30	RR=1.12，95%CI[0.96，1.29]，P =0.15	III

Note: Evidence Synthesis

Data extracted from the included studies will be imported into Review Manager 5.3 software to calculate effect sizes and confidence intervals. For dichotomous variables, the relative risk (RR) with 95% confidence intervals (CI) will be used, while for continuous variables, the mean difference (MD) with 95% CI will be reported.

Annex 2

Work Report on the First Round of Expert Questionnaire Survey of "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia"

The design of the first-round expert questionnaire for the "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia" was based on evidence-based medicine principles and the Delphi method. Building on literature research, the project team conducted thorough discussions to select relevant items tailored to the study's focus. These items were provided to experts for assigning scores to each indicator and submitting written supplementary or revision suggestions. A total of 35 valid questionnaires were collected from experts. The analysis and summary of these 35 responses are as follows:

1. Statistical Analysis of Expert Basic Information and Expert Response Rate

1.1 Statistical analysis of basic information of experts

Gender		Degree			Years of work experience (years)
Male	Female	Bachelor's	Master's	Doctorate	Average Years (of Work Experience)
22（62.86%）	13（37.15%）	6（17.14%）	4（11.43%）	25（71.43%）	32±9.61
Title			-	-	-
Chief Physician	Associate Chief Physician	Attending Physician	-	-	-
34（97.14%）	1（2.86%）	0	-	-	-
Occupation					
TCM Physician	Integrated Chinese and Western Medicine Physician	Western medicine physician	Acupuncturist	Scientific researchers	Other (Nurse)
14（40%）	8（22.86%）	8（22.86%）	1（2.86%）	2（5.71%）	2（5.71%）

Note: Percentages for each category are indicated in parentheses.

1.2 Expert Response Rate

A total of 38 questionnaires were distributed in the first round of the expert survey, and 35 valid responses were received, yielding a response rate of 92.1%.

2.Analysis of the Expert Questionnaire

2.1 Composition and Evaluation Methodology of the Expert Questionnaire

The first-round expert questionnaire for the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” was structured into three main sections: TCM Syndrome Differentiation, TCM Treatment, and Lifestyle Guidance. Following each section, experts were invited to provide specific written comments, supplementary suggestions, and revisions.

2.1.2 Evaluation Method

The responses to all items in the expert questionnaire were uniformly evaluated using the following scale: Agree; Agree with minor reservations; Agree with major reservations; Disagree with reservations; Strongly disagree; assigned 5, 4, 3, 2, and 1 points, respectively.

2.1.3 Statistical Analysis Method

The agreement rate was calculated as the combined proportion of responses categorized under "Agree," "Agree with minor reservations," and "Agree with major reservations" in the expert questionnaire, denoted as the consensus level. Items with a consensus level > 70% were categorized as reaching consensus, while those with a consensus level ≤70% were flagged for further discussion during expert consensus meetings.

2.1.3.1 Main process

Items	Primary Indicator	Secondary Indicator	Agreement Rate	Consensus Reached?
1	TCM Syndrome Differentiation	Syndrome of intermingled heat and cold	91.42%	Yes
2		Syndrome of liver depression and spleen deficiency	65.71%	No
3		Syndrome of liver depression and qi stagnation	62.85%	No
4		Syndrome of Spleen Deficiency and Qi Stagnation	85.71%	Yes
5		Syndrome of	94.28%	Yes

		incoordination between liver and stomach		
6		Syndrome of dampness-heat of spleen and stomach	71.43%	Yes
7		Syndrome of internal accumulation of damp-heat	62.86%	No
8		Syndrome of deficient cold (weakness) of spleen and stomach	91.42%	Yes
9		Syndrome of qi deficiency in the spleen and stomach	60%	No
10		Syndrome of stomach deficiency, qi stagnation and phlegm obstruction	34.29%	No
11	TCM Treatment	Classic TCM Formulas	100%	Yes
12		Chinese patent medicines	100%	Yes
13		External therapies	100%	Yes
14	Lifestyle Guidance	Daily Lifestyle Routines	100%	Yes
15		Mental Health	100%	Yes
16		Dietary Regulation and Care	100%	Yes

Annex 3

Work Report on the Second Round of Expert Questionnaire Survey of "International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia"

Based on literature research and the first round of expert questionnaires, the project team has reached a preliminary consensus on the core components of TCM syndrome differentiation, TCM treatment, and lifestyle guidance. However, specific recommendations require further deliberation. Following a systematic review of commonly used classic TCM formulas, Chinese patent medicines, and external therapies, the second-round expert consultation aimed to refine these details. A total of 38 valid responses were collected from experts in this round. The analysis and summary of the 38 questionnaires are presented below:

1. Statistical Analysis of Expert Basic Information and Expert Response Rate

1.1 Statistical analysis of basic information of experts

Gender		Degree			Years of work experience (years)
Male	Female	Bachelor's	Master's	Doctorate	Average Years (of Work Experience)
24（63.16%）	14（36.84%）	8（21.05%）	5（13.16%）	25（65.79%）	35±9.61
Title			-	-	-
Chief Physician	Associate Chief Physician	Attending Physician	Other	-	-
34（89.47%）	1（2.63%）	0	3（7.89%）	-	-
Occupation					
TCM Physician	Integrated Chinese and Western Medicine Physician	Western medicine physician	Acupuncturist	Scientific researchers	Other
14（36.84%）	8（21.05%）	8（21.05%）	1（2.63%）	2（5.26%）	5（13.15%）

Note: Percentages for each category are indicated in parentheses.

1.2 Expert Response Rate

In the second round of the expert questionnaire survey, 38 questionnaires were

distributed, and 38 completed responses were received, resulting in a 100% response rate.

2.Analysis of the Expert Questionnaire

2.1 Expert questionnaire and evaluation method

The second-round expert questionnaire for the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” focused on specific recommendations, with experts invited to provide detailed written comments, supplementary suggestions, and revisions following each section.

2.1.2 Evaluation Method

The strength of recommendations is determined using the GRADE grid voting method. A consensus is reached if any voting grid, except for "C," receives more than 50% of votes, allowing direct determination of the recommendation direction and strength:

A: Strong recommendation

B: Weak recommendation

C: Uncertain

D: Weak against recommendation

E: Strong against recommendation

If no single grid exceeds 50% of votes, but the combined votes of the two grids adjacent to "C" on either side exceed 70%, consensus is also considered achieved, and the recommendation strength is classified as "weak".

2.1.3.1 Recommendation voting results

No.	Recommendation Items	Votes for Recommendation Strength/Direction					Voting Rounds	Consensus Reached?
		↑↑	↑	／	↓	↓↓		
1	For patients with FD syndrome of intermingled heat and cold, Banxia Xiexin Decoction is recommended.	30	7	0	0	1	1	Yes
2	For FD patients with spleen deficiency and qi stagnation syndrome, Xiangsha Liujunzi Decoction is recommended.	32	6	0	0	0	1	Yes
3	For FD patients with spleen deficiency and qi stagnation syndrome, Zhishi Xiaopi Wan is recommended.	28	10	0	0	0	1	Yes

4	For FD patients with spleen deficiency and qi stagnation syndrome, Chinese patent medicine Xiangsha Liujun Pill is recommended.	30	8	0	0	0	1	Yes
5	For FD patients with spleen deficiency and qi stagnation syndrome, Chinese patent medicine Zhizhu Kuanzhong Capsule is recommended.	32	6	0	0	0	1	Yes
6	For FD patients with syndrome of incoordination between liver and stomach, Chaihu Shugan San is recommended..	27	11	0	0	0	1	Yes
7	For FD patients with syndrome of incoordination between liver and stomach, Chinese patent medicine Qizhi Weitong Keli /Pian is recommended.	34	4	0	0	0	1	Yes
8	For FD patients with syndrome of incoordination between liver and stomach, Chinese patent medicine Beiling weitong Keli is recommended.	32	5	1	0	0	1	Yes
9	For FD patients with syndrome of incoordination between liver and stomach, Chinese patent medicine Dalitong keli is recommended.	22	16	0	0	0	1	Yes
10	For FD patients with syndrome of incoordination between liver and stomach, Chinese patent medicine Aurantii Fructus Immaturus flavonoid Tablets is recommended.	29	8	1	0	0	1	Yes
11	For FD patients with syndrome of dampness-heat of the spleen and stomach in FD, Lianpo Decoction is recommended.	21	17	0	0	0	1	Yes

12	For FD patients with syndrome of Dampness is heavier than heat in the Spleen-Stomach Dampness-Heat, it is recommended to use the Chaihu Dayuan Decoction.	25	11	1	1	0	1	Yes
13	For patients with FD syndrome of Equal Predominance of Dampness and Heat in the Spleen-Stomach Dampness-Heat, Sanren Decoction is recommended.	20	17	1	0	0	1	Yes
14	For FD patients with syndrome of deficient cold of spleen and stomach, Fuzi Lizhong Decoction is recommended.	28	9	1	0	0	1	Yes
15	For FD patients with Syndrome of Spleen and Stomach Deficiency, Sijunzi Decoction is recommended.	28	10	0	0	0	1	Yes
16	For FD patients with spleen and stomach coldness syndrome, Chinese patent medicine Fuzi Lizhong Pills is recommended.	26	10	2	0	0	1	Yes
17	For FD patients with Syndrome of Spleen and Stomach Deficiency Syndrome, Chinese patent medicine Shenling Baizhu Keli is recommended.	26	9	3	0	0	1	Yes
18	Acupuncture or Electroacupuncture is recommended to improve the 4-week response rate and clinical efficacy, as well as to enhance Nepean Dyspepsia Symptom Index (NDSI) and Nepean Dyspepsia Life Quality Index (NDLQI) scores.	28	10	0	0	0	1	Yes

19	It is recommended to use Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) to improve the symptoms and quality of life of FD.	23	14	1	0	0	1	Yes
20	It is recommended to use Auricular Acupoint Therapy to improve FD symptoms and quality of life.	15	22	1	0	0	1	Yes
21	It is recommended to use Acupoint Embedding Therapy to enhance clinical efficacy in FD.	14	22	2	0	0	1	Yes

Annex 4

“International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” (Draft)

Minutes of the expert argumentation meeting

Meeting Date: January 25, 2025

Location: Online Tencent Meeting

Attendees: Wei Wei, Rong Peijing, Liu Jianping, Chen Wei, Zhang Xuezhi, Su Xiaolan, Wang Hongbing, Du Zhengguang, Wang Yangang, Fang Jiliang, Shi Zhaohong, Su Juanping, Wang Chuijie, Ding Xia, Chi Lili, Gong Yang, Liu Huayi, Hu Yunlian, Ke Xiao, Shen Hong, Yang Qian, Huang Suiping, Liu Qiquan, Yu Tao, Li Jingnan, Wang Huahong, Xia Zhiwei, Ding Shigang, Du Shiyu, Lan Yu, Zhang Xiaolan, Wang Bangmao, Tang Yanping, Xiao Xiaohe, Wang Linheng, He Ling, Suo Biao, Cao Junling, Liu Jianxun, Sun Xiaobo, Cao Yanxia, Chen Yixiu

Meeting Chair: Zhang Shiyi

Organizing Committee: Zhang Shiyi, Jiang Han, Yu Fanya, Qian Zixing, Wang Chun

Project Secretary Jiang Han briefed the experts on the working group's progress:

The development of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” officially commenced in November 2022. Under the guidance of the International Expert Steering Group for Functional Dyspepsia, a working group was established by the end of December 2022. Following its formation, the group initiated a literature review, retrieving 9,699 articles related to functional dyspepsia. After screening, a literature review summary was prepared.

Based on this research, the project team collaboratively designed an expert questionnaire, which was distributed to specialists nationwide. By the end of January 2025, two rounds of expert surveys had been completed, with statistical analyses and survey summaries conducted after each round.

Through literature research and expert consultations, the working group drafted the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” and submitted it for review at the expert consensus meeting.

Professor Chen Wei, a guideline development expert, delivered a presentation titled Introduction to Expert Consensus Methods: This session outlined common methodologies for forming expert consensus, including the Delphi method, Nominal Group Technique (NGT), Consensus Conference Method, and Modified Delphi method. A detailed analysis was provided on the strengths, limitations, and practical applications of each approach.

Following this, Project Secretary Zhang Shiyi presented the draft content of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” to the expert panel, highlighting key issues requiring focused discussion.

Prior to the meeting, experts had received and reviewed the electronic draft of

the guidelines. During the session, participants actively contributed insights. In-depth discussions were held on specific aspects of the draft, resulting in broad consensus and actionable revisions. Key modifications included:

(1) Revise recommendation statements to: "For FD patients with [specific syndrome], [specific herbal formula] is recommended." Ensure terms like "effective rate" or "total effective rate" align with definitions in cited literature.

(2) Verify the original herbal compositions of classic TCM formulas and revise descriptions of individualized modifications.

(3) Update administration guidelines to: "One dose daily, decocted twice in water to yield 300–400 ml. Divide into two portions (150–200 ml each) and take orally before morning and evening meals, or as prescribed by the physician."

(4) Add sections on recommended treatment duration and safety information

(5) In Chinese patent medicines, it is recommended to add Xiangsha Liujun Pills for syndrome of spleen deficiency and qi stagnation syndrome, Aurantii Fructus Immaturus flavonoid Tablets for syndrome of incoordination between liver and stomach, and Fuzi Lizhong Pills (Concentrated Pills) for syndrome of deficient cold (weakness) of spleen and stomach.

(6) Clarify operational procedures and standardize treatment duration for auricular therapy.

Following thorough evaluation, the expert panel concluded that the draft of the “International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia” has been largely finalized. The project working group carefully deliberated on the proposed revisions, implemented minor adjustments to less precise sections, and prepared the initial draft of the guidelines. This draft will now be submitted to the expert steering group for further review and validation.

“International Clinical Practice Guideline of Chinese Medicine for Functional Dyspepsia”
Guideline Development Team
February 12, 2025