ICS 11.020.99

SCM

世界中医药学会联合会
World Federation of Chinese Medicine Societies

SCM 92-2025

国际中医临床实践指南
功能性消化不良

International clinical practice guideline of Chinese medicine
Functional dyspepsia
（发布稿，International Standard）

世界中联国际组织标准
International Standard of WFCMS

2025-12-17 发布实施
Issued & implemented on December 17, 2025

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前　言

主要起草单位：中国中医科学院望京医院、首都医科大学附属北京中医医院、澳大利亚纽卡斯尔大学、多伦多大学消化病学分部、美国密西根大学医学院、美国凯斯西储大学、北京协和医院、北京大学医学部、华中科技大学同济医学院附属协和医院、中国中医科学院中医临床基础医学研究所、广州中医药大学第一附属医院、北京中医药大学循证医学中心。

参与起草单位：香港浸会大学、北京大学第一医院、北京中医药大学第三附属医院、中国中医科学院广安门医院、武汉市第一医院、山西省中医院、辽宁中医药大学附属医院、北京中医药大学东直门医院、山东中医药大学附属医院、天津市中医药研究院附属医院、厦门市中医院、广东省中医院、河北省中医院、陕西省中医医院、中日友好医院、河北医科大学第二医院、天津医科大学总医院、天津市南开医院、解放军 302 医院、北京中医药大学东方医院、南京中医药大学附属医院、江西中医药大学附属医院、首都医科大学附属北京积水潭医院、湖北省中医院、福建省第二人民医院、沈阳军区总医院、中国科学院动物研究所。

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本文件起草程序遵守了世界中医药学会联合会发布的《世界中联国际组织标准管理办法》和 SCM1.1-2021《标准化工作导则第 1 部分：标准制修订与发布》。

引　　言

目前已发布多项关于功能性消化不良的中医药诊疗相关指南与专家共识，如《功能性消化不良中医诊疗专家共识意见（2017）》、《功能性消化不良中西医结合诊疗共识意见（2017）》、《中成药治疗功能性消化不良临床应用指南（2021 年）》、《功能性消化不良中医诊疗专家共识意见（2023）》等，为临床实践提供了参考框架。但既往指南制定过程中多以专家共识作为推荐标准，国际认可度普遍较低。随着中医药领域循证医学研究的快速发展，证据水平更高的研究成果不断涌现。本文件在既往指南的基础上，根据高质量临床研究对功能性消化不良的治疗进行严格的质量评估，为中医药治疗功能性消化不良的临床应用提供循证依据。

本文件是依据现有的研究证据、特定的方法制定出的声明性文件。在临床实践中，医师可参考本文件并结合患者具体情况进行个体化治疗。

本文件的研制方法见附录 A，证据说明见附录 B。

推荐意见汇总表

序号	推荐意见	推荐等级
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	III级证据，强推荐
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	III级证据，强推荐
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	III级证据，强推荐
4	针对脾虚气滞证 FD 患者，推荐使用中成药枳术宽中胶囊	II级证据，强推荐
5	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	III级证据，强推荐
6	针对肝胃不和证 FD 患者，推荐使用中成药气滞胃痛颗粒（片）	I级证据，强推荐
7	针对肝胃不和证 FD 患者，推荐使用中成药荜铃胃痛颗粒	I级证据，强推荐
8	针对肝胃不和证 FD 患者，推荐使用中成药达立通颗粒	III级证据，弱推荐
9	针对肝胃不和证 FD 患者，推荐使用中成药枳实总黄酮片	I级证据，强推荐
10	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	III级证据，弱推荐
11	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	II级证据，弱推荐
12	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	III级证据，弱推荐
13	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	III级证据，强推荐
14	针对脾胃虚弱证 FD 患者，推荐使用中医经典方剂四君子汤	III级证据，强推荐
15	针对 FD 脾胃虚弱证的患者，推荐使用中成药参苓白术颗粒	II级证据，弱推荐
16	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）	针刺：III级（4 周应答率及临床有效率）/II级证据（NDSI 和 NDLQI），强推荐 电针：II级证据，强推荐
17	推荐使用经皮耳迷走神经刺激改善 FD 症状及生活质量	I级证据，弱推荐
18	推荐使用耳穴疗法改善 FD 症状及生活质量	III级证据，弱推荐
19	推荐使用温和灸疗法改善 FD 临床有效率	III级证据，弱推荐

国际中医临床实践指南 功能性消化不良

1 范围

本文件规定了中医药治疗功能性消化不良的术语与定义、病因病机、诊断、辨证、中医药治疗、其他疗法、生活指导等内容。

本指南适用于不同医疗服务环境中参与功能性消化不良诊疗的医疗专业人员，包括中医医师及从事整合医学实践的临床医师。适用场景包括专科医疗机构、综合医疗机构及基层医疗卫生机构，同时可为国际范围内开展中医药或整合医学服务的临床实践提供参考。

2 规范性引用文件

本文件没有规范性文件。

3 术语和定义

下列术语和定义适用于本文件。

3.1

功能性消化不良

具有餐后饱胀不适、早饱感、上腹痛、上腹烧灼感中的一项或多项的症状，而不能用器质性、系统性或代谢性疾病等来解释产生症状原因的疾病[1]。

注 1：2016 年，罗马委员会将功能性胃肠疾病定义为脑肠互动异常性疾病（即脑肠轴功能紊乱）[1]。罗马Ⅳ标准将 功能性消化不良分为餐后不适综合征和上腹痛综合征两个亚型。

注 2：中医古籍中对功能性消化不良的描述包括“痞满”“胃痞”“嘈杂”“胃脘痛”“胃痛”等，为了更好地与功能性消化不良诊断及亚型划分对应，将上腹痛综合征定义为中医的“胃痛”，餐后不适综合征定义为中医的“胃痞”。

表 1 FD 亚型—中医病证对应表

FD 亚型	核心症状特征	中医病名	核心中医症状	常见中医证候
餐后不适综合征（PDS）	餐后饱胀、早饱感	胃痞	胃脘痞满、胃脘痞闷、胃脘胀满、脘腹痞满	脾虚气滞证
上腹痛综合征（EPS）	上腹部烧灼感、疼痛	胃痛	胃脘疼痛、脘腹疼痛、胃脘隐痛、、胃脘灼痛	肝胃不和证
混合型（PDS-EPS 重叠）	同时存在 PDS 与 EPS 症状	胃痞-胃痛	胃脘胀痛、痞满伴隐痛、胀痛并作	寒热错杂证、脾虚气滞证、肝胃不和证、脾胃湿热证、脾胃虚寒（弱）证

4 病因病机

本病病位在胃，与肝、脾两脏关系密切。常见病因为情志失调或（和）劳倦过度或（和）先天禀赋不足或（和）饮食不节或（和）感受外邪等。本病初期多以寒凝、食积、气滞、痰湿等为主，邪气久客耗伤正气，则病机由实转虚，也可虚实夹杂。病久或入络瘀阻，或化热而寒热互见。本病基本病机应为脾虚气滞，胃失和降，病性多表现为本虚标实，虚实夹杂，以脾虚为本，气滞、食积、痰湿、血瘀等邪实为标。

5 诊断

5.1 西医诊断

功能性消化不良的临床表现和诊断标准见附录 D。

5.2 中医辨证[3-5]

5.2.1 寒热错杂证

主症：①胃脘痞满或疼痛，遇冷加重；②口干或口苦。
次症：①纳呆；②嘈杂；③恶心或呕吐；④肠鸣；⑤便溏。
舌脉：①舌淡红，苔黄；②脉弦细滑。

5.2.2 脾虚气滞证

主症：①胃脘痞闷或胀痛；②纳呆。
次症：①嗳气；②疲乏；③便溏。
舌脉：①舌淡，苔薄白；②脉细弦。

5.2.3 肝胃不和证

主症：①胃脘胀满或疼痛；②两胁胀满。
次症：①每因情志不畅而发作或加重；②心烦；③嗳气频作；④善叹息。
舌脉：①舌淡红，苔薄白；②脉弦。

5.2.4 脾胃湿热证

主症：①脘腹痞满或疼痛；②口干或口苦。
次症：①口干不欲饮；②纳呆；③恶心或呕吐；④小便短黄。
舌脉：①舌红，苔黄厚腻；②脉滑。

5.2.5 脾胃虚寒（弱）证

主症：①胃脘隐痛或痞满；②喜温喜按。
次症：①泛吐清水；②食少或纳呆；③疲乏；④手足不温；⑤便溏。
舌脉：①舌淡，苔白；②脉细弱。

5.2.6 诊断标准

主症 2 项，加次症 2 项，参考舌脉，即可诊断。

6 中医治疗

6.1 辨证方药治疗

6.1.1 寒热错杂证

治则：辛开苦降，和胃开痞。

推荐 1：半夏泻心汤（**Ⅲ级证据，强推荐**）

半夏泻心汤药物组成：半夏，干姜，黄芩，黄连，党参，炙甘草，大枣。

加减方法：嗳气者，加代赭石、旋覆花；情志不畅者，加郁金、合欢花；便秘者，加大黄、枳实、厚朴；腹痛者，加白芍、元胡。

用药建议：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。疗程 4 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

6.1.2 脾虚气滞证

治则：健脾和胃，理气消胀。

推荐 1：香砂六君子汤（**Ⅲ级证据，强推荐**）

药物组成：党参，白术，茯苓，甘草，陈皮，半夏，砂仁，木香。

加减方法：胸胁胀满疼痛者，加木香、郁金、川楝子；泛酸者，加乌贼骨、浙贝母；便溏者，加炒薏苡仁、炒扁豆等。

用药建议：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。疗程 4 周。

安全性：纳入的 1 项研究在治疗过程中报告无严重不良反应出现。

推荐 2：枳实消痞丸（**Ⅲ级证据，强推荐**）

药物组成：黄连、干姜、炙甘草、厚朴、白术、茯苓、半夏、麦芽、党参、枳实等。

加减方法：恶心呕吐者，加陈皮、竹茹；反酸者，加海螵蛸、煅瓦楞；腹痛腹胀者，加木香、延胡索等。

用药建议：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。疗程 4 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

6.1.3 肝胃不和证

治则：理气解郁，和胃降逆。

推荐 1：柴胡疏肝散（**Ⅲ级证据，强推荐**）

药物组成：陈皮、柴胡、川芎、香附、枳壳、芍药、甘草等。

用药建议：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。疗程 4 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

6.1.4 脾胃湿热证

治则：清热化湿，理气和中。

推荐 1：连朴饮（脾胃湿热证中湿热并重，**Ⅲ级证据，弱推荐**）

药物组成：厚朴、黄连、石菖蒲、半夏、豆豉、栀子、芦根。

加减方法：伴疼痛者，加延胡索；两胁胀满者，加枳壳、柴胡；纳食减少者，加鸡内金，谷麦芽；食积者，加焦麦芽，焦山楂，焦神曲。

用药建议：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。疗程 2 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

推荐 2：柴胡达原饮（脾胃湿热证中湿重于热，**Ⅱ级证据，弱推荐**）

药物组成：柴胡、枳壳、厚朴、青皮、甘草、黄芩、桔梗、草果、槟榔、荷叶梗。

用药建议：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。疗程 4 周。

安全性：纳入的研究中试验组（柴胡达原饮）未报告不良反应，对照组（莫沙必利）1 例轻度腹泻，不良反应发生率差异无统计学意义。

推荐 3：三仁汤（脾胃湿热证湿热并重，**Ⅲ级证据，弱推荐**）

药物组成：杏仁、滑石、通草、白蔻仁、竹叶、厚朴、薏苡仁、半夏。

用药建议：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。疗程 2 周。

安全性：纳入的 2 项研究在治疗过程中均报告无严重不良反应出现。

6.1.5 脾胃虚寒（弱）证

治则:健脾和胃，温中散寒。

推荐 1：附子理中汤（脾胃虚寒证，**Ⅲ级证据，强推荐**）

药物组成：附子、党参、白术、干姜、炙甘草。

用药建议：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。疗程 4 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

推荐 2：四君子汤。（脾胃虚弱证，**Ⅲ级证据，强推荐**）

药物组成：党参，白术，茯苓，甘草。

用药建议：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。疗程 4 周。

安全性：一项 RCT（n=90）中，对照组（n=45）中出现 8 例轻度不良事件（腹部不适、排气过多或腹泻），发生率为 17.78%，无严重不良反应事件发生。两组在不良反应发生率方面无显著差异，RR=0.6，95%CI[0.00,0.09],P = 0.05。

6.2 中成药治疗

建议 1：中成药香砂六君丸（**专家共识，强推荐**）

药物组成：木香、砂仁、党参、炒白术、茯苓、炙甘草、陈皮、姜半夏。辅料：生姜、大枣。

功能主治：益气健脾，和胃。用于脾虚气滞，消化不良，嗳气食少，脘腹胀满，大便溏泄。

用药建议：口服。一次 6-9 克，一日 2-3 次。或遵医嘱。疗程两周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

推荐 2：中成药枳术宽中胶囊（Ⅱ级证据，强推荐）

药物组成：白术（炒），枳实、柴胡、山楂。

功能主治：用于功能性消化不良伴有呕吐、反胃、纳呆、反酸及体疲倦乏力等症状；慢性胃炎消化不良伴有抑郁、焦虑状态症状；功能性便秘；胃轻瘫；肠易激综合症；小儿厌食症等。

用药建议：口服，一次 3 粒，每日 3 次，或遵医嘱。疗程两周。

安全性：有 1 项 RCT（n=403）对研究过程中的不良反应进行报告，试验组（n=298）2 例，对照组（n=105）3 例，不良反应发生率分别为 0.67%和 2.86%，均为轻度不良反应事件，无严重不良反应事件发生。两组在不良反应发生率方面无显著差异，RR=0.1，95%CI[0.02,0.59],P = 0.01。说明书报告常见不良反应包括服药后偶见胃痛或大便次数增多。

推荐 3：中成药气滞胃痛颗粒（片）（Ⅰ级证据，强推荐）

药物组成：柴胡、醋延胡索、枳壳、醋香附、白芍、炙甘草。

功能主治：舒肝理气，和胃止痛。用于肝郁气滞，胸痞胀满，胃脘疼痛。

用药建议：颗粒剂：开水冲服，一次 2.5g，每日 3 次。或遵医嘱。疗程 4 周。片剂：口服，一次 3 片，每日 3 次。疗程 4 周。或遵医嘱。

安全性：纳入的 1 项 RCT（n=197）在治疗过程中，试验组（n=99）和对照组（n=98）不良事件发生率分别为 3.03%和 3.06%，，均为轻度不良反应事件，无严重不良反应事件发生。两组在不良反应发生率方面无显著差异，RR=0.99，95%CI[0.20,4.79],P = 0.99。

推荐 4：中成药荜铃胃痛颗粒（Ⅰ级证据，强推荐）

药物组成：荜澄茄、川楝子、延胡索、酒大黄、黄连、吴茱萸、香附、香橼、佛手、海螵蛸、瓦楞子。

功能主治：行气活血，和胃止痛。用于气滞血瘀所致的胃院痛；慢性胃炎见有上述证候者。

用药建议：口服，一次 5g，每日 3 次。或遵医嘱。疗程六周。

安全性：纳入的 RCT（n=238）中，，28 例患者共发生 41 例不良事件。试验组（n=120）中 15 例（12.5%）患者共发生 23 例不良事件，其中 1 例（0.83%）为不良反应（腹泻），未见严重不良事件。安慰剂组（n=118）中 13 例（10.93%）患者发生 18 例不良事件。均为轻度不良反应事件。两组不良事件发生率无显著性差异，RR=0.94，95%CI[0.47,1.88],P = 0.87。

推荐 5：中成药达立通颗粒（Ⅲ级证据，弱推荐）

药物组成：柴胡、枳实、木香、陈皮、清半夏、蒲公英、山楂（炒焦）、焦槟榔、鸡矢藤、党参、延胡索、六神曲（炒）。

功能主治：清热解郁，和胃降逆，通利消滞，用于肝胃郁热所致痞满证，症见胃脘胀满、嗳气、纳差、胃中灼热、嘈杂泛酸、脘腹疼痛、口干口苦；运动障碍型功能性消化不良见上述症状者。

用药建议：温开水冲服，一次 1 袋，一日 3 次，于饭前服用。或遵医嘱。疗程 2-4 周。

安全性：有 8 项研究对研究过程中的不良反应进行报告，其中 3 项未发生不良事件，其余 5 项研究（n=965）无严重不良反应事件出现，试验组与对照组在不良反应发生率方面无显著差异，RR=0.95，95%CI[0.40,2.27],P = 0.91。说明书报告个别患者服药后可能出现腹痛。

推荐 6：中成药枳实总黄酮片（**Ⅰ级证据，强推荐**）

药物组成：枳实总黄酮提取物。

功能主治：行气消积、散痞止痛。用于功能性消化不良，症见餐后饱胀感、早饱、上腹烧灼感和上腹疼痛等。

用药建议：餐前 30 分钟温水服用，每天 3 次，每次 3 片。或遵医嘱。疗程 4 周。

安全性：纳入的 1 项 RCT（n=239）中，66 名患者共发生 95 例不良事件，其中试验组（n=120）23 例（19.17%）对照组（n=119）43 例（36.13%），除 4 例为中度不良事件外,其余均为轻度不良事件，未报告严重不良事件。试验组与对照组在不良反应发生率方面存在差异，RR=0.51，95%CI[0.32,0.79],P = 0.003。

建议 7：中成药附子理中丸（浓缩丸）（**专家共识，弱推荐**）

药物组成：附子、党参、白术、干姜、甘草。

功能主治：温中健脾。用于脾胃虚寒，脘腹冷痛，呕吐泄泻，手足不温。

用药建议：口服，一次 8-12 丸，一日 3 次。或遵医嘱。疗程 2 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

推荐 8：中成药参苓白术颗粒。（**Ⅱ级证据，弱推荐**）

药物组成：人参、茯苓、白术（炒）、山药、白扁豆（炒）、莲子、薏苡仁（炒）、砂仁、桔梗、甘草。

功能主治：补脾胃，益肺气。用于脾胃虚弱，食少便溏，气短咳嗽，肢倦乏力。

用药建议：口服，一次 3 g，每日 3 次。或遵医嘱。疗程 2 周。

安全性：推荐意见的安全性证据尚不充分，工作组专家进行讨论后认为上述药物总体安全性良好，临床医生在使用时需注意观察患者实际用药安全性。

6.3 体表医学疗法

推荐 1：针刺疗法可提高临床有效率（**Ⅲ级证据**）、改善中医证候积分（**Ⅱ级证据**）、提升患者生活质量（**Ⅱ级证据**）。（**强推荐**）

主穴：中脘、气海、天枢、内关、足三里、上巨虚、公孙、膻中、百会。

辨证选穴：脾虚气滞证，加太冲、期门；肝胃不和证，加太冲；脾胃湿热证，加阴陵泉、内庭穴；脾胃虚寒（弱）证，加脾俞、胃俞穴；寒热错杂证，加三阴交、阴陵泉、曲池穴。

操作：采取合适体位，以患者舒适，方便操作为主。穴位消毒后，根据穴位选择适当长度毫针并刺入适宜深度，在穴位上进行捻转、提插操作，以产生得气感（酸、麻、胀、痛）。实证用泻法，虚证用补法。每次留针 30min，期间行针 2 次。

疗程：每周治疗 3 次，4 周为 1 疗程。

注意事项：凝血障碍者、皮肤异常者禁止针刺。

推荐 2：电针疗法，可提高临床有效率（**Ⅱ级证据**）、改善中医证候积分（**Ⅲ级证据**）、降低患者尼平消化不良症状指数（**Ⅱ级证据**）和 FD 单项症状量化分级表评分（**Ⅱ级证据**）、提升患者生活质量（**Ⅱ级证据**）。（**强推荐**）

主穴：同针刺。

辨证选穴：同针刺。

操作：同针刺。针刺得气后，连接电针。电针参数：疏密波，2/100Hz, 2mA-10mA。每次留针 30min。

疗程：每周治疗 3 次，4 周为 1 疗程。

注意事项：凝血障碍者、皮肤异常者禁止针刺。安装心脏起搏器及其他严重器质性心脏疾病者不可使用电针。

推荐 3：经皮耳迷走神经刺激，改善功能性消化不良症状（**Ⅰ级证据**）及生活质量（**Ⅰ级证据**）。（弱推荐）

刺激点：双侧耳甲区，迷走神经分布丰富。方法：将一个电极夹贴在一只耳朵上，另一个电极贴在另一只耳朵上（SNM-功能性消化不良 C01）。

刺激参数：根据患者的耐受性，启动时间为 2 秒，关闭时间为 3 秒，脉冲宽度为 0.5 秒，脉冲频率为 25 Hz，脉冲振幅为 0.5 mA 至 1.5 mA。

疗程：每天早餐和晚餐后各 30 分钟，持续 2 周。

推荐 4：温和灸，可提高临床有效率。（**Ⅲ级证据，弱推荐**）

取穴：中脘、足三里

操作：取患者仰卧位，此时将灸条点燃置于患者穴位周边进行灸治，使皮肤有温热感而无灼痛感。

疗程：每灸 30min，每日治疗 1 次，4 周为 1 疗程。

推荐 5：耳穴疗法，可改善功能性消化不良症状及生活质量。（**Ⅲ级证据，弱推荐**）

耳穴：主穴：肝、脾、胃、肾、十二指肠；配穴：内分泌、交感、神门、皮质下。

方法：将王不留行籽贴于已选好的耳穴上，每次选择一侧耳穴，双侧耳穴轮流使用。

疗程：每周贴 3 次，每贴至少间隔 1d。指导患者每日按压 3~5 次以加强刺激，每穴每次按压 1~2 分钟。治疗 4 周。耳穴疗法可在常规治疗或西医治疗的基础上加用。

7 生活指导

7.1 规律生活与适度运动（专家共识，强推荐）

规律作息，保证充足睡眠；根据天气变化及时增减衣服，注意腹部保暖；进行规律的且能耐受的运动，如太极拳、散步、慢跑等；应避免餐后立刻运动，以免增加胃肠负担。

7.2 形成健康饮食习惯（专家共识，强推荐）

每日定时、定量进餐，细嚼慢咽，勿暴饮暴食，勿过快进餐。宜饮食清淡、易消化、少油腻，避免冷食、辛辣刺激食物、生食、产气食物的摄入。

7.3 保持心理健康（专家共识，强推荐）

保持乐观开朗，心情舒畅。医生应了解患者心理状态，建立良好的医患信任关系，及时安慰、教育指导和沟通；患者应多与他人进行沟通，学会自我调节，必要时可咨询心理医生，寻求专业治疗。心理治疗可作为症状严重、药物治疗无效的功能性消化不良患者的补救治疗。

附录 A
（规范性）
指南研制方法

A.1 证据评价及分级[86]

表 A.1 中医药临床研究证据的分级标准

证据等级	有效性	安全性
I 级	随机对照试验及其系统综述、N-of-1 试验系统综述	随机对照试验及其系统综述、队列研究及其系统综述
II 级	非随机临床对照试验、队列研究、N-of-1 试验	上市后药物流行病学研究、V 期临床试验、主动监测（注册登记、数据库研究）
III级	病例对照研究，前瞻性病例系列	病例对照研究
IV 级	规范化的专家共识[1]、回顾性病例系列、历史性对照研究	病例系列/病例报告
V 级	非规范化专家共识[2]、病例报告、经验总结	临床前安全性评价,包括致畸、致癌、半数致死量、致敏和致毒评价

注 1:规范化的专家共识，指通过正式会议方法（如德尔菲法、名义群组法、共识会议法以及改自德尔菲法等），总结专家意见制订的，为临床决策提供依据的文件。

注 2:非规范化的专家共识，指早期应用非正式共识方法如集体讨论、会议等，所总结的专家经验性文件。

表 A.2 系统综述质量评价标准

条目	评价指标
1	有明确的临床问题，并正确按照 PICO 原则进行结构化（2 分）
2	纳入标准恰当（1 分）
3	纳入研究的选择和数据提取具有可重复性（1 分）
4	检索全面、提供了明确的检索策略（1 分）
5	描述纳入研究的特征（1 分）
6	评价和报道了纳入研究的方法学质量（1 分）
7	数据综合方法正确（2 分）
8	无相关利益冲突（1 分）

注：降级的标准为：总分 9～10 分,不降级;3~8 分,降一级 0~2 分,降两级。

表 A.3　RCT 方法学质量评价标准

条目	评价项目	评价指标
1	随机序列的产生	计算机产生的随机数字或类似方法（2 分）未描述随机分配的方法（0 分） 采用交替分配的方法如单双号（0 分）
2	随机化隐藏	中心或药房控制分配方案、或用序列编号一致的容器、现场计算机控制、密封不透光的信封或其他使临床医生和受试者无法预知分配序列的方法（1 分） 未描述随机隐藏的方法（0 分） 交替分配、病例号、星期日数、开放式随机号码表、系列编码信封以及任何不能防止分组可预测性的措施（0 分） 未使用（0 分）
3	盲法	采用了完全一致的安慰剂片或类似方法,且文中描述表明不会被破盲（2 分） 未施行盲法，但对结果不会严生偏倚（2 分）只提及盲法，但未描述具体方法（1 分） 未采用双盲或盲的方法不恰当，如片剂和注射剂比较（0 分）
4	不完整结局报告	无研究对象失访（1 分） 虽然有研究对象失访,但与总样本对比,失访人数小且失访理由与治疗无关,失访情况对结果不会造成影响（1 分） 未报告失访情况或失访情况会对结果造成偏倚（0 分）
5	选择性报告结局	研究方案可及,未改变研究方案中的结局指标（1 分） 研究方案不可及，但是报告了该疾病公认的重要结局（1 分） 研究方案不可及，未报告该疾病公认的重要结局（0 分） 文章的结果部分与方法学部分的结局指标不符（0 分）
6	样本含量	提供了样本含量估算公式,样本含量计算正确，保证足够的把握度（1 分） 未提及如何计算样本含量（0 分）

注：降级的标准为：总分 7~8 分,不降级；5~6 分,降一级：0~4 分降两级。

A.2 推荐原则[87]

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”。

附录 B
（资料性）
证据说明

B.1 辨证方药治疗

B.1.1 寒热错杂证

推荐意见 1：1 项半夏泻心汤（加减法）治疗功能性消化不良寒热错杂证（n=60）的 RCT 结果显示[6]，半夏泻心汤（加减法）与促胃动力药相比，临床总有效率更高 RR=2.00，95%CI[1.69，2.31]，P＜0.00001。

B.1.2 脾虚气滞证

推荐意见 1：2 项香砂六君子汤（加减法）治疗功能性消化不良脾虚气滞证（n=208）的 RCT 结果显示[7,8]，香砂六君子汤（加减法）与促胃动力药、抑酸药联合使用相比，临床总有效率更高 RR=1.30，95%CI[1.12，1.51]，P=0.0007。

推荐意见 2：1 项枳实消痞丸（加减法）治疗功能性消化不良脾虚气滞证（n=80）的 RCT 结果显示[9]，枳实消痞丸（加减法）与促胃动力药相比，临床总有效率更高 RR=1.33，95%CI [1.11，1.59]，P=0.002；在降低主要症状（腹胀、嗳气、纳差、恶心）积分[MD $_{积分}$=4.08 分，95%CI （3.73，4.43），P＜0.00001]方面更优。

B.1.3 肝胃不和证

推荐意见 1：1 项柴胡疏肝散（加减法）治疗功能性消化不良肝胃不和证（n=56）的 RCT 结果显示[10]，柴胡疏肝散（加减法）与促胃动力药相比，临床总有效率更高 RR=1.67，95% CI[1.15，2.41]，P=0.007。

B.1.4 脾胃湿热证

推荐意见 1：1 项连朴饮（加减法）治疗功能性消化不良脾胃湿热证（n=60）的 RCT 结果显示[11]，连朴饮（加减法）与促胃动力药相比，临床总有效率更高 RR=1.33，95%CI[1.04，1.72]，P=0.03。

推荐 1 意见 2：1 项柴胡达原饮（加减法）治疗功能性消化不良脾胃湿热证（n=72）的 RCT 结果显示[12]，柴胡达原饮（加减法）与促胃动力药相比，临床总有效率更高 RR=2.38，95%CI[171，3.32]，P<0.00001；在降低头身困重 MD $_{积分}$=-0.8 分，95%CI[-1.2，-0.4]，P＜0.0001；口苦口黏 MD $_{积分}$=-0.83 分，95%CI[-1.22，-0.44]，P＜0.0001；小便短黄 MD $_{积分}$=-0.93 分，95%CI[-1.39，-0.47]，P＜0.0001 症状积分方面更优。

推荐意见 3：2 项三仁汤（加减法）治疗功能性消化不良脾胃湿热证（n=194）的 RCT 结果显示[13-14]，三仁汤（加减法）与促胃动力药相比，临床有效率更高 RR=1.13，95%CI[1.01，1.27]，P =0.03。

B.1.5 脾胃虚寒（弱）证

推荐意见 1：1 项附子理中汤（加减法）治疗功能性消化不良脾胃虚寒证（n=92）的 RCT 结果显示[15]，附子理中汤（加减法）与抑酸药相比，临床总有效率更高 RR=1.22，95%CI[1.05，1.41]，P=0.01；在降低腹部疼痛 MD 积分=-0.36 分，95%CI[-0.44，-2.08]，P＜0.00001；腹部

烧灼 MD 积分=-0.51 分，95%CI[-0.59，-0.43]，P＜0.00001；胃胀 MD 积分=-0.58 分，95%CI[-0.68，-0.48]，P＜0.00001；嗳气 MD 积分=-0.41 分，95%CI[-0.56，-0.37]，P＜0.00001 症状积分方面更优。

推荐意见 2：1 项四君子汤（加减法）治疗功能性消化不良脾胃虚弱证（n=90）的 RCT 结果显示[16]，四君子汤（加减法）与促胃动力药相比，在降低主要症状积分（腹胀痞满、食欲不振或易饱、疲乏无力）MD 积分=6.50 分，95%CI [6.32，6.68]，P＜0.00001 方面更优。

B. 2 中成药治疗

推荐意见 1：3 项枳术宽中胶囊治疗功能性消化不良（n=411）的 RCT 结果显示[17-19]，枳术宽中胶囊与促胃动力药相比，临床总有效率更高 RR=1.26，95%CI[1.04，1.51]，P=0.02。

推荐意见 2：1 项气滞胃痛颗粒治疗功能性消化不良（n=165）的 RCT 结果显示[20]，气滞胃痛颗粒与安慰剂相比，临床总有效率更高 RR=3.65，95%CI[2.36，5.66]，P < 0.00001。

推荐意见 3：1 项荜铃胃痛颗粒治疗功能性消化不良（n=238）的 RCT 结果显示[21]，荜铃胃痛颗粒与安慰剂相比，临床总有效率更高 RR=3.02，95%CI[2.25，4.05]，P＜0.00001；在提高生活质量评分 MD $_{评分}$=16.21 分，95%CI[12.33，20.09]，P＜0.00001 方面更优。

推荐意见 4：10 项达立通颗粒治疗功能性消化不良（n=1817）的 RCT 结果显示[22-31]，达立通颗粒与促胃动力药相比，临床总有效率更高 RR=1.33，95%CI[1.05，1.22]，P=0.002。

推荐意见 5：1 项枳实黄酮苷治疗功能性消化不良（n=239）的 RCT 结果显示[32]，枳实黄酮苷与促胃动力药相比，治疗后症状（餐后饱胀感 、早饱感、上腹烧灼感及疼痛）消失率 RR=0.90，95%CI[0.63，1.28]*，P=0.54 相当，治疗 4 周后症状（餐后饱胀感 、早饱感、上腹烧灼感及疼痛）消失率 RR=4.96，95%CI[1.96，12.52]，P=0.0007 更优。

推荐意见 6：2 项参苓白术颗粒治疗功能性消化不良（n=125）的 RCT 结果显示[33,34]，参苓白术颗粒与促胃动力药相比，临床有效率更高 RR=1.38，95%CI[1.11，1.72]，P =0.004。

B. 3 体表医学疗法

B. 3. 1 针刺疗法

推荐意见 1：6 项针刺疗法治疗功能性消化不良（n=130）的 RCT 结果显示[35-40]，与假针刺相比，针刺可提升 FD 患者的有效率，OR=6.4，95%CI[2.83，14.51]，P < 0.00001（**Ⅲ级证据**）；3 项针刺疗法治疗功能性消化不良（n=188）的 RCT 结果显示[35,41,42]，与假针刺相比，针刺可改善 FD 患者的中医证候积分 MD $_{评分}$=3.2，95%CI [1.58，4.82]，P < 0.0001（**Ⅱ级证据**）。31 项针刺疗法治疗功能性消化不良（n=2301）的 RCT 结果显示[43-73]，与西药相比，针刺可提升 FD 患者的有效率，OR=3.96，95%CI[3.07，5.1]，P < 0.00001（**Ⅲ级证据**）；2 项针刺治疗功能性消化不良（n=133）的 RCT 结果显示[46,49]，与西药相比，针刺在提升尼平消化不良生活质量评分（NDLQI）MD $_{评分}$=3.43 分，95%CI[1.29，5.57]，P <=0.002 方面更优（**Ⅱ级证据**）；2 项针刺治疗功能性消化不良（n=120）的 RCT 结果显示[51,53]，与西药相比，针刺在提升功能性消化不良生存质量量表（FDDQL）MD $_{评分}$=5.45 分，95%CI[4.02，6.88]，P < 0.00001 方面更优（**Ⅱ级证据**）。

B. 3. 2 电针疗法

推荐意见 1：6 项电针治疗功能性消化不良（n=400）的 RCT 结果显示[74-79]，与西药相比，电针在提升有效率方面效果更佳 OR=4.98，95%CI[2.41，10.3]，P＜0.00001（**Ⅱ级证据**）；2 项电针治疗功能性消化不良（n=140）的 RCT 结果显示[77,79]，与西药相比，电针可显著改善患者的中医证候积分 $MD_{评分}$=2.88 分，95%CI[0.94，4.81]，P = 0.004（**Ⅲ级证据**）；3 项电针治疗功能性消化不良（208）的 RCT 结果显示[75,76,79]，与西药相比，电针可显著降低 FD 患者的单项症状量化分级表 MD 评分=1.63 分，95%CI[0.8，2.46]，P = 0.0001（**Ⅱ级证据**）；2 项电针治疗功能性消化不良（n=124）的 RCT 结果显示[74,79]，与西药相比，电针在提升 FD 患者 FDDQL 评分方面疗效更佳 MD 评分=7 分，95%CI[4.53，9.47]，P ＜ 0.00001（**Ⅱ级证据**）；3 项电针治疗功能性消化不良（n=230）的 RCT 结果显示[80-82]，与西药相比，电针可显著降低 FD 患者的尼平消化不良症状指数（NDSI）MD 评分=9.93 分，95%CI[5.92，13.94]，P ＜ 0.00001（**Ⅱ级证据**）；3 项电针治疗功能性消化不良（n=230）的 RCT 结果显示[80-82]，与西药相比，电针在改善 FD 患者 NDLQI 评分方面疗效更佳 MD 评分=8.36 分，95%CI[5.53，11.2]，P ＜ 0.00001（**Ⅱ级证据**）。

B. 3. 3 经皮耳迷走神经刺激

推荐意见 1：1 项经皮耳迷走神经刺激（双侧耳甲区）治疗功能性消化不良（n=36）的 RCT 结果显示[83]，经皮耳迷走神经刺激（双侧耳甲区）与假经皮耳迷走神经刺激相比，在恢复空腹正常胃慢波百分率 MD 百分率=15%，95%CI[0.13，0.17]，P＜0.00001 及餐后正常胃慢波百分率 MD 百分率=10%，95%CI[0.08，0.13]，P＜0.00001 方面更优。（**Ⅰ级证据**）1 项经皮耳迷走神经刺激（左耳耳甲腔）治疗功能性消化不良（n=90）的 RCT 结果显示[84]，经皮耳迷走神经刺激（左耳耳甲腔）与假经皮耳迷走神经刺激（左耳舟状窝）相比，在降低主要症状积分（上腹痛、上腹烧灼感、餐后饱胀不适、早饱、上腹部胀闷不适、呕吐、反酸和恶心）$MD_{积分}$=-5.02 分，95%CI[-6.34，-3.70]，P＜0.00001 方面更优，在提高生命质量指数（FDDQL）评分 $MD_{评分}$=2.56，95%CI[0.91，4.21]，P= 0.002 方面更优。（**Ⅰ级证据**）

B. 3. 4 温和灸

推荐意见 1：3 项使用温和灸治疗功能性消化不良（n=143）的 RCT 结果显示[93-95]，温和灸与促胃动力药相比，在提升有效率方面效果更佳 OR=8.22，95%CI[3.53，19.15]，P＜0.00001 方面更优。

B. 3. 5 耳穴疗法

推荐意见 1：1 项使用耳穴疗法治疗功能性消化不良（n=60）的 RCT 结果显示[85]，耳穴疗法与促胃动力药相比，在降低尼平症状指数（NDSI）评分 $MD_{评分}$=-4.94 分，95%CI[-9.32，-0.56]，P=0.03；提高生活质量指数（NDLQI）评分 $MD_{评分}$=5.37 分，95%CI[2.95，7.79]，P＜0.0001 方面更优。

附录 C
（资料性）
功能性消化不良临床表现及西医诊断

C.1 临床表现

主要症状包括上腹痛、上腹灼热感、餐后饱胀和早饱之一种或多种，可同时存在上腹胀、嗳气、食欲不振、恶心、呕吐等症状。常以某一个或某一组症状为主，在病程中症状也可发生变化。本病起病多缓慢，病程经年累月，呈持续性或反复发作。部分患者有饮食、精神等诱发因素。

根据临床特点，罗马Ⅳ标准将本病分为不同亚型：①餐后不适综合征（postprandial distress syndrome，PDS），特点是进餐诱发消化不良症状；②上腹痛综合征（epigastric pain syndrome，EPS），指上腹痛和（或）上腹部烧灼感，不仅特指发生在餐后，可能发生在空腹，甚至可能进餐后改善；③PDS 和 EPS 的重叠，特点是进餐诱发消化不良症状和上腹痛或烧灼感。

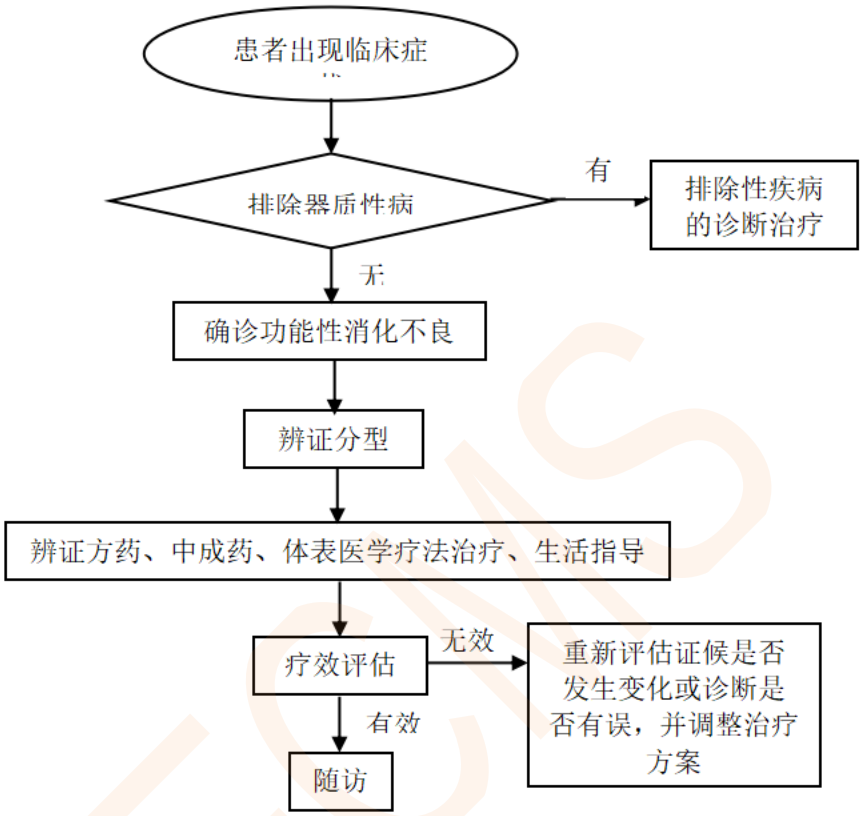
C.2 诊断标准

参照 2016 年罗马 IV 学术委员会制定的功能性消化不良诊断标准[2]：

包括餐后不适综合征（PDS）：餐后饱胀不适、早饱感；上腹痛综合征（EPS）：上腹疼痛、上腹烧灼感；2 个亚型可重叠出现。诊断前症状出现至少 6 个月，近 3 个月符合以上标准，且没有可解释上述症状的器质性疾病的证据。

注：器质性疾病具体可包括经胃镜检查发现的胃、十二指肠溃疡、糜烂、反流性食管炎等，经腹部 B 超检查发现的胆囊炎、胆囊结石等肝、胆、脾、胰问题。

附录 D
（规范性）
临床应用路径图



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Content

Foreword

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The drafting process adhered to the International Organization Standard Management Measures of the World Federation of Chinese Medicine Societies and SCM1.1-2021 *Standardization Guidelines Part 1: Standard Development, Revision, and Publication*.

Introduction

This document outlines the diagnosis, differential diagnosis, and traditional Chinese medicine (TCM) treatment of functional dyspepsia (FD). It applies to the diagnosis and management of FD in TCM hospitals, general hospitals, integrated Chinese–Western medicine hospitals, and primary healthcare institutions.

Several guidelines and expert consensuses on the TCM diagnosis and treatment of functional dyspepsia have been published, including the 2017 Expert Consensus on TCM Diagnosis and Treatment of Functional Dyspepsia, the 2017 Integrated Chinese–Western Medicine Consensus on FD, the 2021 Clinical Application Guidelines for Chinese Patent Medicines in FD, and the 2023 Expert Consensus on TCM Diagnosis and Treatment of Functional Dyspepsia. These documents have provided reference frameworks for clinical practice. However, previous guideline development relied largely on expert consensus, resulting in relatively limited international recognition. With the development of evidence-based research in the field of TCM, studies with higher levels of evidence have gradually emerged. Based on previous guidelines, this document rigorously evaluates TCM treatments for functional dyspepsia using high-quality clinical studies, providing evidence support for the clinical application of TCM in FD.

This document is a statement developed based on available research evidence and predefined methodologies. In clinical practice, clinicians may refer to this document and tailor management according to individual patient conditions.

The methodology for the development of this document is presented in Appendix A, and the evidence summaries are provided in Appendix B.

Summary of Recommendations

No.	Recommendation	Recommendation Grade
1	For patients with FD syndrome of mixed cold and heat, Banxia Xiexin Decoction is recommended.	Level III evidence, strong recommendation
2	For FD patients with spleen deficiency and qi stagnation syndrome, Xiangsha Liujunzi Decoction is recommended.	Level III evidence, strong recommendation
3	For patients with FD syndrome of spleen deficiency Qi stagnation syndrome accompanied by cold and heat, Zhishi Xiaopi Wan is recommended.	Level III evidence, strong recommendation
4	For patients with FD Syndrome of Spleen	Level II evidence, strong

	Deficiency and Qi Stagnation, Zhizhu Kuanzhong Capsule is recommended.	recommendation
5	For patients with FD syndrome of incoordination between liver and stomach, it is recommended to use Chaihu Shugan San.	Level III evidence, strong recommendation
6	For patients with FD syndrome of incoordination between liver and stomach, it is recommended to use Qizhi Weitong Keli /Pian.	Level I evidence, strong recommendation
7	For patients with FD syndrome of incoordination between liver and stomach accompanied by blood stasis, it is recommended to use Beiling weitong Keli.	Level I evidence, strong recommendation
8	For the patients with FD syndrome of incoordination between liver and stomach accompanied by stagnant heat, it is recommended to use Dalitong granules.	Level III Evidence, Weak Recommendation
9	For FD patients with Liver-Stomach Disharmony Syndrome, use the Aurantii Fructus Immaturus favonoid Tablets.	Level I evidence, strong recommendation
10	For patients with syndrome of dampness-heat of the spleen and stomach in FD, Lianpo Decoction is recommended.	Level III Evidence, Weak Recommendation
11	For patients with FD syndrome of dampness-heat of the spleen and stomach accompanied by syndrome of pathogen hidden in moyuan, syndrome of pathogen hidden in interpleuro-diaphramatic space, it is recommended to use the Chaihu Dayuan Decoction.	Level II Evidence, Weak Recommendation
12	For patients with FD syndrome of dampness-heat of the spleen and stomach, particularly with a predominance of dampness, Sanren Decoction is recommended	Level III Evidence, Weak Recommendation
13	For FD patients with syndrome of deficient cold of spleen and stomach, Fuzi Lizhong Decoction is recommended,	Level III evidence, strong recommendation
14	For FD patients with Syndrome of Spleen and Stomach Deficiency, Sijunzi Decoction is recommended.	Level III evidence, strong recommendation
15	For FD patients with Syndrome of Spleen and Stomach Deficiency Syndrome, it is recommended to use Shenling Baizhu Keli.	Level II Evidence, Weak Recommendation

16	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.	Acupuncture: Level III (for 4-week response rate and clinical response rate) / Level II (for NDSI and NDLQI), Strong Recommendation. Electroacupuncture: Level II evidence, Strong Recommendation.
17	Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) to Improve FD Symptoms and Quality of Life.	Level I Evidence, Weak Recommendation
18	Auricular Acupoint Therapy for Improving FD Symptoms and Quality of Life.	Level III Evidence, Weak Recommendation
19	Mild Moxibustion Therapy for Enhancing Clinical Efficacy in FD.	Level III Evidence, Weak Recommendation

International Clinical Practice Guideline of Chinese Medicine

Functional Dyspepsia

1 Scope

This document covers the terminology and definitions, etiology and pathogenesis, diagnosis, syndrome differentiation, traditional Chinese medicine–based interventions, other therapeutic approaches, and lifestyle guidance for the management of functional dyspepsia.

This guideline applies to healthcare professionals involved in the diagnosis and management of functional dyspepsia across different healthcare settings, including practitioners of traditional Chinese medicine and clinicians engaged in integrative medical practice. It is intended for use in specialist centers, general hospitals, and primary healthcare institutions, and may also serve as a reference for clinical practice in international settings where traditional Chinese medicine or integrative medicine is provided.

2 Normative References

This document does not have any normative documents

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1
Functional Dyspepsia
FD

One or more symptoms including postprandial fullness, early satiety, epigastric pain, or epigastric burning, which cannot be explained by structural, systemic, or metabolic diseases[1]。

Note 1: In 2016, the Rome Committee defined functional gastrointestinal disorders (FGIDs) as disorders of gut-brain interaction, also known as brain-gut axis dysfunction [1].The Rome IV criteria classify FD into two subtypes: postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS).

Note 2: Traditional Chinese medicine (TCM) classical texts describe functional dyspepsia using terms such as "痞满" (pǐ mǎn, epigastric fullness), "胃痞" (wèi pǐ, stomach fullness), "

嘈杂" (cáo zá, gastric discomfort), "胃脘痛" (wèi wǎn tòng, epigastric pain), and "胃痛" (wèi tòng, stomach pain). To align with modern diagnostic criteria and subtype classification for functional dyspepsia, epigastric pain syndrome corresponds to the TCM term stomach pain, while postprandial distress syndrome corresponds to stomach fullness.

Correspondence Table: FD Subtypes and Traditional Chinese Medicine Patterns

FD Subtype	Core Symptom Characteristics	TCM Disease Name	Core TCM Symptoms	Common TCM Patterns
Postprandial Distress Syndrome (PDS)	Postprandial fullness, Early satiety	stomach fullness	epigastric fullness/ stomach fullness/	Syndrome of Spleen Deficiency and Qi Stagnation
Epigastric Pain Syndrome (EPS)	Epigastric burning sensation, Pain	stomach pain	gastric discomfort/ epigastric pain	Syndrome of incoordination between liver and stomach
PDS-EPS Overlap	Simultaneous presence of PDS and EPS symptoms	stomach fullness -stomach pain	Stomach bloating and pain	Syndrome of mixed cold and heat/ Syndrome of Spleen Deficiency and Qi Stagnation/ Syndrome of incoordination between liver and stomach/ Syndrome of dampness-heat of spleen and stomach/ Syndrome of deficient cold (weakness) of spleen and stomach

4 Etiology and Pathogenesis

The disease is in the stomach and closely related to the liver and spleen. Common

etiologies include emotional disturbances, overwork, congenital insufficiency, dietary irregularities, or external pathogenic factors. Early stages involve cold coagulation, food retention, qi stagnation, or phlegm-dampness. Prolonged illness leads to deficiency or mixed deficiency-excess patterns. The core pathogenesis is spleen deficiency with qi stagnation and impaired stomach descent, characterized by a root deficiency (spleen deficiency) and branch excess (qi stagnation, food retention, phlegm-dampness, blood stasis).

5 Diagnosis

5.1 Diagnosis in Western Medicine

The clinical manifestations and diagnostic criteria for functional dyspepsia are detailed in Annex D.

5.2 TCM Syndrome Differentiation[3-5]

5.2.1 Syndrome of mixed cold and heat

Primary Symptoms: ① Epigastric fullness/pain worsened by cold; ② Dry mouth or bitter taste.
Secondary Symptoms: ① Anorexia; ② Gastric upset; ③ Nausea/vomiting; ④ Borborygmus; ⑤ Loose stools.
Tongue/Pulse: ① Pale tongue with a yellow coating; ② Wiry, thready, or slippery pulse.
Diagnosis: Diagnosis: Two primary symptoms + two secondary symptoms + tongue/pulse signs.
Treatment Principle: Disperse cold, clear heat, harmonize the stomach.

5.2.2 Syndrome of Spleen Deficiency and Qi Stagnation

Primary Symptoms: ① Epigastric distension/pain; ② Anorexia.
Secondary Symptoms: ① Belching; ② Fatigue; ③ Loose stools.
Tongue/Pulse: ① Pale tongue with a thin white coating; ② Thready, wiry pulse.
Diagnosis: Diagnosis: Two primary symptoms + two secondary symptoms + tongue/pulse signs.
Treatment Principle: Strengthen spleen, harmonize stomach, regulate qi.

5.2.3 Syndrome of incoordination between liver and stomach

Primary Symptoms: ① Epigastric distension/pain; ② Hypochondriac distension.
Secondary Symptoms: ① Worsened by emotional stress; ② Irritability; ③

Frequent belching; ④ Sighing.
Tongue/Pulse: ① Pale-red tongue with a thin white coating; ② Wiry pulse.
Diagnosis: Diagnosis: Two primary symptoms + two secondary symptoms + tongue/pulse signs.
Treatment Principle: Soothe liver, regulate qi, harmonize stomach.

5.2.4 Syndrome of dampness-heat of spleen and stomach

Primary Symptoms: ① Epigastric fullness/pain; ② Dry/bitter mouth.
Secondary Symptoms: ① Thirst without desire to drink; ② Anorexia; ③ Nausea/vomiting; ④ Dark urine.
Tongue/Pulse: ① Red tongue with a thick, yellow, or greasy coating; ② Slippery pulse.
Diagnosis: Diagnosis: Two primary symptoms + two secondary symptoms + tongue/pulse signs.
Treatment Principle: Clear heat, resolve dampness, regulate qi.

5.2.5 Syndrome of deficient cold (weakness) of spleen and stomach

Primary Symptoms: ① Dull epigastric pain/fullness; ② Relieved by warmth/pressure.
Secondary Symptoms: ① Watery regurgitation; ② Poor appetite; ③ Fatigue; ④ Cold limbs; ⑤ Loose stools.
Tongue/Pulse: ① Pale tongue a with white coating; ② Thready, weak pulse.
Diagnosis: Diagnosis: Two primary symptoms + two secondary symptoms + tongue/pulse signs.
Treatment Principle: Warm spleen, strengthen stomach, dispel cold.

6 TCM Treatment

6.1 Syndrome differentiation prescription treatment

6.1.1 Syndrome of mixed cold and heat

Recommendation 1: Banxia Xiexin Decoction. (Evidence Level: Grade Ⅲ, recommended intensity: strong recommendation)
Recommendation Details:
Composition of Banxia Xiexin Decoction: Pinellia Tuber (Rhizoma Pinelliae), Dried Ginger (Zingiberis Rhizoma), Scutellaria Root (Radix Scutellariae), Coptis Root (Rhizoma Coptidis), Codonopsis Root (Radix Codonopsis), Licorice Root (Radix et Rhizoma Glycyrrhizae), and Jujube Fruit (Fructus Jujubae).

Methods of addition or subtraction: For symptoms of belching, add Hematite (Lithargyri Rubra) and Inula Flower (Flos Inulae); for emotional depression, add Curcuma Zedoaria Rhizome (Rhizoma Curcumae Zedoariae) and Albizia Flower (Flos Albizziae); for constipation, add Rhubarb Root (Radix et Rhizoma Rhei), Aurantium Immature Fruit (Fructus Aurantii Immaturus), and Magnolia Bark (Cortex Magnoliae Officinalis); for abdominal pain, add White Peony Root (Radix Paeoniae Lactiflorae) and Corydalis Rhizome (Rhizoma Corydalis).

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

6.1.2 Syndrome of Spleen Deficiency and Qi Stagnation

Recommendation 1: Xiangsha Liujunzi Decoction. (Evidence Level: Grade Ⅲ, recommended intensity: strong recommendation)

Recommendation Details:

Composition of Xiangsha Liujunzi Decoction: Codonopsis Root (Radix Codonopsis), Atractylodes Macrocephala Rhizome (Rhizoma Atractylodis Macrocephalae), Poria (Poria), Licorice Root (Radix et Rhizoma Glycyrrhizae), Dried Tangerine Peel (Pericarpium Citri Reticulatae), Pinellia Tuber (Rhizoma Pinelliae), Amomum Fruit (Fructus Amomi), and Costus Root (Radix Aucklandiae).

Methods of addition or subtraction: For patients with distending pain in the chest and hypochondria, add Costus Root (Radix Aucklandiae), Curcuma Zedoaria Rhizome (Rhizoma Curcumae Zedoariae), and Toona Fruit (Fructus Toonae); for those with acid regurgitation, add Cuttlebone (Os Sepiae) and Zhejiang Fritillary Bulb (Bulbus Fritillariae Thunbergii); for those with loose stools, add Stir-fried Job's Tears (Semen Coicis) and Stir-fried Hyacinth Bean (Semen Dolichoris).

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: One study reported adverse reactions during the study, with no adverse events.

Recommendation 2: Zhishi Xiaopi Wan. (Evidence Level: Grade Ⅲ, recommended intensity: strong recommendation)

Recommendation Details:

Composition of Zhishi Xiaopi Wan: Coptis Root (Rhizoma Coptidis), Dried Ginger (Zingiberis Rhizoma), Honey-fried Licorice Root (Radix et Rhizoma Glycyrrhizae Preparata), Magnolia Bark (Cortex Magnoliae Officinalis), Atractylodes Macrocephala Rhizome (Rhizoma Atractylodis Macrocephalae), Poria (Poria), Pinellia Tuber (Rhizoma Pinelliae), Barley Malt (Fructus Hordei Germinatus), Codonopsis Root (Radix Codonopsis), Aurantium Immature Fruit (Fructus Aurantii Immaturus).

Methods of addition or subtraction: For nausea and vomiting, add Dried Tangerine Peel (Pericarpium Citri Reticulatae) and Bamboo Shavings (Caulis Bambusae in Taeniam); for acid reflux, add Cuttlebone (Os Sepiae) and Calcined Oyster Shell (Concha Ostreae Praeparata); for abdominal pain and bloating, add Costus Root (Radix Aucklandiae) and Corydalis Rhizome (Rhizoma Corydalis), among others.

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

6.1.3 Sndrome of incoordination between liver and stomach

Recommendation 1: Chaihu Shugan San. (Evidence Level: Grade Ⅲ, recommended intensity: strong recommendation)

Recommendation Details:

Composition of Chaihu Shugan San: Dried Tangerine Peel (Pericarpium Citri Reticulatae), Bupleurum Root (Radix Bupleuri), Sichuan Lovage Rhizome (Rhizoma Chuanxiong), Cyperi Rhizome (Rhizoma Cyperi), Aurantium Immature Fruit (Fructus Aurantii Immaturus), Peony Root (Radix Paeoniae Lactiflorae), and Licorice Root (Radix et Rhizoma Glycyrrhizae).

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently

limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

6.1.4 Spleen-Stomach Damp-Heat Syndrome

Recommendation 1: Lianpo Decoction. (Evidence Level: Grade III, recommended intensity: weak recommendation)

Recommendation Details:

Composition of Lianpo Decoction: Processed Magnolia Bark (Cortex Magnoliae Officinalis), Coptis Rhizome (stir-fried with ginger juice) (Rhizoma Coptidis), Acorus Tatarinowii Rhizome (Rhizoma Acori Tatarinowii), Processed Pinellia Rhizome (Rhizoma Pinelliae Preparata), Fragrant Soybean (Semen Sojae Praeparatum), Charred Gardenia Fruit (Fructus Gardeniae Carbonisatus), Reed Rhizome (Rhizoma Phragmitis).

Methods of addition or subtraction: For those with abdominal pain, add Corydalis (Yanhusuo).For those with distension and fullness in the hypochondriac regions, add Aurantium (Zhike) and Bupleurum (Chaihu).For those with reduced appetite, add Gallus (Jineijin) and sprouted grains of Coix (Guya) and Triticum (Maiya).For those with food stagnation, add roasted sprouted grains of Triticum (Jiaomaiya), roasted Hawthorn (Jiaoshanzha), and roasted Aspergillus (Jiaoshenqu).

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

Recommendation 2: Chaihu Dayuan Decoction. (Dampness is heavier than heat in the Spleen-Stomach Dampness-Heat Syndrome, Evidence Level: Grade II, recommended intensity: weak recommendation)

Recommendation Details:

Composition of Chaihu Dayuan Decoction： Bupleurum Root (Radix Bupleuri), Scutellaria Root (Radix Scutellariae), Pinellia Rhizome (Rhizoma Pinelliae), Aurantium Immature Fruit (Fructus Aurantii Immaturus), Magnolia Bark (Cortex Magnoliae Officinalis), Areca Seed (Semen Arecae), Amomum Fruit (Fructus Amomi), Green Tangerine Peel (Pericarpium Citri Reticulatae Viride), Red Peony

Root (Radix Paeoniae Rubra), Licorice Root (Radix Glycyrrhizae).
Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.
Safety: In the included studies, no adverse reactions were reported in the experimental group treated with Chaihu Dachuan Decoction. In the control group treated with Mosapride, one case of mild diarrhea was reported. There was no statistically significant difference in the incidence of adverse reactions between the two groups.

Recommendation 3: Sanren Decoction. (Equal Predominance of Dampness and Heat in the Spleen-Stomach Dampness-Heat Syndrome, Evidence Level: Grade III, recommended intensity: weak recommendation)
Recommendation Details:
Drug composition of Sanren Decoction: Coix Seed (Semen Coicis), Bitter Almond (Semen Armeniacae Amarum), White Cardamom (Fructus Amomi Kravanh), Magnolia Bark (Cortex Magnoliae Officinalis), Talc (Talcum), Stemona Root (Herba Stemoneae), Light Bamboo Leaf (Folium Bambusae in Taeniam), Pinellia Rhizome (Rhizoma Pinelliae)Medication suggestion: twice a day, 1 dose each time, decocted with water (once in the morning and once in the evening).
Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.
Safety: In the two included studies, no serious adverse reactions were reported during the treatment process.

6.1.5 Spleen-Stomach Deficiency-Cold (Deficiency) Syndrome

Recommendation 1: Fuzi Lizhong Decoction. (Spleen-Stomach Deficiency-Cold Syndrome, Evidence Level: Grade III, recommended intensity: strong recommendation）
Recommendation Details:
Composition of Fuzi Lizhong Decoction: Aconite Root (Radix Aconiti) (decocted first), Ginseng (Radix Ginseng), Dried Ginger (Rhizoma Zingiberis), Atractylodes Macrocephala (Rhizoma Atractylodis Macrocephalae), Licorice (Radix Glycyrrhizae Preparata).
Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken

before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently limited. However, following expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use, particularly for potential toxicity due to Fuzi.

Recommendation 2: Sijunzi Decoction. (Spleen-Stomach deficiency syndrome, Evidence Level: Grade III, recommended intensity: strong recommendation）

Recommendation Details:

Composition of Sijunzi decoction: Ginseng (Radix Ginseng), Atractylodes Macrocephala (Rhizoma Atractylodis Macrocephalae), Poria (Sclerotium Poriae), Licorice (Radix Glycyrrhizae Preparata).

Medication suggestion: Take 1 dose daily. Decoct the herbs twice in water to obtain 300-400 ml of liquid. Divide this into two equal portions to be taken before breakfast and before dinner. Each portion should be 150-200 ml. Use as directed by a physician.

Safety: In one RCT (n=90), 8 mild adverse events (abdominal discomfort, excessive flatulence, or diarrhea) occurred in the control group (n=45), with an incidence rate of 17.78%. No serious adverse events were reported. There was no significant difference in the incidence of adverse events between the two groups, RR = 0.6, 95% CI [0.00, 0.09], P = 0.05.

6.2 Proprietary Chinese medicine treatment

Recommendation 1: TCM patent medicine medicine Xiangsha Liujun Pills. (Expert consensus, recommended intensity: strong recommendation)

Recommendation Details:

Ingredients: Codonopsis Root, Atractylodes Macrocephala Rhizome (stir-fried), Poria, Pinellia Tuber (processed), Dried Tangerine Peel, Costus Root, Amomum Fruit, Licorice Root (honey-fried).

Medication suggestion: This medicine tonifies the spleen, boosts Qi, harmonizes the stomach, and transforms dampness. It is used for symptoms of indigestion, poor appetite, sallow complexion, belching, and loose stools due to spleen deficiency and dampness with Qi stagnation. Use as directed by a physician.

Dosage and Administration: Take 6-9 grams of water pills orally, 2-3 times per day. The treatment duration is 2 weeks. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently

limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

Recommendation 2: TCM patent medicine Zhizhu Kuanzhong Capsule. (Evidence Level: Grade Ⅱ, recommended intensity: strong recommendation)

Recommendation Details:

Ingredients: Atractylodes Rhizome (Rhizoma Atractylodis Macrocephalae Stir-Fried) , Immature Orange Fruit (Fructus Aurantii Immaturus) , Chinese Thorowax Root (Radix Bupleuri) , Hawthorn Fruit (Fructus Crataegi).

Medication suggestion: For functional dyspepsia with symptoms such as vomiting, nausea, anorexia, acid regurgitation, and fatigue and weakness.

Dosage and Administration: Take 3 capsules orally, 3 times a day. The treatment duration is 2 weeks. Use as directed by a physician.

Safety: One RCT (n=403) reported adverse events during the study. In the experimental group (n=298), 2 cases were reported, while in the control group (n=105), 3 cases were reported, with adverse event incidence rates of 0.67% and 2.86%, respectively. All were mild adverse events, and no serious adverse events occurred. There was no significant difference in the incidence of adverse events between the two groups, RR = 0.1, 95% CI [0.02, 0.59], P = 0.01. The product label reports that common adverse reactions include occasional stomach pain or increased frequency of bowel movements.

Recommendation 3: TCM patent medicine Qizhi Weitong Keli /Pian. (Evidence Level: Grade Ⅰ, recommended intensity: strong recommendation）

Recommendation Details:

Ingredients: Bupleurum Root (Radix Bupleuri), Rhizoma Corydalis (vinegar-prepared), Immature Bitter Orange (Fructus Aurantii Immaturus), Cyperi Rhizome (vinegar-prepared), White Peony Root (Radix Paeoniae Alba), and Licorice Root (Radix Glycyrrhizae Preparata).

Medication suggestion: To soothe the liver, regulate Qi, and relieve pain by harmonizing the stomach. Indicated for symptoms of chest fullness, epigastric pain due to liver qi stagnation.

Dosage and Administration: For Qizhi Weitong Keli, dissolve 2.5 grams in boiling water and take orally three times daily. For Qizhi Weitong Pian: take orally, three tablets at a time, three times daily. The treatment course is 4 weeks. Use as directed by a physician.

Safety: One included RCT (n=197) reported adverse events during treatment. The incidence rates of adverse events in the experimental group (n=99) and the control group (n=98) were 3.03% and 3.06%, respectively. All were mild

adverse events, and no serious adverse events occurred. There was no significant difference in the incidence of adverse events between the two groups, RR = 0.99, 95% CI [0.20, 4.79], P = 0.99.

Recommendation 4: TCM patent medicine Beiling weitong Keli. (Evidence Level: Grade I , recommended intensity: strong recommendation)

Recommendation Details:

Ingredients: Bupleurum Root (Radix Bupleuri), Aurantium Fruit (Fructus Aurantii), Aucklandia Root (Radix Aucklandiae), Tangerine Peel (Pericarpium Citri Reticulatae), Pinellia Rhizome (Rhizoma Pinelliae), Dandelion Herb (Herba Taraxaci Mongolici), Hawthorn Fruit (Fructus Crataegi) Charred, Areca Seed (Semen Arecae) Charred, Paederia Vine (Caulis Paederiae), Codonopsis Root (Radix Codonopsis), Corydalis Rhizome (Rhizoma Corydalis), Fermented Medicinal Mass (Massa Medica Fermentata).

Medication suggestion:Indicated for epigastric fullness, discomfort, belching, anorexia, gastric burning, acid reflux, and epigastric pain.

Dosage and Administration: Dissolve in warm boiled water. Take one bag three times daily before meals. The recommended treatment duration is 2 to 4 weeks. Use as directed by a physician.

Safety: In one included RCT (n=238), 41 adverse events occurred in 28 patients. In the experimental group (n=120), 15 patients (12.5%) experienced 23 adverse events, one of which (0.83%) was an adverse reaction (diarrhea). No serious adverse events were observed. In the placebo group (n=118), 13 patients (10.93%) experienced 18 adverse events. All were mild adverse events. There was no significant difference in the incidence of adverse events between the two groups, RR = 0.94, 95% CI [0.47, 1.88], P = 0.87.

Recommendation 5: TCM patent medicine Dalitong granules. (Evidence Level: Grade III, recommended intensity: weak recommendation)

Recommendation Details:

Ingredients: Bupleurum chinense DC. (Radix Bupleuri) , Citrus aurantium L. (Fructus Aurantii Immaturus) , Aucklandia lappa Decne. (Aucklandiae Radix) , Citrus reticulata Blanco (Pericarpium Citri Reticulatae) , Pinellia ternata (Thunb.) Breit. (Rhizoma Pinelliae Preparata) , Taraxacum mongolicum Hand.-Mazz. (Herba Taraxaci) , Crataegus pinnatifida Bunge (Fructus Crataegi) , Areca catechu L. (Semen Arecae Preparata) , Paederia foetida L. (Paederiae Foetidae Caulis) , Codonopsis pilosula (Franch.) Nannf. (Radix Codonopsis) , Corydalis yanhusuo W. T. Wang (Rhizoma Corydalis) , Aspergillus oryzae (koji) (Medicinal Fermented Soybean).

Medication suggestions: for abdominal distension, belching, poor appetite,

burning in the stomach, noisy pantothenic acid, abdominal pain, dry mouth bitter mouth.

Dosage and Administration: Take with warm water, 1 bag at a time, 3 times a day. Take it before meals. The treatment duration is 2-4 weeks. Use as directed by a physician.

Safety: Eight studies reported adverse events during the study, among which three reported no adverse events. The remaining five studies (n=965) reported no serious adverse events. There was no significant difference in the incidence of adverse events between the experimental and control groups, RR = 0.95, 95% CI [0.40, 2.27], P = 0.91. The product label reports that individual patients may experience abdominal pain after taking the medication.

Recommendation 6: TCM patent medicine Aurantii Fructus Immaturus favonoid Tablets (Evidence Level: Grade I , recommended intensity: strong recommendation).

Recommendation Details:

Ingredients: Aurantium Total Flavonoids (Flavonoida Aurantii).

Medication suggestions: To promote Qi and eliminate accumulation, disperse swelling and relieve pain. Indicated for functional dyspepsia presenting with postprandial fullness, early satiety, epigastric burning, and pain.

Dosage and Administration: Take orally, three tablets at a time, three times daily, 30 minutes before meals with warm water. Treatment duration is 4 weeks. Use as directed by a physician.

Safety: In one included RCT (n=239), 95 adverse events occurred in 66 patients. In the experimental group (n=120), 23 cases (19.17%) were reported, while in the control group (n=119), 43 cases (36.13%) were reported. Except for 4 cases of moderate adverse events, all others were mild adverse events. No serious adverse events were reported. A difference in the incidence of adverse reactions was observed between the experimental group and the control group, RR = 0.51, 95% CI [0.32, 0.79], P = 0.003.

Recommendation 7: TCM patent medicine Fuzi Lizhong Wan (Concentrated Pills). (Spleen-Stomach Deficiency-Cold Syndrome, Expert consensus, recommended intensity: weak recommendation)

Recommendation Details:

Ingredients: Processed Aconite Root (Radix Aconiti Praeparata), Codonopsis Root (Radix Codonopsis), Fried Atractylodes Macrocephala Rhizome (Rhizoma Atractylodis Macrocephalae, fried), Dried Ginger (Rhizoma Zingiberis), and Licorice Root (Radix et Rhizoma Glycyrrhizae).

Medication Suggestion: Indicated for symptoms of spleen and stomach

cold-deficiency, epigastric and abdominal cold pain, vomiting and diarrhea, and cold extremities.

Dosage and Administration: Take orally. 8-12 pills at a time, three times daily. The treatment duration is 2 weeks. Use as directed by a physician.

Safety: The safety evidence for the recommended interventions is currently limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

Recommendation 8: TCM patent medicine Shenling Baizhu Keli. (Spleen-Stomach deficiency syndrome, Evidence Level: Grade Ⅱ, recommended intensity: weak recommendation)

Recommendation Details:

Ingredients: Ingredients: Ginseng Root (Radix Ginseng), Poria (Poria), Atractylodes Macrocephala Rhizome (wheat-fried), Chinese Yam (Rhizoma Dioscoreae), Lablab (Semen Lablab, fried), Lotus Seed (Semen Nelumbinis), Coix Seed (Semen Coicis, fried), Amomum Fruit (Fructus Amomi), Platycodon Root (Radix Platycodi), and Licorice Root (Radix et Rhizoma Glycyrrhizae). Excipients: sucrose and dextrin.

Medication suggestion: To tonify the spleen and stomach, and to benefit lung qi. Indicated for symptoms of spleen and stomach deficiency, poor appetite, loose stools, shortness of breath, cough, and fatigue.

Dosage and Administration: Dissolve in boiling water. Take 3 grams, three times daily

Safety: The safety evidence for the recommended interventions is currently limited. However, after expert discussion within the working group, it has been concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

6.3 Surface medical therapies

Recommendation 1: Acupuncture therapy may improve the clinical response rate (Evidence Level: Grade Ⅲ), reduce TCM symptom scores (Evidence Level: Grade Ⅱ), and enhance patients' quality of life (Evidence Level: Grade Ⅱ). (Recommended intensity: strong recommendation)

Recommendation Details:

Primary Acupoints: Zhongwan (CV 12), Qihai(CV 6), Tianshu (ST 25), Neiguan (PC 6), Zusanli (ST 36), Shangjuxu (ST 37), Gongsun(SP 4), Danzhong(RN 17), Baihui (GV 20).

For syndrome differentiation, the following acupoints are added: for Syndrome of mixed cold and heat, add Sanyinjiao (SP 6), Yinlingquan (SP 9), Quchi (LI 11); for Syndrome of Spleen Deficiency and Qi Stagnation, add Taichong (LR 3), Qimen (LR 14); for Liver-Stomach Disharmony Syndrome, add Taichong (LR 3); for Damp-Heat in the Spleen and Stomach Syndrome, add Yinlingquan (SP 9), Neiting (ST 44); for Spleen and Stomach Deficiency-Cold Syndrome, add Pishu (BL 20), Weishu (BL 21).

Methods: Adopt a suitable position, with patient comfort and ease of operation as the main focus. After standard disinfection, insert appropriately sized filiform needles to optimal depths at selected acupoints, then perform rotating, lifting and thrusting manipulations to elicit deqi (characterized by soreness, numbness, distension or heaviness). Apply reducing methods for excess patterns and reinforcing methods for deficiency patterns. Needles are retained for 30 minutes per session, with manipulation repeated twice during retention.

Treatment Course: Three times per week for a total of 4 weeks.

Note: Acupuncture is contraindicated in patients with coagulation disorders or abnormal skin conditions.

Recommendation 2: Electroacupuncture therapy may improve the clinical response rate (Evidence Level: Grade Ⅱ), reduce TCM symptom scores (Evidence Level: Grade Ⅲ), lower patient-reported scores on the Nepean Dyspepsia Index (Evidence Level: Grade Ⅱ) and the FD-Symptom Scale (Evidence Level: Grade Ⅱ), and enhance patients' quality of life (Evidence Level: Grade Ⅱ). (Recommended intensity: strong recommendation)

Recommendation Details:

Primary Acupoints: Same as acupuncture therapy.

For syndrome differentiation, the following acupoints are added: Same as acupuncture therapy.

Methods: Same as acupuncture therapy. Electroacupuncture (EA) parameters: Alternative waves with two different frequencies, 2/100Hz, 2mA-10mA. Retain needles for 30 minutes per session.

Treatment Course: Three times per week for a total of 4 weeks.

Note: Acupuncture is contraindicated in patients with coagulation disorders or abnormal skin conditions. Contraindicated in patients with cardiac pacemakers or other severe organic heart diseases.

Recommendation 3: Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) to Improve FD Symptoms (Evidence Level: Grade Ⅰ) and Quality of

Life (Evidence Level: Grade Ⅰ). (Recommended intensity: weak recommendation)

Recommendation Details:

Stimulation Points: Bilateral concha areas of the auricle, where the vagus nerve is densely distributed.

Method: One electrode is clipped to one ear, and the other electrode to the opposite ear (SNM-FDC01).

Stimulation Parameters: the stimulation parameters are set as follows: on-time of 2 seconds, off-time of 3 seconds, pulse width of 0.5 ms, pulse frequency of 25 Hz, and pulse amplitude ranging from 0.5 mA to 1.5 mA based on patient tolerance.

Treatment duration: 30 minutes after breakfast and dinner, lasting for two weeks.

Recommendation 4: Mild moxibustion may improve clinical efficacy. (Evidence Level: Grade Ⅲ, recommended intensity: weak recommendation)

Recommendation Details:

Primary Acupoints: Zhongwan (CV12), Zusanli (ST36)

Method: Position the patient in supine posture. Ignite the moxa stick and hold it near the designated acupoints until the patient experiences a sensation of warmth without burning.

Treatment duration: Treatment course: 30 minutes per session, once daily. Four weeks constitute one treatment course.

Recommendation 5: Auricular Acupoint Therapy for Improving FD Symptoms and Quality of Life (Evidence Level: Grade Ⅲ, recommended intensity: weak recommendation)

Recommendation Details:

Primary Acupoints: Liver, Spleen, Stomach, Kidney, Duodenum.

Adjunctive Acupoints: Endocrine, Sympathetic, Shenmen, Subcortex.

Method: Vaccaria seeds are applied to the selected auricular acupoints. One ear is treated at a time, with alternating use of the contralateral ear. Seeds are applied three times per week, with a minimum interval of 1 day between applications. Patients are instructed to manually stimulate each acupoint 3–5 times daily for 1–2 minutes per session to enhance therapeutic effects.

Treatment Duration: 4 weeks.

Auricular acupuncture therapy can be used as an adjunct to standard or Western medical treatments.

7 Lifestyle Guidance

7.1 Regular Lifestyle and Moderate Exercise (Expert consensus, recommended intensity: strong recommendation)

Maintain a regular schedule and ensure adequate sleep. Adjust clothing promptly according to weather changes, paying attention to keeping the abdomen warm. Engage in regular, tolerable exercise such as Taiji, walking, or jogging. Avoid exercising immediately after meals to prevent adding burden to the gastrointestinal tract.

7.2 Develop Healthy Eating Habits (Expert consensus, recommended intensity: strong recommendation)

Eat meals at fixed times daily with appropriate portions; chew thoroughly; avoid overeating or eating too quickly. Opt for a light, easily digestible, and low-fat diet. Avoid consuming cold foods, spicy and irritating foods, raw foods, and gas-producing foods.

7.3 Maintain Mental Health (Expert consensus, recommended intensity: strong recommendation)

Maintain an optimistic, cheerful, and relaxed mood. Doctors should understand the patient's psychological state, establish a good doctor-patient trust relationship, and provide timely reassurance, education, guidance, and communication. Patients should communicate more with others and learn self-regulation. Consult a psychologist and seek professional treatment if necessary. Psychotherapy can serve as a remedial treatment for patients with severe symptoms of functional dyspepsia who do not respond to drug therapy.

Annex A
(Normative)
Development Methods

A.1 Evidence Evaluation and Grading[86]

Table A.1 Grading Standards for Clinical Research Evidence in Chinese Medicine

Evidence Level	Efficacy	Safety
Level I	Randomized controlled trials (RCTs) and their systematic reviews, N-of-1 trial systematic reviews	RCTs and their systematic reviews, cohort studies and their systematic reviews
Level II	Non-randomized controlled clinical trials, cohort studies, N-of-1 trials	Post-marketing pharmacoepidemiological studies, phase V clinical trials, active monitoring (e.g., registry studies, database research)
Level III	Case-control studies, prospective case series	Case-control studies
Level IV	Standardized expert consensus[1], retrospective case series, historical control studies	Case series/case reports
Level V	Non-standardized expert consensus[2], case reports, experience summaries	Preclinical safety evaluations, including assessments of teratogenicity, carcinogenicity, median lethal dose (LD50), sensitization, and toxicity

Note 1: Standardized expert consensus refers to documents formulated based on formal consensus methods (e.g., Delphi method, nominal group technique, consensus conferences, or modified Delphi methods), which serve as a basis for clinical decision-making.

Note 2: Non-standardized expert consensus refers to early-stage expert opinions summarized using informal methods such as group discussions or meetings.

Table 2: Quality Evaluation Criteria for Systematic Reviews

Item	Evaluation Criteria Score
1	Clearly defined clinical question, structured correctly according to the PICO principle(2 points)

2	Appropriate inclusion criteria(1 point)
3	Reproducibility in study selection and data extraction(1 point)
4	Comprehensive search with a clearly defined search strategy(1 point)
5	Description of characteristics of included studies(1 point)
6	Evaluation and reporting of methodological quality of included studies(1 point)
7	Correct methods for data synthesis(2 points)
8	No conflicts of interest(1 point)

Note: Downgrading Criteria:

Total score 9-10: No downgrade

Total score 3-8: Downgrade by one level

Total score 0-2: Downgrade by two levels

Table A.3 Methodological Quality Assessment Criteria for RCTs

Item	Evaluation Criteria	Score
1	Generation of Random Sequence	Computer-generated random numbers or similar methods (2 points) Randomization method not described (0 points) Use of alternate allocation methods such as odd-even numbers (0 points)
2	Allocation Concealment	Allocation controlled by a central pharmacy, sequentially numbered containers, on-site computer control, sealed opaque envelopes, or other methods preventing clinicians and participants from predicting allocation (1 point) Method of allocation concealment not described (0 points) Use of alternate allocation, case numbers, days of the week, open random number tables, sequentially coded envelopes, or other methods that do not prevent predictability (0 points) Not used (0 points)

3	Blinding	Use of identical placebo tablets or similar methods, with explicit descriptions ensuring blinding integrity(2 points) No blinding, but outcome measurement is unlikely to be biased (2 points) Blinding mentioned but method not described (1 point) No double-blinding or inappropriate blinding (e.g., comparison between tablets and injections)(0 points)
4	Incomplete Outcome Reporting	No loss to follow-up (1 point) Some loss to follow-up, but the number is small relative to total sample size, reasons unrelated to treatment, and no impact on results (1 point) Loss to follow-up not reported, or loss may introduce bias in results (0 points)
5	Selective Outcome Reporting	Study protocol available, with no changes to pre-specified outcome measures (1 point) Protocol unavailable, but important and commonly accepted disease outcomes reported (1 point) Protocol unavailable, and important disease outcomes not reported (0 points) Outcomes reported in the results section differ from those in the methodology section (0 points)
6	Sample Size	Sample size estimation formula provided, with correct calculation ensuring sufficient statistical power

		(1 point) Sample size calculation not mentioned (0 points)

Note: Downgrading Criteria:

Total score 7-8: No downgrade

Total score 5-6: Downgrade by one level

Total score 0-4: Downgrade by two levels

A.2 Recommendation Principles [87]

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."

Annex B
(Informative)
Evidence Explanation

B.1 Syndrome differentiation prescription treatment

B.1.1 Syndrome of mixed cold and heat

Recommendation 1: Results of a RCT study of Banxia Xiexin Decoction (with modifications) for treating functional dyspepsia with syndrome of mixed cold and heat (n=60) showed that the clinical efficacy rate of Banxia Xiexin Decoction (with modifications) was higher than that of gastric prokinetics, RR=2.00, 95%CI[1.69, 2.31], P < 0.00001.[6].

B.1.2 Syndrome of Spleen Deficiency and Qi Stagnation

Recommendation 1: Results of Two RCTs[7,8] (n=208) with Xiangsha Liujunzi Decoction (with modifications) for the treatment of functional dyspepsia with spleen deficiency qi retarding syndromeshowed that the clinical efficacy rate of Xiangsha Liujunzi Decoction (with modifications) was higher than that of the combination of gastric prokinetic and acid suppressive Medications, RR=1.30, 95%CI[1.12, 1.51],P=0.0007.

Recommendation 2: Results of 1 RCT[9] (n=80) with Zhi Shi Xiao Pi Wan (with modifications) for the treatment of functional dyspepsia with spleen deficiency and qi stagnation syndrome showed that compared with prokinetics, Zhi Shi Xiao Pi Wan (with modifications) had a higher clinical total effective rate, RR=1.33, 95% CI [1.11, 1.59], P=0.002; it was also superior in reducing the main symptom scores (abdominal bloating, belching, poor appetite, nausea), with a mean difference (MD) of 4.08 points, 95% CI [3.73, 4.43], P<0.00001.

B.1.3 Syndrome of incoordination between liver and stomach

Recommendation 1: The results of a RCT[10] (n=56) with Modified Chaihu Shugan San for the treatment of functional dyspepsia with the syndrome of incoordination between liver and stomach showed that Modified Chaihu Shugan San resulted in a higher clinical efficacy rate compared with gastric prokinetics RR=1.67, 95% CI [1.15, 2.41], p=0.007.

B.1.4 Spleen-Stomach Damp-Heat Syndrome

Recommendation 1: Results of 1 RCT[11] (n=60) with Lianpu Decoction (with modifications) for the treatment of functional dyspepsia with damp-heat of the spleen and stomach syndrome showed that compared with prokinetics, Lianpu

Decoction (with modifications) had a higher clinical total effective rate, RR=1.33, 95% CI [1.04, 1.72], P=0.03.

Recommendation 2: Results of 1 RCT[12] (n=72) with Chaihu Dayuan Decoction (with modifications) for the treatment of functional dyspepsia with damp-heat of the spleen and stomach syndrome showed that compared with prokinetics, Chaihu Dayuan Decoction (with modifications) had a higher clinical total effective rate, RR=2.38, 95% CI [1.71, 3.32], P<0.00001; it was also superior in reducing the symptom scores, with mean differences (MD) of -0.80 points for heaviness of the body (95% CI [-1.2, -0.4], P<0.0001), -0.83 points for bitter taste and sticky mouth (95% CI [-1.22, -0.44], P<0.0001), and -0.93 points for short and yellow urine (95% CI [-1.39, -0.47], P<0.0001).

Recommendation 3: Results of 2 RCTs[13,14] (n=194) with Sanren Tang (with modifications) for the treatment of functional dyspepsia with damp-heat of the spleen and stomach syndrome showed that compared with prokinetics, Sanren Tang (with modifications) had a higher clinical efficacy rate, RR=1.13, 95% CI [1.01, 1.27], P=0.03.

B.1.5 Spleen-Stomach Deficiency-Cold (Deficiency) Syndrome

Recommendation 1: Results of 1 RCT[15] (n=92) with Fuzi Lizhong Decoction for the treatment of functional dyspepsia with syndrome of deficient cold of spleen and stomach showed that the clinical total effective rate of Fuzi Lizhong Decoction was higher than that of acid inhibitors, RR=1.22, 95% CI [1.05, 1.41], P=0.01; it was also superior in reducing symptom scores, with mean differences (MD) of -0.36 points for abdominal pain (95% CI [-0.44, -2.08], P<0.00001), -0.51 points for epigastric burning (95% CI [-0.59, -0.43], P<0.00001), -0.58 points for bloating (95% CI [-0.68, -0.48], P<0.00001), and -0.41 points for belching (95% CI [-0.56, -0.37], P<0.00001).

Recommendation 2: Results of 1 RCT[16] (n=90) with Sijunzi Decoction for the treatment of functional dyspepsia with Syndrome of Spleen and Stomach Deficiency showed that the clinical efficacy of Sijunzi Decoction was superior to that of prokinetics in reducing the main symptom scores (abdominal bloating, poor appetite or early satiety, and fatigue), with a mean difference (MD) of 6.50 points, 95% CI [6.32, 6.68], P<0.00001.

B.2 Proprietary Chinese medicine treatment

Recommendation 1: Results of 3 RCTs[17-19] (n=411) with Zhizhukuanzhong capsules for the treatment of functional dyspepsia showed that the clinical efficacy rate of Zhizhukuanzhong capsules was higher than that of prokinetics , RR=1.26, 95%CI[1.04, 1.51], P=0.02.

Recommendation 2: Results of a 1 RCT [20] (n=165) with Qi-Zhi Wei-Tong Keli for the treatment of functional dyspepsia demonstrated that the clinical total effective rate of Qi-Zhi Wei-Tong Keli was significantly higher than that of placebo, with a relative risk (RR) of 3.65 (95% CI [2.36, 5.66], P < 0.00001).

Recommendation 3: Results of a 1 RCT [21] (n=238) with Biling Weitong Granules for the treatment of functional dyspepsia demonstrated that Biling Weitong Granules were significantly more effective than placebo in improving clinical efficacy (RR = 3.02, 95% CI [2.25, 4.05], P < 0.00001) and in enhancing quality of life scores (MD = 16.21, 95% CI [12.33, 20.09], P < 0.00001).

Recommendation 4: Results of 10 RCTs [22-31] (n=1817) with Dalitong Granules for the treatment of functional dyspepsia demonstrated that Dalitong Granules were significantly more effective than prokinetics in improving clinical efficacy (RR = 1.35, 95% CI [1.18, 1.54], P < 0.001).

Recommendation 5: Results of a 1 RCT [32] (n=239) with Aurantii Fructus Immaturus Flavonoid Tablets for the treatment of functional dyspepsia demonstrated that compared to prokinetics, the disappearance rate of symptoms (postprandial fullness, early satiety, epigastric burning, and pain) after treatment with Aurantii Fructus Immaturus Flavonoid Tablets was similar at RR = 0.90 (95% CI [0.63, 1.28], P = 0.54). However, after 4 weeks of treatment, the disappearance rate of symptoms was significantly higher with Aurantii Fructus Immaturus Flavonoid Tablets, with RR = 4.96 (95% CI [1.96, 12.52], P = 0.0007).

Recommendation 6: Results of two RCTs[33-34] (n=125) with Shenling Baizhu Keli for the treatment of FD patients showed that the clinical efficacy rate of Shenling Baizhu Keli was higher than that of gastric prokinetics, RR=1.38, 95%CI[1.11, 1.72], P =0.004.

B.3 Body surface medical therapies

B.3.1 Acupuncture therapy

Recommendation 1: Results of six RCTs of acupuncture therapy for functional dyspepsia (n=130) showed[35-40] that acupuncture boosted the efficacy rate in patients with FD, compared with sham acupuncture (OR=6.4, 95% CI [2.83, 14.51], P < 0.00001) **(Evidence Level: Grade Ⅲ)**. Results of 3 RCTs of acupuncture therapy for functional dyspepsia (n=188) showed[35,41,42] that acupuncture improved the Chinese medicine evidence score in patients with FD compared with sham acupuncture(MD =3.2, 95% CI [1.58, 4.82], P < 0.0001) (**Evidence Level: Grade Ⅱ**). Results of 31 RCTs of acupuncture therapy for functional dyspepsia (n=2301) showed[43-73] that acupuncture enhanced the efficiency of patients with FD compared with Western medicine(OR = 3.96, 95%

CI [3.07, 5.1], P < 0.00001) (**Evidence Level: Grade Ⅲ**). Results of 2 RCTs of acupuncture for functional dyspepsia (n=133) showed[46,49] that acupuncture was superior in elevating the nipin dyspepsia quality of life index (NDLQI)compared with Western medicine (MD = 3.43, 95% CI [1.29, 5.57], P <= 0.002) (**Evidence Level: Grade Ⅱ**). Results of 2 RCTs of acupuncture for functional dyspepsia (n=120) showed[51,53] that acupuncture was superior in improving the Functional Dyspepsia Dyspepsia Quality of Survival Scale (FDDQL) when compared with Western medicine(MD = 5.45, 95% CI [4.02, 6.88], P < 0.00001) (**Evidence Level: Grade Ⅱ**).

B.3.2 Electroacupuncture therapy

Recommendation 1: Results of 6 RCTs of electroacupuncture for functional dyspepsia (n = 400) showed[74-79] that electroacupuncture was more effective in improving the effectiveness rate compared with western medicine (OR = 4.98, 95% CI [2.41, 10.3], P < 0.00001) (**Evidence Level: Grade Ⅱ**). Results of 2 RCTs of electroacupuncture for functional dyspepsia (n=140) showed[77, 79], electroacupuncture significantly improved patients' TCM evidence score (MD = 2.88, 95% CI [0.94, 4.81], P = 0.004) (**Evidence Level: Grade Ⅲ**). Results of 3 RCTs of electroacupuncture in the treatment of functional dyspepsia (n = 208) showed[75,76,79] that electroacupuncture significantly reduced the quantification of a single symptom in patients with FD, as compared with western medicine Grading scale(MD = 1.63, 95% CI [0.8, 2.46], P = 0.0001) (**Evidence Level: Grade Ⅱ**). Results of 2 RCTs of electroacupuncture for the treatment of functional dyspepsia (n=124) showed[74,79] that electroacupuncture was more efficacious in enhancing FDDQL scores in FD patients compared with western medicine (MD = 7, 95% CI [4.53, 9.47], P < 0.00001) (**Evidence Level: Grade Ⅱ**). Results of 3 RCTs of electroacupuncture for the treatment of functional dyspepsia (n=230) showed[80-82] that electroacupuncture significantly reduced the Nepean Dyspepsia Symptom Index (NDSI) in patients with FD compared to western drugs (MD = 9.93, 95% CI [5.92, 13.94], P < 0.00001) (**Evidence Level: Grade Ⅱ**). Results of 3 RCTs of electroacupuncture in the treatment of functional dyspepsia (n=230) showed[80-82] that electroacupuncture was more efficacious in improving the NDLQI score in FD patients compared to Western medicine (MD = 8.36, 95% CI [5.53, 11.2], P < 0.00001) (**Evidence Level: Grade Ⅱ**).

B.3.3 Transcutaneous Auricular Vagus Nerve Stimulation

Recommendation 1: Results of a 1 RCT [83] (n=36) demonstrated that transcutaneous auricular vagus nerve stimulation (bilateral concha areas) significantly improved the percentage of normal gastric slow-wave activity

during fasting compared to sham stimulation (MD = 15%, 95% CI [0.13, 0.17], P < 0.00001) and postprandially (MD = 10%, 95% CI [0.08, 0.13], P < 0.00001). **(Evidence Level: Grade Ⅰ).**Results of a 1 RCT [84] (n=90) with transcutaneous auricular vagus nerve stimulation (left concha cavity) for the treatment of functional dyspepsia demonstrated that this therapy was significantly more effective than sham stimulation (left scaphoid fossa) in reducing the total symptom score (including epigastric pain, epigastric burning, postprandial fullness, early satiety, abdominal bloating, emesis, acid reflux, and nausea) (MD = -5.02, 95% CI [-6.34, -3.70], P < 0.00001) and in enhancing the Functional Dyspepsia Disease-specific Quality of Life (FDDQL) score (MD = 2.56, 95% CI [0.91, 4.21], P = 0.002) **(Evidence Level: Grade Ⅰ).**

B.3.4 Mild Moxibustion

Recommendation 1: Results of 3 RCTs [93-95] (n=143) with mild moxibustion for the treatment of functional dyspepsia demonstrated that mild moxibustion was significantly more effective than prokinetic medications in improving response rates (OR=8.22 95%CI [3.53, 19.15], P<0.00001).

B.3.5 Auricular Acupoint Therapy

Recommendation 1: Results of a 1 RCT [85] (n=60) with auricular therapy for the treatment of functional dyspepsia demonstrated that auricular therapy was significantly more effective than prokinetic medications in reducing the Nepean Dyspepsia Symptom Index (NDSI) score (MD = -4.94, 95% CI [-9.32, -0.56], P = 0.03) and in improving the Nepean Dyspepsia Life Quality Index (NDLQI) score (MD = 5.37, 95% CI [2.95, 7.79], P < 0.0001).

Annex C
(Informative)
Clinical manifestations and Western medicine diagnosis of functional dyspepsia

C.1 Clinical Manifestations

The main symptoms include epigastric pain, epigastric burning sensation, postprandial fullness, and/or early satiety, which may coexist with bloating, belching, loss of appetite, nausea, or vomiting. Patients often present with one primary symptom or a cluster of symptoms, which may vary over the course of the disease. The onset is typically insidious, with a chronic course lasting years, characterized by persistent or recurrent episodes. Dietary factors or emotional stress may trigger symptoms in some patients.

According to clinical manifestations, the Rome IV criteria classify functional dyspepsia into the following subtypes:

Postprandial Distress Syndrome (PDS): Characterized by meal-induced dyspeptic symptoms (e.g., postprandial fullness, early satiety).

Epigastric Pain Syndrome (EPS): Defined by epigastric pain and/or burning sensation, which may occur irrespective of meals (e.g., fasting state) and occasionally improve after eating.

Overlap of PDS and EPS: Features both meal-induced dyspeptic symptoms and epigastric pain/burning.

C.2 Diagnostic Criteria

Refer to the 2016 Rome IV diagnostic criteria for FD[2]:

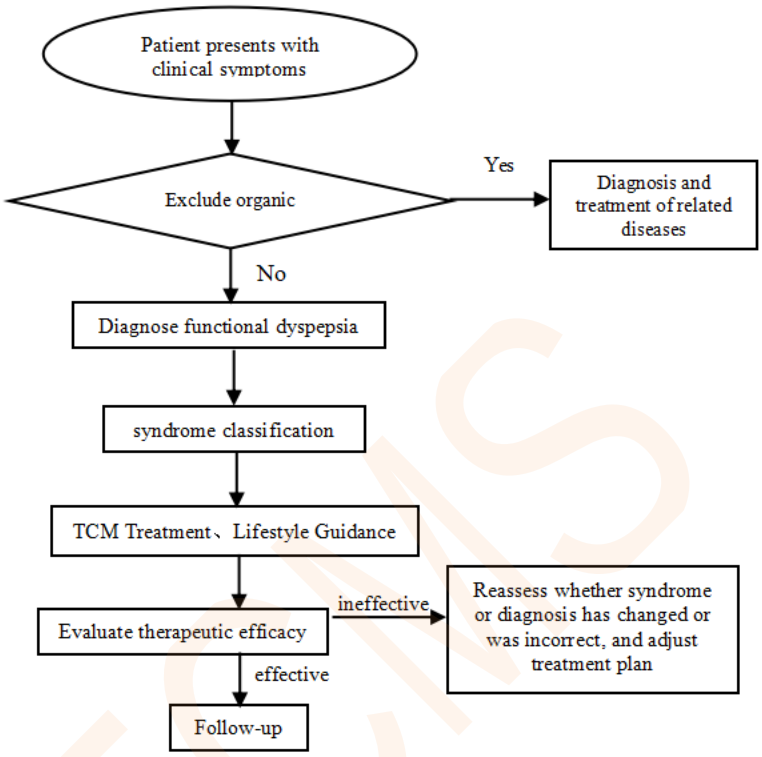
PDS: Postprandial fullness or early satiety.

EPS: Epigastric pain or burning.

Symptoms present ≥6 months, active ≥3 months, with no structural explanation.

Note: Structural exclusions include peptic ulcers, reflux esophagitis (identified via endoscopy), cholecystitis, and gallstones (identified via abdominal ultrasound).

Annex D
(Normative)
Clinical Application Pathway Diagram



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