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SCM

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

SCM **-20**

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

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

20**-**-**发布实施
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目　次

前　言

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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

本文件规定了中医药治疗功能性消化不良的诊断标准、鉴别诊断、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。本文件简明实用，可操作性强，具有指导性、普适性和可参照性，可作为临床实践、诊疗规范和质量评价的重要参考依据。

目前已发布的《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）》自施行以来，对功能性消化不良的中医药诊疗发挥了较好的指导作用。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，以提高中医药治疗功能性消化不良的临床疗效。

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，推荐意见快速查询表见附录 C。

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诊断标准、鉴别诊断、中医药辨证及治疗等。

本文件适用于各级中医院、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。

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、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”。

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 中医辨治[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，苔黄；②脉弦细滑。
证候诊断：主症 2 项，加次症 2 项，参考舌脉，即可诊断。
治法：辛开苦降，和胃开痞。

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。
证候诊断：主症 2 项，加次症 2 项，参考舌脉，即可诊断。
治法：健脾和胃，理气消胀。

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。
证候诊断：主症 2 项，加次症 2 项，参考舌脉，即可诊断。
治法：理气解郁，和胃降逆。

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。
证候诊断：主症 2 项，加次症 2 项，参考舌脉，即可诊断。
治法：清热化湿，理气和中。

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。
证候诊断：主症 2 项，加次症 2 项，参考舌脉，即可诊断。
治法：健脾和胃，温中散寒。

6 中医药治疗

6.1 寒热错杂证

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；情绪抑郁者，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。

6.2 脾虚气滞证

推荐 1：香砂六君子汤（Ⅲ级证据，强推荐）

香砂六君子汤药物组成：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，加炒米仁、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：有 1 项研究对研究过程中的不良反应进行报告，未出现不良事件。

推荐 2：枳实消痞丸（Ⅲ级证据，强推荐）

枳实消痞丸药物组成：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。

推荐 3：中成药香砂六君丸（专家共识，强推荐）

主要成分：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。

用药建议：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。口服。一次 6-9 克，一日 2-3 次。或遵医嘱。疗程两周。

安全性：说明书记载不良反应尚不明确。

推荐 4：中成药枳术宽中胶囊（Ⅱ级证据，强推荐）

主要成分：白术（炒），枳实、柴胡、山楂。

用药建议：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。口服，一次 3 粒，每日 3 次，或遵医嘱。疗程两周。

安全性：有 1 项研究对研究过程中的不良反应进行报告，试验组（枳术宽中胶囊）1 例胃痛，未用药物自行缓解，对照组（西沙必利）2 例轻度腹痛，1 例中度胃脘部不适，停药后自行缓解。两组在不良反应发生率方面无显著差异。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。

6.3 肝胃不和证

推荐 1：柴胡疏肝散（Ⅲ级证据，强推荐）

柴胡疏肝散药物组成：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。

推荐 2：中成药气滞胃痛颗粒（片）（Ⅰ级证据，强推荐）

主要成分：柴胡、醋延胡索、枳壳、醋香附、白芍、炙甘草。

用药建议：用于肝郁气滞，胸痞胀满，胃脘疼痛。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：纳入的研究中，试验组（气滞胃痛颗粒）中 1 例胆固醇轻度升高，1 例轻度口干。对照组（安慰剂）中 1 例轻度便秘，1 例中度尿蛋白升高。两组在不良反应发生率差异无统计学意义。

推荐 3：中成药荜铃胃痛颗粒（Ⅰ级证据，强推荐）

主要成分：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。

用药建议：用于气滞血瘀所致的胃脘痛。口服，一次 5g，每日 3 次。或遵医嘱。疗程六周。

安全性：纳入的研究试验组（荜铃胃痛颗粒）中 1 例腹泻。两组不良事件发生率无显著性差异。

推荐 4：中成药达立通颗粒（Ⅲ级证据，弱推荐）

主要成分：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）。

用药建议：用于胃脘胀满、嗳气、纳差、胃中灼热、嘈杂泛酸、脘腹疼痛、口干口苦。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 2 项未发生不良事件，其余 6 项研究显示，两组在不良反应发生率方面无显著差异，说明书报告个别患者服药后可能出现腹痛。

推荐 5：中成药枳实总黄酮片（Ⅰ级证据，强推荐）

主要成分：枳实总黄酮提取物。

用药建议：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。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：纳入的研究中未报告严重不良事件。

6.4 脾胃湿热证

推荐 1：连朴饮（脾胃湿热证中湿热并重，Ⅲ级证据，弱推荐）

连朴饮药物组成：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）

柴胡达原饮药物组成：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）

三仁汤药物组成：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。

6.5 脾胃虚寒（弱）证

推荐 1：附子理中汤（脾胃虚寒证，Ⅲ级证据，强推荐）

附子理中汤药物组成：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）

四君子汤药物组成：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：纳入的研究中试验组（四君子汤）未报告不良反应；对照组（多潘立酮）中 8 例腹部不适、排气过多或腹泻。两组比较有显著性差异。

建议 3：中成药附子理中丸（浓缩丸）（脾胃虚寒证，专家共识，弱推荐）

主要成分：附子、党参、白术、干姜、甘草。

用药建议：用于功能性消化不良脾胃虚寒，脘腹冷痛，呕吐泄泻，手足不温等症状。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 4：中成药参苓白术颗粒。（脾胃虚弱证，Ⅱ级证据，弱推荐）

主要成分：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。

用药建议：用于脾胃虚弱、食少便溏、气短咳嗽、肢倦乏力等症状。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。

7 其他疗法

推荐 1：针刺或电针疗法，可提高功能性消化不良 4 周应答率（Ⅰ级证据）、临床有效率（Ⅱ级证据），改善尼平消化不良症状（NDSI）评分（Ⅲ级证据）和生活质量（NDLQI）评分（Ⅱ级证据）。（强推荐）

主穴选择：百会、中脘、气海、天枢、内关、足三里、公孙、膻中，以足阳明经脉和任脉为主。

辨证取穴：脾虚气滞型，加太冲、期门；肝胃不和型，加太冲；脾胃湿热型，加内庭、阴陵泉；脾胃虚寒（弱）型，加脾俞、上脘、下脘、四神聪；寒热错杂型，加阴陵泉、曲池、三阴交、神阙、太溪。

针刺方法：在每一个穴位上进行 30 秒的捻转、提插操作，以达到针刺后立即产生的得气感（酸痛、麻木、膨胀和沉重），留针 15-30 分钟。疗程：每周 3 次，持续 4 周。

电针方法：穴位上可放置便携式神经调控装置（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 2s，关闭时间为 3s，脉冲宽度为 0.6ms，脉冲频率为 25Hz，脉冲振幅为 2mA 至 10mA。

疗程：在餐后 2 小时内每天进行 3 次刺激，持续 4 周。

推荐 2：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 3：耳穴疗法，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：将王不留行籽贴于己选好的耳穴上，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。

推荐 4：穴位埋线疗法，改善功能性消化不良临床有效率。（Ⅲ级证据，弱推荐）

穴位：中脘、天枢、肝俞、足三里、脾俞、胃俞。

方法：局部消毒，铺一灭菌洞巾。每穴用 1%利多卡因 0.5~1 mL 局部麻醉(皮试阴性后)。用不锈钢大号三角皮针，穿选好的消毒线(2~3 号铬制羊肠线，体瘦用 2 号体胖用 3 号)，左手抓起皮肤，右手用持针器在原定部位(单穴时以该穴中点上下各 1cm 从上至下进针)，通过穴底穿过出针，在另一端紧贴皮肤处把线剪断，用纱布按摩使线头退入皮下。为了加强刺激可提线两端，提拉数十次后再剪断。

8 生活指导

8.1 生活起居方面，应慎起居，适寒温，防六淫，注意腹部保暖。适当参加体育锻炼，增强体质，但应避免餐后立刻运动，以免增加胃肠负担。**（专家共识，强推荐）**

8.2 保持心理健康，注意精神调摄，保持乐观开朗，心情舒畅。**（专家共识，强推荐）**医生应及时了解患者心理状态，建立良好的医患信任关系，加强安慰、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。

8.3 注重饮食调护，养成良好的饮食习惯，每日定时、定量进餐。患者应节制饮食，勿暴饮暴食，勿过快进餐，应避免烟、酒、刺激性食物等。饮食宜清淡，忌肥甘厚味、辛辣醇酒以及生

凉之品。**（专家共识，强推荐）**

8.4 尽量避免服用非甾体类抗炎药物，对于无法停用非甾体类抗炎药物者应同时服用质子泵抑制剂 PPI 等。**（专家共识，强推荐）**

附录 A
（规范性）
研制方法

A.1 证据评价及分级[76]

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[77]

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 方药及中成药治疗

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。

推荐意见 4：3 项枳术宽中胶囊治疗功能性消化不良脾虚气滞证（n=411）的 RCT 结果显示[10-12]，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。

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[13]，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。

推荐意见 2：1 项气滞胃痛颗粒治疗功能性消化不良肝胃不和证（n=165）的 RCT 结果显示[14]，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肝胃不和证（n=238）的 RCT 结果显示[15]，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肝胃不和证（n=1817）的 RCT 结果显示[16-25]，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肝胃不和证（n=239）的 RCT 结果显示[26]，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。

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[27]，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[28]，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[29,30]，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[31]，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[32]，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。

推荐意见 4：2 项参苓白术颗粒治疗功能性消化不良脾胃虚弱证（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. 2 其他疗法

B. 2. 1 针刺或电针疗法

推荐意见 1：1 项针刺疗法治疗功能性消化不良（n=229）的 RCT 结果显示[35]，与假针刺相比，在提高 4 周应答率 RR=1.60，95% CI[1.32，1.95]，P < 0.00001 方面更优。**（Ⅰ级证据）**26 项针刺、电针疗法治疗功能性消化不良（n=2011）的 RCT 结果显示[36-61]，与西药相比，临床有效率更高 RR=1.21，95%CI[1.16，1.25]，P < 0.00001**（Ⅱ级证据）**；5 项针刺、电针疗法治疗功能性消化不良（n=519）的 RCT 结果显示[62-66]，与假针刺组相比，临床有效率更高 RR=2.33，95%CI[1.99，2.74]，P < 0.00001**（Ⅰ级证据）**。5 项针刺、电针疗法治疗功能性消化不良（n=423）的 RCT 结果显示[67-71]，与西药相比，在降低尼平消化不良症状（NDSI）评分 MD $_{评分}$=-7.44 分，95%CI[-9.79，-5.08]，P < 0.00001 方面更优，在提高尼平消化不良生活质量评分（NDLQI）MD $_{评分}$=5.71 分，95%CI[4.20，7.23]，P < 0.00001 方面更优**（Ⅱ级证据）**；1 项针刺疗法治疗功能性消化不良（n=58）的 RCT 结果显示[62]，与假针刺组相比，在降低尼平消化不良症状（NDSI）评分 MD $_{评分}$=MD=-9.94 分，95%CI[-16.33，-3.55]，P = 0.002 方面更优**（Ⅲ级证据）**。

B. 2. 2 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=75）的 RCT 结果显示[72]，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[73]，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. 2. 3 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[74]，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。

B. 2. 4 穴位埋线疗法

推荐意见 1：1 项穴位埋线疗法治疗功能性消化不良（n=90）的 RCT 结果显示[75]，穴位埋线疗法与促胃动力药相比，临床有效率相当，RR=1.12，95%CI[0.96，1.29]*，P =0.15。

附录 C
（资料性）
推荐意见快速查询表

序号	推荐意见
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
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
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
4	针对脾虚气滞证 FD 患者，推荐使用中成药枳术宽中胶囊
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
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）
7	针对肝胃不和证 FD 患者，推荐使用中成药荜铃胃痛颗粒
8	针对肝胃不和证 FD 患者，推荐使用中成药达立通颗粒
9	针对肝胃不和证 FD 患者，推荐使用中成药枳实总黄酮片
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
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
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
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
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
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
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）
17	推荐使用经皮耳迷走神经刺激改善 FD 症状及生活质量
18	推荐使用耳穴疗法改善 FD 症状及生活质量
19	推荐使用穴位埋线疗法改善 FD 临床有效率

附录 D
（资料性）
功能性消化不良临床表现及西医诊断

D.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。

D.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。

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Content

Foreword

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Introduction

This document outlines the diagnosis, differential diagnosis, and TCM treatment for 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. This document is concise, practical, and highly actionable, providing guidance, universality, and reference for clinical practice, diagnostic standardization, and quality evaluation.

Existing guidelines, including the 2017 Expert Consensus on TCM Diagnosis and Treatment of Functional Dyspepsia, 2017 Integrated Chinese-Western Medicine Consensus on FD, 2021 Clinical Application Guidelines for Chinese Patent Medicines in FD, and 2023 Expert Consensus on Traditional Chinese Medicine Diagnosis and Treatment of Functional Dyspepsia , have provided significant guidance. However, previous guidelines relied heavily on expert consensus, limiting international recognition. Advancements in evidence-based TCM research have led to the emergence of higher-quality evidence. This document builds on prior guidelines, rigorously evaluating FD treatments through high-quality clinical studies to enhance TCM clinical efficacy.

This document builds upon previous guidelines, rigorously evaluating FD treatments through high-quality clinical studies to improve TCM clinical efficacy. Clinicians should tailor recommendations to the specific circumstances of each patient.

International Clinical Practice Guideline of Chinese Medicine: Functional Dyspepsia

1 Scope

This document outlines the diagnostic criteria, differential diagnosis, TCM syndrome differentiation, and treatment for FD.

This document applies to the diagnosis and treatment of FD in TCM hospitals, general hospitals, integrated Chinese-Western medicine hospitals, and primary healthcare settings.

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 "胃痛" (wèi tòng), while postprandial distress syndrome corresponds to "胃痞" (wèi pǐ).

4 Etiology and Pathogenesis

The disease is located 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 intermingled heat and cold

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 (All Recommendations)

6.1 Syndrome of intermingled heat and cold

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

6.2 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. After expert discussion within the working group, it is concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

Recommendation 3: 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: Adverse reactions are not clearly defined.

Recommendation 4: 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 study reported adverse reactions during the trial. In the treatment group (ZhiShu KuanZhong Capsules), one case of mild epigastric pain resolved spontaneously. In the control group (Cisapride), two cases of mild abdominal pain and one case of moderate epigastric discomfort resolved after discontinuation. There were no significant differences in the incidence of adverse reactions between the two groups. The product insert reports that common adverse reactions include occasional epigastric pain or increased bowel movements following administration.

6.3 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. After expert discussion within the working group, it is 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 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: In the included studies, the treatment group (QiZhi WeiTong Keli) reported one case of mild elevation in cholesterol and one case of mild dry mouth. The control group (placebo) reported one case of mild constipation and one case of moderate proteinuria. No statistically significant differences were observed in the incidence of adverse reactions between the two groups.

Recommendation 3: 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 the included studies, the treatment group (Biling Weitong Keli) reported one case of diarrhea. No significant differences were observed in the incidence of adverse events between the treatment and control groups.

Recommendation 4: 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: Among the eight studies reporting adverse reactions during the trial, two reported no adverse events. The remaining 6 studies demonstrated no significant differences in the incidence of adverse reactions between the treatment and control groups. The product insert reports that individual patients may experience abdominal pain after taking the medication.

Recommendation 5: 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: No severe adverse events reported.

6.4 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. After expert discussion within the working group, it is 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.

6.5 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. After expert discussion within the working group, it is concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use. Monitor 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 the studies reviewed, the experimental group (Sijunzi Decoction) did not report adverse reactions. In the control group (Domperidone), 8 cases experienced abdominal discomfort, excessive flatulence, or diarrhea. A significant difference was found between the two groups.

Recommendation 3: 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. After expert discussion within the working group, it is concluded that the

overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

Recommendation 4: 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. After expert discussion within the working group, it is concluded that the overall safety profile of the aforementioned medications is favorable. Clinicians should closely monitor patient safety during clinical use.

7 Other therapies

Recommendation 1: 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. (Recommended intensity: strong recommendation)

Recommendation Details:

Primary Acupoints: Baihui (GV20), Zhongwan (CV12), Qihai (CV6), Tianshu (ST25), Neiguan (PC6), Zusanli (ST36), Gongsun (SP4), Tanzhong (CV17); primarily based on the Stomach Meridian of Foot-Yangming and the Conception Vessel (Ren Meridian).

For syndrome differentiation, the following acupoints are added: for Syndrome of Spleen Deficiency and Qi Stagnation, Taichong (LR3) and Qimen (LR14); for Liver-Stomach Disharmony Syndrome, Taichong (LR3); for Damp-Heat in the Spleen and Stomach Syndrome, Neiting (ST44) and Yinlingquan (SP9); for Spleen

and Stomach Deficiency-Cold Syndrome, Pishu (BL20), Shangwan (RN13), Xiaowan (RN10), and Sishencong (EX-HN1); for Mixed Cold and Heat Syndrome, Yinlingquan (SP9), Quchi (LI11), Sanyinjiao (SP6), Shenque (RN8), and Taixi (KI3).

7.1 Acupuncture Technique:

Method: Each acupoint is manipulated with a combination of twisting and lifting-inserting for 30 seconds to achieve the immediate sensation of deqi (characterized by soreness, numbness, distension, and heaviness) following needle insertion. The needle is retained for 15–30 minutes.

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

7.2 Electroacupuncture Technique:

Method: A portable neuromodulation device (SNM-FDC01) is applied to the acupoints.

Stimulation Parameters: Based on patient tolerance, the device is set with an on-time of 2 seconds, off-time of 3 seconds, pulse width of 0.6 ms, pulse frequency of 25 Hz, and pulse amplitude ranging from 2 mA to 10 mA.

Treatment Course: Three times daily, two hours after meals, for four weeks.

Recommendation 2: Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) to Improve FD Symptoms and Quality of Life (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: Based on patient tolerance, 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.

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

Recommendation 3: 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.

Recommendation 4: Acupoint Embedding Therapy for Enhancing Clinical Efficacy in FD (Evidence Level: Grade Ⅲ, recommended intensity: weak recommendation)

Recommendation Details:

Acupoints: Zhongwan (CV12), Tianshu (ST25), Ganshu (BL18), Zusanli (ST36), Pishu (BL20), Weishu (BL21).

Method: Perform local disinfection and apply a sterile fenestrated drape.Administer 0.5–1 mL of 1% lidocaine for local anesthesia at each acupoint (after confirming a negative skin test).Use a large-gauge triangular stainless steel needle with sterilized thread (No. 2 or No. 3 chromic catgut suture; select No. 2 for individuals with a leaner body habitus and No. 3 for those with a heavier body habitus).Lift the skin with the left hand and use a needle holder to insert the needle at the predetermined site (for single acupoint, insert the needle from 1 cm above to 1 cm below the acupoint, from top to bottom). Pass through the acupoint base and exit on the other side.Cut the thread at the exit point, close to the skin, and massage with gauze to retract the thread end into the subcutaneous tissue.To enhance stimulation, lift the thread ends and perform tens to dozens of pulling motions before cutting.

8 Lifestyle Guidance

8.1 In daily living, patients should maintain regular routines, adapt to temperature changes appropriately, and protect themselves from external pathogenic factors (six evils). Special attention should be given to keeping the abdominal area warm. Moderate physical exercise is encouraged to enhance overall health; however, strenuous activity should be avoided immediately after meals to prevent excessive gastrointestinal burden. **(Expert consensus, recommended intensity: strong recommendation)**

8.2 Mental well-being should be prioritized. Patients should regulate their emotions, maintain an optimistic and positive mindset, and strive for emotional stability. **(Expert consensus, recommended intensity: strong recommendation)**

Physicians should assess the psychological state of patients in a timely manner, foster a strong doctor-patient relationship, and provide reassurance, educational guidance, and effective communication. Patients are encouraged to engage in social interactions, practice self-regulation techniques, and seek professional psychological consultation when necessary. Psychotherapy may serve as a complementary treatment for FD patients with severe symptoms or those unresponsive to pharmacotherapy.

8.3 Dietary management should be emphasized, and patients should cultivate healthy eating habits by consuming meals at regular times and in appropriate portions. Overeating, rapid eating, and excessive food intake should be avoided. Patients should also refrain from smoking, alcohol consumption, and spicy or irritating foods. A light, easily digestible diet is recommended, while rich, greasy, spicy, alcoholic, and raw/cold foods should be avoided. **(Expert consensus, recommended intensity: strong recommendation)**

8.4 The use of nonsteroidal anti-inflammatory Medications (NSAIDs) should be minimized whenever possible. For patients who must continue NSAID therapy, proton pump inhibitors (PPIs) or other protective agents should be co-administered. **(Expert consensus, recommended intensity: strong recommendation)**

Annex A
(Normative)
Development Methods

A.1 Evidence Evaluation and Grading[76]

Table A.1 Grading Standards for Clinical Research Evidence in Traditional 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 Reporting	Outcome	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 Reporting	Outcome	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 [77]

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 Herbal Formulas and TCM Patent Medicine Treatments

B.1.1 Syndrome of intermingled heat and cold

Recommendation 1: Results of a RCT study of Banxia Xiexin Decoction (with modifications) for treating functional dyspepsia with syndrome of intermingled heat and cold (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.

Recommendation 4: Results of 3 RCTs[10-12] (n=411) with Zhizhukuanzhong capsules for the treatment of functional dyspepsia with spleen deficiency qi stagnation syndrome 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.

B.1.3 Sndrome of incoordination between liver and stomach

Recommendation 1: The results of a RCT[13] (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.

Recommendation 2: Results of a 1 RCT [14] (n=165) with Qi-Zhi Wei-Tong Keli for the treatment of functional dyspepsia with syndrome of incoordination between liver and stomach 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 [15] (n=238) with Biling Weitong Granules for the treatment of functional dyspepsia with liver-stomach disharmony syndrome 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 [16-25] (n=1817) with Dalitong Granules for the treatment of functional dyspepsia with liver-stomach disharmony syndrome 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 [26] (n=239) with Aurantii Fructus Immaturus Flavonoid Tablets for the treatment of functional dyspepsia with liver-stomach disharmony syndrome 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).

B.1.4 Spleen-Stomach Damp-Heat Syndrome

Recommendation 1: Results of 1 RCT[27] (n=60) with Lianpu Decoction (with modifications) for the treatment of functional dyspepsia with damp-heat of the spleen and stomach syndromeshowed 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[28] (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[29,30] (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[31] (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[32] (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.

Recommendation 4: Results of two RCTs (n=125) with Shenling Baizhu Keli for the treatment of FD patients with Syndrome of Spleen and Stomach Deficiency-Cold or Weakness 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.2 Other therapies

B.2.1 Acupuncture or Electroacupuncture

Recommendation 1: Results of a 1 RCT[35] (n=229) with acupuncture for the treatment of functional dyspepsia demonstrated that acupuncture was significantly more effective than sham acupuncture in improving the 4-week

response rate (RR = 1.60, 95% CI [1.32, 1.95], P < 0.00001) **(Evidence Level: Grade Ⅰ)**. Results of 26 RCTs[36-61] (n=2011) with acupuncture and electroacupuncture for the treatment of functional dyspepsia demonstrated that these therapies were significantly more effective than Western medicine in improving clinical efficacy (RR = 1.21, 95% CI [1.16, 1.25], P < 0.00001) **(Evidence Level: Grade Ⅱ)**. Results of 5 RCTs[62-66] (n=519) with acupuncture and electroacupuncture for the treatment of functional dyspepsia demonstrated that these therapies were significantly more effective than sham acupuncture in improving clinical efficacy (RR = 2.33, 95% CI [1.99, 2.74], P < 0.00001) **(Evidence Level: Grade Ⅰ)**. Results of 5 RCTs[67-71] (n=423) with acupuncture and electroacupuncture for the treatment of functional dyspepsia demonstrated that these therapies were significantly more effective than Western medicine in reducing Nepean Dyspepsia Symptom Index (NDSI) scores (MD = -7.44, 95% CI [-9.79, -5.08], P < 0.00001) and in improving Nepean Dyspepsia Life Quality Index (NDLQI) scores (MD = 5.71, 95% CI [4.20, 7.23], P < 0.00001) **(Evidence Level: Grade Ⅱ)**. Results of a 1 RCT [62] (n=58) with acupuncture for the treatment of functional dyspepsia demonstrated that acupuncture was significantly more effective than sham acupuncture in reducing the Nepean Dyspepsia Symptom Index (NDSI) score (MD = -9.94, 95% CI [-16.33, -3.55], P = 0.002) **(Evidence Level: Grade Ⅲ)**.

B.2.2 Transcutaneous Auricular Vagus Nerve Stimulation

Recommendation 1: Results of a 1 RCT [72] (n=75) 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 [73] (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.2.3 Auricular Acupoint Therapy

Recommendation 1: Results of a 1 RCT [74] (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).

B.2.4 Acupoint Embedding Therapy

Recommendation 1: Results of a 1 RCT [75] (n=90) with acupoint embedding therapy for the treatment of functional dyspepsia demonstrated that acupoint embedding therapy was similarly effective to prokinetic medications in terms of clinical efficacy (RR = 1.12, 95% CI [0.96, 1.29], P = 0.15).

Annex C
(Informative)
Recommendation Quick Search Form

No.	Recommendation
1	For patients with FD syndrome of intermingled heat and cold, Banxia Xiexin Decoction is recommended.
2	For FD patients with spleen deficiency and qi stagnation syndrome, Xiangsha Liujunzi Decoction is recommended.
3	For patients with FD syndrome of spleen deficiency Qi stagnation syndrome accompanied by cold and heat, Zhishi Xiaopi Wan is recommended.
4	For patients with FD Syndrome of Spleen Deficiency and Qi Stagnation, Zhizhu Kuanzhong Capsule is recommended.
5	For patients with FD syndrome of incoordination between liver and stomach, it is recommended to use Chaihu Shugan San.
6	For patients with FD syndrome of incoordination between liver and stomach, it is recommended to use Qizhi Weitong Keli /Pian.
7	For patients with FD syndrome of incoordination between liver and stomach accompanied by blood stasis, it is recommended to use Beiling weitong Keli.
8	For the patients with FD syndrome of coordination between liver and stomach accompanied by stagnant heat, it is recommended to use Dalitong granules.
9	For FD patients with Liver-Stomach Disharmony Syndrome, use the Aurantii Fructus Immaturus favonoid Tablets.
10	For patients with syndrome of dampness-heat of the spleen and stomach in FD, Lianpo Decoction is recommended.
11	For patients with syndrome of Dampness is heavier than heat in the Spleen-Stomach Dampness-Heat, it is recommended to use the Chaihu Dayuan Decoction.
12	For patients with FD syndrome of Equal Predominance of Dampness and Heat in the Spleen-Stomach Dampness-Heat, Sanren Decoction is recommended.
13	For FD patients with syndrome of deficient cold of spleen and stomach, Fuzi Lizhong Decoction is recommended.
14	For FD patients with Syndrome of Spleen and Stomach Deficiency, Sijunzi Decoction is recommended.
15	For FD patients with Syndrome of Spleen and Stomach Deficiency Syndrome, it is recommended to use Shenling Baizhu Keli.
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.
17	Transcutaneous Auricular Vagus Nerve Stimulation (taVNS) to Improve FD Symptoms and Quality of Life.
18	Auricular Acupoint Therapy for Improving FD Symptoms and Quality of Life.
19	Acupoint Embedding Therapy for Enhancing Clinical Efficacy in FD.

Annex D

(Informative)

Clinical manifestations and Western medicine diagnosis of functional dyspepsia

D.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.

D.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).

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