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

SCM 000*-20**

国际中医临床实践指南 变应性鼻炎
International guidelines for clinical practice of Chinese medicine
Allergic rhinitis

(征求意见稿)
(Working draft)

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前 言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

主要起草单位：成都中医药大学附属医院、广州中医药大学第二附属医院、北京中医药大学东直门医院

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引 言

本文件遵循国际循证指南制定规范，重视推荐细节及实用性，证据充分，具有较好指导性、普适性、可参照性和可操作性，能够为国际范围内中医师治疗变应性鼻炎的临床实践提供中医药策略与方法。本文件整合海内外古今中医药变应性鼻炎研究成果与证据，结合专家共识，既突出中医药传承及中西医结合特色，又注重方法学与临床实践的国际性。

目前中国已发布的《中医耳鼻咽喉科常见病诊疗指南》（2012 版）、《循证针灸临床实践指南 过敏性鼻炎》（2015 版）、《中医治未病实践指南·鼻鼽》（2018 版）、《中医儿科临床诊疗指南·小儿鼻鼽》（2020 版）对变应性鼻炎的中医药诊疗发挥了较好的指导作用。但是，既往中医临床指南限于研究条件，多以专家共识作为推荐标准，国际认可度较低；或仅针对特定治疗措施、患者群体或干预理念。

随着循证医学研究在中医药领域的快速发展和应用，证据级别较高的研究成果不断涌现，本文件在既往指南基础上，广泛征求专家意见，对中医药治疗变应性鼻炎相关随机对照试验进行严格的质量评价，在中医药治疗变应性鼻炎的高质量研究中筛选出临床疗效可靠、安全、便于推广的治疗方法。同时，与海外中医学学术团体交流合作，结合专家共识推荐意见，分别对各个纳入范畴的中医药疗法作出综合证据及推荐评价分级，有助于循证医学原则在中医临床实践中得到更好的贯彻和实施，从而规范医生的医疗行为，提高中医诊疗疗效。

此外，团队在本文件的研制过程中搜集、整理既往中医临床指南中循证评价方面的方法学问题，求同存异，衷中参西，发掘、分析共同国际指南间的差异与关联。基于国际指南通用的 GRADE 标准，通过专家方法学共识，优化并提出新的中医药国际循证证据评价标准（GRADE-TCM），旨在“以 GRADE 为主保持国际化，以权威客观资料为辅减少证据偏移，以古代文献为鉴彰显传承性”（附录 A）。同时，参考“德尔菲”法与“名义组”法，本文件也对专家共识过程及推荐原则进行了优化（附录 B）。最后，团队遵循中医药核心指标集“国际标准+中医特色”的原则，通过指标分析与专家共识，注册并开发了变应性鼻炎中医药诊疗核心结局指标集（COS-AR-TCM，附录 G）。

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。

国际中医药临床实践指南 变应性鼻炎

1 范围

本文件规定了变应性鼻炎的中医辨证、西医诊断、西医分型分期分度、中医药治疗、临床疗效等内容。

本文件适用于临床变应性鼻炎的诊断、治疗和疗效评价。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ZYYXH/T307-321-2012 中医耳鼻咽喉科常见病诊疗指南

ZYYXH/T-473-2015 中医临床诊疗指南编制通则

ZJ/T-E016-2015 循证针灸临床实践指南—过敏性鼻炎

3 术语和定义

3.1

变应性鼻炎

变态反应性鼻炎

过敏性鼻炎

以阵发性发作鼻痒、喷嚏频作、大量清水样涕、鼻塞为典型表现的鼻粘膜的 I 型（速发型）变态反应性疾病。

注：属于中医“鼻鼽”之范畴，又称“鼽嚏”。

4 诊断

4.1 中医辨证

4.1.1 肺气虚弱，外感风寒证

发作性鼻痒难耐、喷嚏频作、清涕量多，鼻粘膜肿胀、色淡，可伴鼻塞、嗅觉减退，多遇冷风发作。常素体恶风恶寒，易感冒，倦怠乏力，气短自汗。舌质淡，苔薄白或滑，脉虚弱，或见浮象。

4.1.2 肺经伏热，上犯鼻窍证

发作性鼻痒，喷嚏连作，清涕量多，间有粘稠涕，鼻塞、嗅觉减退；鼻黏膜偏红、肿胀。口干，小便黄，大便或干结。舌红，苔薄白或薄黄，脉数。

4.1.3 脾气虚弱，清阳不升，水湿泛鼻证

鼻塞较重，清涕量多，清稀或黏白，可见鼻痒、喷嚏连作；嗅觉减退；鼻黏膜色淡或灰暗、肿胀。纳差便溏，倦怠乏力，神疲气短。舌淡或淡胖，边有齿痕，苔薄白或白，脉细弱或濡缓。

4.1.4 肾阳亏虚，鼻窍失温证

常年性发作性鼻痒、清涕，可见喷嚏连作、鼻塞、嗅觉减退；鼻黏膜苍白或紫暗，肿胀。畏寒肢冷，腰膝酸软，小便清长。舌淡，苔薄白或白，脉沉细或见弱象。

4.2 西医诊断及分型、分期、分度

变应性鼻炎的西医诊断及分型、分期、分度见附录 C。

5 治疗

5.1 方药治疗

5.1.1 肺气虚弱，外感风寒证

5.1.1.1 治法

温肺散寒，益气固表。

5.1.1.2 方药

a) 玉屏风散（《究原方》）：黄芪、白术、防风。（GRADE-TCM 1B^U：强推荐，证据级别 B）

b) 温肺止流丹（《辨证录》）：诃子、甘草、桔梗、石首、鱼脑石、荆芥、细辛、人参。（GRADE-TCM 1B^U：强推荐，证据级别 B）

5.1.1.3 加减

鼻部症状较重者，可酌加苍耳子、辛夷、薄荷、白芷。风寒盛，营卫不和者，可酌加桂枝、芍药、生姜、大枣、甘草。鼻、眼和（或）咽喉部瘙痒感严重，喷嚏尤多者，可酌加蜈蚣、全蝎、地龙、蝉蜕。

5.1.1.4 其他事项

a) 季节性、持续性、发作期患者优先考虑本证（为主）辨治，常年性、间歇性、静止期患者建议考虑本证（为主）辨治。

b) 备选弱推荐方药：当受制于如个人过敏、体质不适用或无法获得特定药材时，以下方剂为弱推荐，可供参考及加减使用：桂枝汤、麻黄附子细辛汤、补中益气汤、苍耳子散、小青龙汤、川芎茶调散、苓甘五味姜辛汤。（见附录 D）

5.1.2 肺经伏热，上犯鼻窍证

5.1.2.1 治法

清热祛风，通窍达嚏。

5.1.2.2 方药

辛夷清肺饮（《外科正宗》）：辛夷、黄芩、山梔、麦门冬、百合、石膏、知母、甘草、枇杷叶、升麻。（GRADE-TCM 1C：强推荐，证据级别 C）

5.1.2.3 加减

伏热较盛者，可酌加知母、黄柏、牡丹皮。阳气（或气）虚弱所致热伏鼻窍者，可酌加黄芪、人参、白术、炙甘草、当归、陈皮、升麻、柴胡、生姜、大枣。

5.1.2.4 其他事项

a) 季节性、间歇性、发作期患者建议考虑本证（为主）辨治，常年性、持续性、静止期患者不建议考虑本证（为主）辨治。

b) 当受制于如个人过敏、体质不适用或无法获得特定药材时，以下方剂为弱推荐，可供参考及加减使用：苍耳子散。（见附录 D）

5.1.3 脾气虚弱，清阳不升，水湿泛鼻证

5.1.3.1 治法

益气健脾，升阳化湿

5.1.3.2 方药

a) 补中益气汤（《内外伤辨惑论》）：黄芪、人参、白术、炙甘草、当归、陈皮、升麻、柴胡、生姜、大枣。（GRADE-TCM 1B^u：强推荐，证据级别 B）

b) 参苓白术散（《太平惠民和剂局方》）加减：白扁豆、白术、茯苓、甘草、桔梗、莲子、人参、砂仁、山药、薏苡仁。（GRADE-TCM 1B^u：强推荐，证据级别 B）

5.1.3.3 加减

发作期可酌加细辛、五味子、辛夷、白芷。清涕不止可酌加乌梅、诃子。鼻粘膜肿胀严重者，可酌加车前子、泽泻、浙贝母、半夏。

5.1.3.4 其他事项

a) 季节性、常年性、持续性、发作期患者优先考虑本证（为主）辨治，间歇性、静止期患者建议考虑本证（为主）辨治。

b) 当受制于如个人过敏、体质不适用或无法获得特定药材时，以下方剂为弱推荐，可供参考及加减使用：理中汤、玉屏风散、四君子汤、缩泉丸。（见附录 D）

5.1.4 肾阳亏虚，鼻窍失温证

5.1.4.1 治法

补肾益气，温阳固表

5.1.4.2 方药

a) 金匱腎氣丸（《金匱要略》）：地黃、茯苓、山藥、山茱萸、牡丹皮、澤瀉、桂枝、牛膝、車前子、附子。（GRADE-TCM 1D^U：強推薦，證據級別 D）

b) 右歸丸（《景岳全書》）：熟地黃、附子、肉桂、山藥、山茱萸、菟絲子、鹿角膠、枸杞子、當歸、杜仲。（GRADE-TCM 1B^U：強推薦，證據級別 B）

5.1.4.3 加減

病程較久，陽弱血瘀甚者，可酌加當歸尾、赤芍、川芎。伴有腎陰不足者，可酌加熟地、山藥、山茱萸、菟絲子、枸杞子、鹿角膠、龜板膠、川牛膝。

5.1.4.4 其他事項

a) 常年性、持續性患者優先考慮本證（為主）辨治，間歇性、季節性、靜止期、發作期患者建議考慮本證（為主）辨治。

b) 當受制於如個人過敏、體質不適用或無法獲得特定藥材時，以下方劑為弱推薦，可供參考及加減使用：真武湯、桂枝加附子湯、縮泉丸。（參見附錄 D）

5.2 中成藥治療

5.2.1 肺氣虛弱，外感風寒證

辛芩顆粒（膠囊/片）（GRADE-TCM 1C：強推薦，證據級別 C）。

5.2.2 肺經伏熱，上犯鼻竇證

通竅鼻炎顆粒（膠囊/片）（GRADE-TCM 1C：強推薦，證據級別 C）、香菊膠囊（顆粒/片）（GRADE-TCM 2C：弱推薦，證據級別 C）、鼻炎康片（GRADE-TCM 2C：弱推薦，證據級別 C）、蒼耳子鼻炎滴丸（膠囊）（GRADE-TCM 2C：弱推薦，證據級別 C）、辛夷鼻炎丸（GRADE-TCM 2C：弱推薦，證據級別 C）。

5.2.3 脾氣虛弱，清陽不升，水濕泛鼻證

附子理中丸（片）（GRADE-TCM 2E：弱推薦，證據級別 E）。

5.2.4 其他證型

鼻淵通竅顆粒（用於外邪犯肺型）（GRADE-TCM 2C：弱推薦，證據級別 C）。

注：請根據臨床情況，選擇適宜的服用方法和療程。

5.3 針刺治療

5.3.1 毫針常規針刺（GRADE-TCM 1A^U：強推薦，證據級別 A）

肺氣虛弱，外感風寒證患者優先選擇本療法；肺經伏熱，上犯鼻竇證、脾氣虛弱，清陽不升，水濕泛鼻證、腎陽虧虛，鼻竇失溫證患者建議選擇本療法。季節性、常年性、持續性、發作期患者優先選擇本療法；間歇性、靜止期患者建議選擇本療法。

治療時優先局部辨病取穴以通利鼻竇，取迎香、上迎香、印堂、口禾髎；建議辨證取穴以調理體質、扶正祛邪，酌選合谷、足三里、三陰交、肺俞、風池、腎俞、百會、脾俞、列缺、大椎、曲池等穴。建議選擇針刺補瀉手法。

5.3.2 蝶腭神经节针刺（GRADE-TCM 2B：弱推荐，证据级别 B）

各中医证型患者建议选择本疗法。发作期患者优先选择本疗法；季节性、常年性、持续性患者建议选择本疗法。

治疗时建议在此基础上局部辨病取穴毫针常规针刺以通利鼻窍，取迎香、上迎香、印堂、口禾髎；建议在此基础上辨证取穴以调理体质、扶正祛邪，酌选合谷、足三里、三阴交、肺俞、风池、肾俞、百会、脾俞、列缺、大椎、曲池等穴。

5.3.3 毫针电针刺（GRADE-TCM 2C：弱推荐，证据级别 C）

各中医证型患者建议选择本疗法。季节性、常年性、间歇性、持续性、发作期患者建议选择本疗法。

治疗时优先局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂、口禾髎；建议辨证取穴以调理体质、扶正祛邪，酌选合谷、足三里、三阴交、肺俞、风池、肾俞、百会、脾俞、曲池等穴。建议选择针刺补泻手法，建议根据病情选择不同的电刺激频率。

5.3.4 毫针温针灸（GRADE-TCM 2C：弱推荐，证据级别 C）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者可考虑选择本疗法。各西医分型、分期患者可考虑选择本疗法。

治疗时建议局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂；建议辨证取穴以调理体质、扶正祛邪，酌选合谷、足三里、三阴交、曲池等穴。建议艾柱燃烧端灸光直接照射穴区皮肤，建议考虑减少艾烟对患者可能的不良影响。

5.4 灸法治疗

5.4.1 热敏灸（GRADE-TCM 1C：强推荐，证据级别 C）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者优先选择本疗法。季节性、常年性、间歇性、持续性、发作期患者优先选择本疗法；静止期患者建议选择本疗法。

治疗时建议局部辨病取穴以通利鼻窍，取迎香、印堂、上迎香、上印堂；建议辨证取穴以调理体质、扶正祛邪，酌情选配肺俞、通天、神阙、上星、风池、蝶腭穴（新吾穴）、大椎、足三里等穴。建议艾柱燃烧端灸光直接照射穴区皮肤，建议考虑减少艾烟对患者可能的不良影响。

儿童患者建议选择本疗法。

5.4.2 常规艾条悬灸（GRADE-TCM 2B^U：弱推荐，证据级别 B）

肺气虚弱，外感风寒证、肾阳亏虚，鼻窍失温证患者优先选择本疗法；脾气虚弱，清阳不升，水湿泛鼻证患者建议选择本疗法。同时，常年性、持续性、静止期患者优先选择本疗法；季节性、间歇性、发作期患者建议选择本疗法。

治疗时建议局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂；优先辨证取穴以调理体质、扶正祛邪，酌选百会、膈俞、上星、悬钟、合谷、足三里、三阴交、涌泉、内关、风池、大椎、肺俞、胆俞、肾俞等穴。建议艾柱燃烧端灸光直接照射穴区皮肤，建议考虑减少艾烟

对患者可能的不良影响。

儿童及妊娠期患者建议选择本疗法。

5.4.3 雷火灸悬灸（GRADE-TCM 2C：弱推荐，证据级别 C）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者建议选择本疗法。各西医分型、分期患者建议选择本疗法。

治疗时优先局部辨病取穴以通利鼻窍，取印堂、迎香、上迎香、素髻、睛明；优先辨证取穴以调理体质、扶正祛邪，酌选上星、合谷、列缺、肺俞、大椎、风门、膏肓、攒竹、肾俞、中脘、关元、气海等穴。建议艾柱燃烧端灸光直接照射穴区皮肤，优先考虑减少艾烟对患者可能的不良影响。

儿童患者建议选择本疗法。

5.4.4 隔物灸（GRADE-TCM 2C：弱推荐，证据级别 C）

脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者优先选择本疗法；肺气虚弱，外感风寒证患者建议选择本疗法。各西医分型、分期患者建议选择本疗法。

治疗时建议局部辨病取穴以通利鼻窍，取迎香、印堂、上迎香；优先辨证取穴以调理体质、扶正祛邪，酌选列缺、合谷、尺泽、足三里、三阴交、神阙、关元、大椎、肺俞、风门、脾俞、肾俞等穴。优先基于患者病情、证型等个性化选择隔物（如姜片、蒜片、附子饼或盐等），优先考虑减少艾烟对患者可能的不良影响。

5.4.5 督灸（GRADE-TCM 2C：弱推荐，证据级别 C）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者优先选择本疗法。季节性、常年性患者优先选择本疗法；间歇性、持续性、静止期、发作期患者建议选择本疗法。

治疗时建议在此基础上局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂；建议辨证取穴以调理体质、扶正祛邪，酌选列缺、合谷、尺泽、足三里、三阴交、神阙、关元等穴。优先考虑减少艾烟对患者可能的不良影响。

5.5 其他中医外治法

5.5.1 中药成分穴位注射（GRADE-TCM 1B^U：强推荐，证据级别 B）

肺气虚弱，外感风寒证患者优先选择本疗法；肺经伏热，上犯鼻窍证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者建议选择本疗法。季节性、常年性、持续性、发作期患者优先选择本疗法；间歇性、静止期患者建议选择本疗法。

治疗时优先局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂；建议辨证取穴以调理体质、扶正祛邪，酌情选配合谷、足三里、三阴交、肺俞、风池、肾俞、脾俞、列缺等穴。建议辨证选取中药注射液，如黄芪注射液、当归注射液、川芎注射液、鱼腥草注射液、柴胡注射液、丹参注射液、红花注射液等。

5.5.2 揶针（GRADE-TCM 2B：弱推荐，证据级别 B）

各中医证型患者建议选择本疗法。季节性、间歇性、持续性、发作期患者建议选择本疗法。

治疗时优先局部辨病取穴以通利鼻窍，取迎香、上迎香、印堂、口禾髎；建议辨证取穴以调理体质、扶正祛邪，酌选合谷、足三里、三阴交、肺俞、风池、肾俞、百会、脾俞、列缺、大椎、曲池等穴。

儿童患者建议选择本疗法。

5.5.3 穴位埋线（GRADE-TCM 2B：弱推荐，证据级别 B）

各中医证型患者建议选择本疗法。季节性、常年性、持续性、发作期患者建议选择本疗法。

治疗时建议局部辨病取穴以通利鼻窍，取迎香、印堂；优先辨证取穴以调理体质、扶正祛邪，酌选肺俞、足三里、大椎、肾俞、脾俞、关元、曲池等穴。

5.5.4 中药穴位敷贴（GRADE-TCM 1B：强推荐，证据级别 B）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者优先选择本疗法；肺经伏热，上犯鼻窍证患者建议选择本疗法。季节性、常年性患者优先选择本疗法；间歇性、持续性、静止期、发作期患者建议选择本疗法。

治疗时优先辨病取穴以通利鼻窍，取迎香、印堂；优先辨证选取其它穴位以调理体质、扶正祛邪，酌选风门、足三里、肺俞、脾俞、膈俞、膏肓、大椎、身柱、气海、关元、肾俞、定喘等穴。除使用常规刺激性中药（白芥子、细辛、甘遂、延胡索）以刺激穴位外，优先辨证选取其它中药（酌情选配黄芪、白术、防风、甘草、荆芥、人参、桂枝、生姜、辛夷、黄芩、山栀、知母、枇杷叶、黄柏、牡丹皮、当归、茯苓等）以调理体质、扶正祛邪。

儿童患者优先选择本疗法，妊娠期患者建议选择本疗法。

5.5.5 耳穴压丸（GRADE-TCM 2B：弱推荐，证据级别 B）

各中医证型及各西医分型、分期患者建议选择本疗法。

治疗时优先辨病取穴以通利鼻窍，取内鼻、外鼻；建议辨证取穴以调理体质、扶正祛邪，酌选肺、肾、脾、肾上腺、风溪、神门、内分泌、皮质下等穴。优先辨病或辨证选取耳穴的基础上，结合压痛感或耳穴探测仪选取耳穴阿是点。

儿童患者优先选择本疗法，妊娠期患者建议选择本疗法。

5.5.6 推拿按摩（GRADE-TCM 2B^U：弱推荐，证据级别 B）

肺气虚弱，外感风寒证、脾气虚弱，清阳不升，水湿泛鼻证、肾阳亏虚，鼻窍失温证患者建议选择本疗法。季节性、常年性、间歇性、持续性、发作期患者建议选择本疗法。

治疗时优先辨病取穴以通利鼻窍，取迎香、上迎香、印堂；优先辨证取穴以调理体质、扶正祛邪，酌选上星、囟会、合谷、曲池、风池、足三里、大椎、肺俞、膈俞、夹脊等穴区。优先选择推拿按摩的补泻手法。

儿童患者优先选择本疗法，妊娠期患者建议选择本疗法。

5.5.7 中药成分液体滴鼻（GRADE-TCM 2C：弱推荐，证据级别 C）

各中医证型及各西医分型、分期患者建议选择本疗法。

建议选择以下中药成分滴鼻剂：葱白滴鼻液、滴鼻灵滴鼻液、辛夷滴鼻液、紫草苍耳子油滴鼻液。治疗时建议辨病选择通利鼻窍的中药成分（如苍耳子、辛夷、薄荷、白芷、路路通、鹅不食草、藿香）滴鼻剂。

5.5.8 鼻部中药成分雾化熏蒸（GRADE-TCM 2D：弱推荐，证据级别 D）

各中医证型及各西医分型、分期患者建议选择本疗法。

治疗时建议辨病选择通利鼻窍的中药成分（如苍耳子、辛夷、薄荷、白芷、路路通、鹅不食草、藿香）熏蒸剂；建议辨证选择其它中药成分（酌情选配黄芪、白术、防风、荆芥、人参、桂枝、生姜、辛夷、黄芩、山栀、知母、枇杷叶、黄柏、牡丹皮、当归、茯苓等）熏蒸剂以调理体质、扶正祛邪。

儿童及妊娠期患者建议选择本疗法。

5.6 中医传统功法

5.6.1 太极拳（GRADE-TCM 2E：弱推荐，证据级别 E）

各中医证型及各西医分型、分期患者建议选择本疗法。

5.6.2 八段锦（GRADE-TCM 2E：弱推荐，证据级别 E）

各中医证型及各西医分型、分期患者建议选择本疗法。

6 疗效判定

变应性鼻炎中医药诊疗核心结局指标集（COS-AR-TCM）参见附录 G。

附录 A

(资料性)

医药国际循证证据评价标准

A.1 GRADE 循证证据评价标准

GRADE 循证证据评价标准遵从 GRADE 协作组循证证据质量评价指南,包括“⊕⊕⊕⊕(高级/4分)”、“⊕⊕⊕○(中级/3分)”、“⊕⊕○○(低级/2分)”和“⊕○○○(极低级/1分)”4个等级,初始评级为高级/4分,采取减分制,具体内容见表 A.1。

表 A.1: GRADE 循证证据评价标准

| 降级/升级因素 | 表示方法 |
|--|-------|
| 可能降低证据质量等级的因素 | |
| 1.研究的局限性 | |
| ·严重 | 减 1 分 |
| ·极其严重 | 减 2 分 |
| 2.研究结果的不一致 | |
| ·严重 | 减 1 分 |
| ·极其严重 | 减 2 分 |
| 3.不能确定是否为直接证据 | |
| ·严重 | 减 1 分 |
| ·极其严重 | 减 2 分 |
| 4.精确度不够或置信区间较宽 | |
| ·严重 | 减 1 分 |
| ·极其严重 | 减 2 分 |
| 5.存在发表偏倚 | |
| ·严重 | 减 1 分 |
| ·极其严重 | 减 2 分 |
| 可能增加证据质量等级的因素 | |
| 1.效应值 | |
| ·大: 2 个或 2 个以上研究的证据一致显示 $RR>2$ 或 $RR<0.5$, 且几乎无混杂因素 | 加 1 分 |
| ·很大: 直接证据显示 $RR>5$ 或 $RR<0.2$, 且不影响其真实性 | 加 2 分 |
| 2.可能的混杂因素会降低疗效 | 加 1 分 |
| 3.剂量-效应关系: 干预措施“剂量”及其效应大小有明显关联 | 加 1 分 |

A.2 GRADE-TCM 循证证据升级条目

GRADE-TCM 循证证据升级条目的选择在本文件专家组讨论与专家方法学共识的基础上,综合参照刘建平教授编写的《传统医学证据体的构成及证据分级的建议》、汪受传教授编写的《“古今医家经验”融入循证中医临床实践指南的方法学探讨》。升级条目充分考虑中医药指南临床证据组成多元性的特点,以及中医药古籍及名家经验传承性的特色,注重在评级中“以 GRADE 为主保持国际化,以权威客观资料为辅减少证据偏移,以古代文献为彰显显传承性”,具体内容见表 A.2。

表 A. 2: GRADE-TCM 循证证据升级条目

| 编号 | 条目 | 符合该条目升级原则的说明 |
|-----|--------------|--|
| I | 公开出版教材纳入 | <p>基于查阅纳入参考范围的 29 部已出版教材，发现干预措施用于变应性鼻炎的明确记录。</p> <p>在此基础上需符合该干预措施在参考教材中被明确记录的频数排序，即：B 级证据拟升 A 级证据的干预措施其教材中记录频数需处于各干预措施(有教材记录的)记录频数排序的前 25%。同理，C 级证据拟升 B 级证据则需为记录频数排序的前 50%，D 级证据拟升 C 级证据则需为记录频数排序的前 75%，E 级证据拟升 D 级证据则需至少有 1 部已出版教材明确记录。</p> |
| II | 既往指南/共识/标准推荐 | <p>基于查阅纳入参考范围的 50 部指南/共识/标准，发现干预措施用于变应性鼻炎的明确推荐。</p> |
| III | 古代文献记载 | <p>基于电脑检索由 1156 本医学古籍组成的数据库，以及手工检索相关古籍，发现干预措施用于变应性鼻炎的明确记载。</p> <p>相关干预措施的历代名称通过检索现代文献库及查阅相关资料获得，疾病名称对应古籍中“鼻鼽”病，及部分“涕”、“嚏”之病症。</p> |
| IV | 近现代中医药名家医案疗效 | <p>基于电脑检索在线医案数据库（古今医案云平台、名老中医学术经验国家服务平台、中医古籍医案数据库）及相关文献报告，以及手工检索相关医案集、学术经验集，发现干预措施用于变应性鼻炎的明确验案。</p> <p>此处的中医药名家包含国医大师、国家级名中医、省级十大名中医、省级名中医，全国名老中医药专家学术经验继承工作指导老师，省级学术技术带头人，国家岐黄学者，享受国务院特殊津贴的中医药专家，以及虽不符合以上认定但享有较高公认声誉的近代中医名家。</p> |

A. 3 GRADE-TCM 循证证据评价标准

GRADE-TCM 循证证据评价标准的制定在本文件专家组讨论与专家方法学共识的基础上，综合参照何庆勇、王阶教授编写的《中医临床证据分级与评分体系研究》、袁敬柏教授编写的《建立适合中医临床诊疗证据评价方法的建议》、李敬华教授编写的《中医治疗文献质量评价方法及应用研究》。同时，“从 GRADE 中来，到 GRADE 中去”，参考 GRADE 循证证据升级方法，以及减少 GRADE-TCM 循证证据升级条目对 GRADE 评级的过度影响，提高本文件的国际认可度，专家组讨论规定基于 GRADE-TCM 循证证据升级条目最多升 1 级，具体内容见表 A.3。

表 A. 3 GRADE-TCM 循证证据评价标准

| 初始 GRADE 证据评级 | 升级判定条件 | GRADE-TCM 证据评级 |
|---------------|--------|----------------|
|---------------|--------|----------------|

| | | | |
|---------|--|---|--------------------------|
| GRADE A | / | | GRADE-TCM A |
| GRADE B | 是否同时符合 GRADE-TCM 循证证据升级条目 中 I、II、III、IV 共 4 项 | 是 | GRADE-TCM A ^U |
| GRADE B | | 否 | GRADE-TCM B |
| GRADE C | 是否同时符合 GRADE-TCM 循证证据升级条目 中 I、II、III、IV 中任意 3 项 | 是 | GRADE-TCM B ^U |
| GRADE C | | 否 | GRADE-TCM C |
| GRADE D | 是否同时符合 GRADE-TCM 循证证据升级条目 中 I、II、III、IV 中任意 2 项 | 是 | GRADE-TCM C ^U |
| GRADE D | | 否 | GRADE-TCM D |
| GRADE E | 是否同时符合 GRADE-TCM 循证证据升级条目 中 I、II、III、IV 中任意 1 项 | 是 | GRADE-TCM D ^U |
| GRADE E | | 否 | GRADE-TCM E |

符合上述相应 GRADE-TCM 循证证据评价标准且其循证证据评级已升级的干预措施会通过上标“^U”（Upgrade）以说明（如“GRADE-TCM 1A^U”、“GRADE-TCM 2B^U”）。此外，当某一干预措施无相关随机对照试验（RCT）纳入，而仅有如非随机（或半随机）对照试验、病例对照试验、病例报告、综述等文献支撑时，予以 GRADE-TCM E 评级。

GRADE-TCM

附录 B
(资料性)
专家共识及推荐原则

B.1 总体原则

本文件专家共识的实施过程采取“德尔菲法”，线上、线下相结合进行。共识推荐结果的达成与判定参考中华中医药学会“形成推荐意见和共识建议”。

共识专家基于临床和(或)科研经验、理论分析、文献记载等，权衡利弊，分别于问卷中各条目勾选非常重要(一定利大于弊)、比较重要(可能利大于弊)、一般(利弊关系不确定,或无明显差异)、比较不重要(可能弊大于利)、非常不重要(一定弊大于利),分别记5、4、3、2、1分。空白选项记录为弃权。统计各条目获投“非常重要”百分比、“比较重要”百分比、“高重要性”百分比、“一般”百分比、“比较不重要”百分比、“非常不重要”百分比、“低重要性”百分比。

B.2 共识建议

如为有GRADE证据支持类条目(各中医药干预措施)时,则结合GRADE-TCM循证证据形成专家推荐意见;如为无GRADE证据支持类条目(如诊断、GRADE-TCM方法学、COS-AR-TCM结局指标)时,则结合相关资料形成专家共识建议。当除“一般”选项外,条目任一选项,即“非常重要”、“比较重要”、“比较不重要”或“非常不重要”,得票百分比大于50%,则达成该共识;此外,当任意一侧,即“高重要性”(“非常重要”+“比较重要”)或“低重要性”(“比较不重要”+“非常不重要”),得票百分比大于等于70%,也可达成相应共识(“弱推荐/可考虑选择”或“弱不推荐/不建议”),否则视为未达成共识。

最终产生的专家推荐意见共4级,对应各重要性(即“非常重要”、“比较重要”、“比较不重要”、“非常不重要”)分别为“强推荐”、“弱推荐”、“弱不推荐”、“强不推荐”。

最终产生的专家共识建议共4级,对应各重要性(即“非常重要”、“比较重要”、“比较不重要”、“非常不重要”)分别为“优先选择”、“建议选择”、“不建议选择”、“不宜选择”。

B.3 变异系数及多轮问卷

统计各条目得分投票数、得分均数(mean)、得分标准差(SD)及得分变异系数(CV)。未达成共识的共识建议或推荐意见,经由本文件专家组确认后予以删除;达成共识且变异系数小于等于0.3的条目,经本文件专家组确认后予以纳入;达成共识但变异系数大于0.3的条目,经本文件专家组讨论或作必要修改后,予以下一轮共识投票或删除。

此外,在变应性鼻炎中医药诊疗核心结局指标集(COS-AR-TCM)的开发中,为提高共识准确性,对参与第一轮投票的条目进行了二轮可重复性测量。同时,各共识的二轮问卷也对一轮问卷中新提出的条目进行了投票与共识。

附录 C

(资料性)

变应性鼻炎西医诊断及分型、分期、分度

C.1 临床表现

C.1.1 病史

变应性鼻炎的诊断应重视患者的个人、家族相关过敏性疾病史。此外酌情询问患者过量或长期使用鼻用减充血剂史，排除药物性鼻炎的相关症状（主要为反跳性鼻塞）。

C.1.2 症状

变应性鼻炎主要症状包括鼻塞、鼻痒、鼻流清涕、连续性喷嚏，部分患者可见眼痒、眼部沙粒异物感及揉擦导致的眼部红肿、流泪。过敏严重者可见在无明显其它原因下经常清嗓子，甚至咳嗽。

C.1.3 体征

变应性鼻炎主要体征可见鼻黏膜的颜色（如苍白、暗红）和（或）形态（如肿胀）异常，下鼻甲、中鼻甲和（或）鼻中隔的异常体征（如肥大），以及下鼻道和（或）中鼻道相关异常情况。亦可见鼻腔分泌物的数量和（或）形态异常。

C.2 理化检查

C.2.1 过敏原检测

- a) 常见过敏原皮肤点刺试验（SPT）：SPT 具有高敏感性和较高特异性，一般均在 80% 以上，因而对 AR 的诊断可提供有价值的证据。在此基础上，该检测既可测出对某种过敏原过敏与否，也可定量评价其反应强度。
- b) 常见过敏原皮内试验：临床较少使用，因其与症状间的关联性较弱，且可能出现假阳性反应甚至全身性不良反应。
- c) 过敏原挑战测试（包括过敏原激发测试、局部过敏原激发试验）：是诊断变应性鼻炎的金标准，可寻找关键致敏原。尤其适用于病史、临床表现上高度怀疑本病，而 SPT 及血清特异性 IgE 阴性的局部变应性鼻炎患者。

C.2.2 IgE 检测

- a) 血清过敏原特异性 IgE 检测阳性：敏感性、特异性较高，广泛用于本病的临床诊断。但其水平值与疾病严重程度不一定相关，且特异性 IgE 阳性也不一定会引起临床症状。
- b) 血清总 IgE 检测阳性：临床较少使用，因其敏感性、特异性均较差。
- c) 鼻分泌物特异性 IgE 检测阳性：对变应性鼻炎的鉴别诊断有一定临床价值。

C.2.3 其他实验室检查

其他实验室检查通常不推荐作为常规使用，仅在病史询问、临床表现、过敏原检测、IgE 检测等其他检查有疑问时才酌情考虑使用，如鼻分泌物嗜酸性粒细胞测试、黏液纤毛功能检测、鼻声反射、嗅觉测试、芯片测试、鼻一氧化氮检测。

C.3 儿童变应性鼻炎诊断

儿童变应性鼻炎的诊断方法总体与成人相似。儿童可见变态反应性着色，即眼眶下有灰

蓝色环形暗影和皱褶。

C.4 鉴别诊断

若患者出现双侧鼻塞，主要需要排除鼻息肉、鼻中隔偏曲；而出现单侧鼻塞主要需要排除鼻中隔偏曲、异物、后鼻孔息肉和肿瘤。

单侧鼻流清涕少见，若患者近期存在头颅外力损伤史，应在简要筛查（如“坐位前倾试验”）的基础上酌情考虑颅底影像学检查，排除脑脊液泄漏。若患者出现鼻流黄涕，则既可见于感染也可见于变应性鼻炎，但应该注意是否排除合并急慢性鼻窦炎；若为单侧淡血色涕，需要排除单侧肿瘤、异物、挖鼻或过用鼻喷雾剂等。

C.5 西医分型

a) 根据变应原种类分型：

——常年性变应性鼻炎，症状常年性发作，常见过敏原为尘螨、蟑螂、动物皮屑等，以室内常年性吸入过敏原以及某些职业性过敏原为主。

——季节性变应性鼻炎，症状季节性发作，常见过敏原为花粉、真菌等，以季节性吸入过敏原为主，具有地区性特征。

b) 根据症状发作时间分型：

——间歇性变应性鼻炎，症状每周发作时间小于 4 天，或症状的连续持续时间小于 4 周。

——持续性变应性鼻炎，症状每周发作时间大于 4 天，且症状的连续持续时间大于等于 4 周。

c) 根据主要症状分型：

——喷嚏、鼻流清涕型，症状以喷嚏、鼻流清涕为主，主要因组胺作用。

——鼻塞型，症状以鼻塞为主，主要因白三烯或其他脂质介质作用。

——复合型，不同症状的重要性介于以上二者之间。

C.6 西医分期

根据是否处于发作状态分期为发作期和静止期。

C.7 西医分度

根据临床表现严重程度及其对生活的影响分度：

a) 轻度：症状轻微，对患者生活质量未产生明显影响。

b) 中-重度：症状较重或严重，对患者生活质量产生明显影响。

附录 D
(资料性)
弱推荐方药

D.1 肺气虚弱，外感风寒证

- a) 桂枝汤（《伤寒论》）。桂枝、芍药、甘草、大枣、生姜。（GRADE-TCM 2B^U：弱推荐，证据级别 B）
- b) 麻黄附子细辛汤（《三因极一病证方论》）。麻黄、附子、细辛。（GRADE-TCM 2C^U：弱推荐，证据级别 C）
- c) 补中益气汤（《内外伤辨惑论》）。黄芪、人参、白术、炙甘草、当归、陈皮、升麻、柴胡、生姜、大枣。（GRADE-TCM 2B^U：弱推荐，证据级别 B）
- d) 苍耳子散（《重订严氏济生方》）。苍耳子、辛夷、薄荷、白芷。（GRADE-TCM 2B^U：弱推荐，证据级别 B）
- e) 小青龙汤（《太平惠民和剂局方》）。麻黄、芍药、细辛、干姜、炙甘草、桂枝、五味子、半夏。（GRADE-TCM 2C：弱推荐，证据级别 C）
- f) 川芎茶调散（《太平惠民和剂局方》）。川芎、白芷、羌活、细辛、防风、荆芥、薄荷、甘草。（GRADE-TCM 2C：弱推荐，证据级别 C）
- g) 苓甘五味姜辛汤（《金匱要略》）。茯苓、甘草、五味子、干姜、细辛。（GRADE-TCM 2E：弱推荐，证据级别 E）

D.2 肺经伏热，上犯鼻窍证

苍耳子散（《重订严氏济生方》）。苍耳子、辛夷、薄荷、白芷。（GRADE-TCM 2B^U：弱推荐，证据级别 B）

D.3 脾气虚弱，清阳不升，水湿泛鼻证

- a) 理中汤（《伤寒论》）。人参、白术、炙甘草、干姜。（GRADE-TCM 2D^U：弱推荐，证据级别 D）
- b) 玉屏风散（《究原方》）。黄芪、白术、防风。（GRADE-TCM 2B^U：弱推荐，证据级别 B）
- c) 四君子汤（《太平惠民和剂局方》）。人参、白术、茯苓、甘草。（GRADE-TCM 2C：弱推荐，证据级别 C）
- d) 缩泉丸（《医方考》）。乌药、山药、益智仁。（GRADE-TCM 2C：弱推荐，证据级别 C）

D.4 肾阳亏虚，鼻窍失温证

- a) 真武汤（《伤寒论》）。茯苓、芍药、生姜、附子、白术。（GRADE-TCM 2C：弱推荐，证据级别 C）
- b) 桂枝加附子汤（《伤寒论》）。桂枝、芍药、甘草、生姜、大枣、附子。（GRADE-TCM 2C：弱推荐，证据级别 C）
- c) 缩泉丸（《医方考》）。乌药、山药、益智仁。（GRADE-TCM 2C：弱推荐，证据级别 C）

附录 E

(资料性)

摘要性快速推荐表

表 E. 1: 变应性鼻炎强推荐中医药疗法

| 综合推荐等级 | 类型 | 干预措施 | |
|-----------------|---------------------|-------------------------------|---|
| GRADE-TCM 1A | 毫针普通针刺 ^U | | |
| GRADE-TCM 1B | 中药方剂（非中成药）口服 | 肺气虚弱，外感风寒证 | 玉屏风散 ^U （《究原方》）、温肺止流丹 ^U （《辨证录》） |
| | | 脾气虚弱，清阳不升，水湿泛鼻证 | 补中益气汤 ^U （《内外伤辨惑论》）；参苓白术散 ^U （《太平惠民和剂局方》） |
| | | 肾阳亏虚，鼻窍失温证 | 右归丸（《景岳全书》） ^U |
| | 中医外治法 | 中药成分穴位注射 ^U 、中药穴位敷贴 | |
| GRADE-TCM 1C | 中药方剂（非中成药）口服 | 肺经伏热，上犯鼻窍证 | 辛夷清肺饮（《外科正宗》） |
| | 中成药的应用 | 辛芩颗粒（胶囊/片）、通窍鼻炎颗粒（胶囊/片） | |
| | 中医外治法 | 热敏灸 | |
| GRADE-TCM 1D/1E | 中药方剂（非中成药）口服 | 肾阳亏虚，鼻窍失温证 | 金匮肾气丸（《金匮要略》）GRADE-TCM 1D ^U |

表 E. 2 变应性鼻炎弱推荐中医药疗法

| 综合推荐等级 | 类型 | 干预措施 | |
|--------------|--------------|---|--|
| GRADE-TCM 2B | 中药方剂（非中成药）口服 | 肺气虚弱，外感风寒证 | 桂枝汤 ^U （《伤寒论》）、补中益气汤 ^U （《内外伤辨惑论》）、苍耳子散 ^U （《重订严氏济生方》） |
| | | 肺经伏热，上犯鼻窍证 | 苍耳子散 ^U （《重订严氏济生方》） |
| | | 脾气虚弱，清阳不升，水湿泛鼻证 | 玉屏风散 ^U （《究原方》） |
| | 中医外治法 | 蝶腭神经节针刺、常规艾条悬灸 ^U 、揶针、穴位埋线、耳穴压丸、推拿按摩 ^U | |
| GRADE-TCM 2C | 中药方剂（非中成药）口服 | 肺气虚弱，外感风寒证 | 麻黄附子细辛汤 ^U （《三因极一病证方论》）、小青龙汤（《太平惠民和剂局方》）、川芎茶调散（《太平惠民和剂局方》） |
| | | 脾气虚弱，清阳不升，水湿泛鼻证 | 四君子汤（《太平惠民和剂局方》）、缩泉丸（《医方考》） |
| | | 肾阳亏虚，鼻窍失温证 | 真武汤（《伤寒论》）、桂枝加附子汤（《伤寒论》）、缩泉丸（《医方考》） |
| | 中成药的应用 | 香菊胶囊（颗粒/片）、鼻炎康片、苍耳子鼻炎滴丸（胶囊）、辛夷鼻炎丸、鼻渊通窍颗粒 | |

| | | | |
|--------------------|------------------|-----------------------------------|-------------------------------|
| | 中医外治法 | 毫针电针刺、毫针温针灸、雷火灸悬灸、隔物灸、督灸、中药成分液体滴鼻 | |
| GRADE-TCM 2D/2E | 中药方剂 (非中成药)口服 | 肺气虚弱, 外感风寒证 | 苓甘五味姜辛汤 (《金匮要略》) GRADE-TCM 2E |
| | | 脾气虚弱, 清阳不升, 水湿泛鼻证 | 理中汤 ^u (《伤寒论》) |
| | 中成药的应用 | 附子理中丸 (片) GRADE-TCM 2E | |
| | 中医外治法 | 鼻部中药成分雾化熏蒸 GRADE-TCM 2D | |
| | 传统功法 | 太极拳 GRADE-TCM 2E、八段锦 GRADE-TCM 2E | |

WVFCM

附录 F
(资料性)

针对变应性鼻炎特殊人群的中医外治法、传统功法共识

表 F. 1 儿童变应性鼻炎患者中医外治法、传统功法共识情况

| | |
|------|--------------------------------|
| 共识强度 | 干预措施 |
| 优先选择 | 中药穴位敷贴、耳穴压丸、推拿按摩 |
| 建议选择 | 热敏灸、常规艾条悬灸、雷火灸悬灸、揸针、鼻部中药成分雾化熏蒸 |

表 F. 2 妊娠期变应性鼻炎患者中医外治法、传统功法共识情况

| | |
|------|------------------------------------|
| 共识强度 | 干预措施 |
| 建议选择 | 常规艾条悬灸、中药穴位敷贴、耳穴压丸、推拿按摩、鼻部中药成分雾化熏蒸 |

WJECM

附录 G

(资料性)

变应性鼻炎中医药诊疗核心结局指标集

变应性鼻炎中医药诊疗核心结局指标集可见表 G.1。

表 G.1 变应性鼻炎中医药诊疗核心结局指标集

| 条目 | 重要性 | |
|----------------|---|--------|
| 症状类结局指标 | 鼻塞的变化 | 关键 |
| | 鼻痒的变化 | 关键 |
| | 鼻涕增多或鼻流清涕的变化 | 关键 |
| | 阵发性喷嚏的变化 | 关键 |
| | 眼痒的变化 | 重要但不关键 |
| | 嗅觉减退、障碍的变化 | 重要但不关键 |
| | 咽痒的变化 | 重要但不关键 |
| | 眼畏光的变化 | 一般且不重要 |
| | 眼灼热的变化 | 一般且不重要 |
| 鼻部疼痛的变化 | 一般且不重要 | |
| 中医特色类结局指标 | 中医证素(证型)评分的变化 注：选用中医体质与分类评分(九种体质)，对 8 种偏颇体质同平和体质(理想健康体质)之间的转化情况进行量化评估，意义在于评估中医药疗法对变应性鼻炎患者整体体质(证型)偏颇的改善 | 关键 |
| | 西药使用总评分(“三步法”)的变化 注：用于研究中医药疗法(或辅助使用时)减少西药的用量、频率及(或)使用时间，即使用口服和(或)局部抗组胺药(鼻用或眼用)，每天计 1 分；鼻用糖皮质激素，每天计 2 分；口服糖皮质激素，每天计 3 分。若合并哮喘，使用 β_2 受体激动剂，每天计 1 分；吸入糖皮质激素，每天计 2 分。所有用药记录总评分即为药物使用总评分 | 关键 |
| 鼻部体征类结局指标 | 鼻粘膜肿胀的变化 | 关键 |
| | 鼻粘膜苍白的变化 | 关键 |
| | 鼻粘膜充血的变化 | 关键 |
| | 鼻腔分泌物量的变化 | 关键 |
| | 鼻腔水样分泌物的性质变化 | 关键 |
| 过敏原相关结局指标 | 常见过敏原皮肤点刺试验(SPT)结果 | 关键 |
| | 常见过敏原血清特异性 IgE 水平的变化 | 关键 |
| | 常见过敏原皮内试验结果 | 重要但不关键 |
| | 血清总 IgE 水平的变化 | 重要但不关键 |
| 实验室检查相关结局指标 | 常见过敏原鼻激发试验结果 | 重要但不关键 |
| | 血清 Th1/Th2 比例的变化 | 关键 |
| | 血清 IL-4 水平的变化 | 重要但不关键 |
| | 血清 IL-5 水平的变化 | 重要但不关键 |
| | 血清 IL-10 水平的变化 | 重要但不关键 |
| 血清 IL-17 水平的变化 | 重要但不关键 | |

| | | |
|------------|--|--------|
| | 血清 Th1 水平的变化 | 重要但不关键 |
| | 血清 Th2 水平的变化 | 重要但不关键 |
| | 血清 IFN- γ 水平的变化 | 重要但不关键 |
| | 血清 TGF- β 水平的变化 | 重要但不关键 |
| | 血清 TNF- α 水平的变化 | 重要但不关键 |
| | 血清 EOS 水平的变化 | 重要但不关键 |
| | 血 T 细胞分化抗原(包括 CD3+、CD4+、CD8+、CD4+/CD8+)水平的变化 | 重要但不关键 |
| | 鼻分泌物涂片细胞学检查结果 | 重要但不关键 |
| | 鼻灌洗液常见过敏原特异性 IgE 水平的变化 | 重要但不关键 |
| 其他检查相关结局指标 | 肺功能检查结果 | 一般且不重要 |
| | 鼻黏膜纤毛传输时间(MTT)水平的变化 | 一般且不重要 |
| | 鼻黏膜纤毛清除速率(MCV)水平的变化 | 一般且不重要 |
| 生活质量相关结局指标 | RQLQ 量表评分的变化 注：包括鼻部症状评分、眼部症状评分、非鼻眼部症状评分、行为问题评分、睡眠评分、日常活动评分、情感反应评分 | 关键 |
| | Mini-RQLQ 评分的变化 | 重要但不关键 |
| | 夜间鼻结膜炎生活质量问卷(NRQLQ) 评分的变化 注：包括 4 个领域的 16 个项目(睡眠问题、睡眠期间的症状，醒着的症状和实践问题) | 重要但不关键 |
| | 抑郁自评量表(SDS)评分的变化 | 一般且不重要 |
| | 焦虑自评量表(SAS)评分的变化 | 一般且不重要 |
| | 明尼苏达多相人格量表(MMPI)评分的变化 | 一般且不重要 |

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Foreword

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. World Federation of Chinese Medicine Societies (WFCMS) shall not be held responsible for identifying any or all such patent rights.

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WFCM

Introduction

This document follows the development norms of international evidence-based guidelines, emphasizes details and practicality of recommendations. With sufficient evidence and good guidance, universality, reference and operability, this document can provide traditional Chinese medicine practitioners with traditional Chinese medicine strategies and methods for clinical diagnosis and treatment of allergic rhinitis on an international scale. This document integrates domestic and international research results and evidence on diagnosis and treatment of allergic rhinitis with traditional Chinese medicine, and combines expert consensus, thus it not only highlights inheritance of traditional Chinese medicine and characteristics of the integration of traditional Chinese medicine with western medicine, but also emphasizes the internationalization of methodology and clinical practice.

At present, *Guidelines for the Diagnosis and Treatment of Common Diseases in Otolaryngology of Traditional Chinese Medicine* (2012 Edition), *Evidence-based Guidelines of Clinical Practice with Acupuncture and Moxibustion: Allergic rhinitis* (2015 Edition), *Traditional Chinese Medicine Practice Guidelines for Prevention and Treatment of Biqu (Allergic rhinitis)* (2018 Edition), and *Clinical Guidelines for Diagnosis and Treatment of Pediatric Diseases in Chinese Medicine: Allergic rhinitis in Children* (2020 Edition), which have been published in China, have played good roles in guiding diagnosis and treatment of allergic rhinitis with traditional Chinese medicine. However, previous clinical guidelines for traditional Chinese medicine are limited due to research conditions, and most of them only rely on expert consensus as recommendation standards, resulting in low international recognition; Some of them only target in specific interventions, patient groups, or intervention concepts.

With the rapid development and application of evidence-based medicine in traditional Chinese medicine research, results with higher levels of evidence continue to emerge. On the basis of previous guidelines, this document extensively solicits consensus from experts, and strictly evaluates the quality of randomized controlled trials related to the traditional Chinese medicine interventions for allergic rhinitis. In the end, we screened out reliable, safe, and easy-to-promote traditional Chinese medicine interventions in high-quality research. At the same time, we carried out exchanges and cooperations with overseas academic groups of traditional Chinese medicine. We combined expert consensus to provide comprehensive evidence and recommendation grading for each included traditional Chinese medicine intervention. This is helpful for better implementing the principles of evidence-based medicine in traditional Chinese medicine clinical practice, so as to standardize doctors' medical behaviors and improve efficacy of traditional Chinese medicine diagnosis and treatment.

In addition, our team collected and summarized methodological problems

related to evidence-based evaluation in previous traditional Chinese medicine clinical guidelines during the development of this document. We strived to seek common ground while reserving differences, to integrate Chinese and western, and analyzed and explored the differences and connections between them and international guidelines. We optimized and designed *the International Grading of Recommendations Assessment, Development and Evaluation Standard for Traditional Chinese Medicine* (GRADE-TCM) based on the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE), which is commonly used in international guidelines, and methodological expert consensus. The GRADE-TCM aims to “maintaining internationalization with GRADE as main focus, reducing evidence bias with authoritative and objective data as a supplement, and highlighting inheritance with ancient literature as reference” (ANNEX A). Meanwhile, by referring to the “Delphi” method and the “nominal group” methods, the processes of expert consensus and recommendation principles in this document were also optimized (ANNEX B). Finally, we followed the principle of “international standards + TCM characteristics” of the *Core Outcome Set in TCM*, and registered and developed the *Core Outcome Set for Allergic Rhinitis* (COS-AR-TCM) through outcome analysis and expert consensus (ANNEX G).

This is a declarative document based on existing research evidence and specific methods. In clinical practice, physicians can refer to this document and provide personalized treatment based on the specific situation of patients.

International guidelines for Clinical Practice of Chinese medicine Allergic rhinitis

1 Scope

This document provides the basic requirements of syndrome differentiation (in traditional Chinese medicine, TCM), diagnosis, classification, staging, grading (in Western medicine), treatment (in TCM), and clinical outcomes for allergic rhinitis.

This document applies to clinical diagnosis, treatment and efficacy evaluation for AR.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ZYYXH/T307-321-2012 Diagnosis and Treatment Guidelines for Common Diseases in Otolaryngology of Traditional Chinese Medicine

ZYYXH/T-473-2015 General principles for the compilation of clinical diagnosis and treatment guidelines in traditional Chinese medicine

ZJ/T-E016-2015 Evidence-based guidelines of clinical practice with acupuncture and moxibustion: allergic rhinitis

3 Terms and Definitions

3.1

Allergic Rhinitis

AR

type I (immediate) allergic disease of nasal mucosa. Typical symptoms of AR include paroxysmal nasal itching, frequent sneezing, large amounts of clear water like mucus, and nasal congestion.

Note: It belongs to the category of "*Bi Qiu*" in TCM, also known as "*Qiu Ti*".

4 Diagnosis

4.1 Syndrome differentiation

4.1.1 Syndrome of lung *qi* deficiency and wind-cold fettering exterior

Patient suffers from paroxysmal nasal itching, frequent sneezing, and (or) a large amount of clear nasal discharge. The nasal mucosa is swollen and pale. Sometimes there is nasal obstruction and (or) decreased sense of smell, which often occurs due to cold wind. The patient often has aversion to wind and cold, and is prone to catch cold, as well as to suffer from fatigue, shortness of breath and (or) spontaneous sweating. The tongue is pale in texture, and white and thin, or slippery in coating, for tongue inspection. The pulse manifestation is weak or (and) floating for pulse diagnosis.

4.1.2 Syndrome of latent heat in lung meridian and attacking nose

Patient suffers from intermittent nasal itching, continuous sneezing, and (or) a large amount of clear or sticky nasal discharge. There is nasal obstruction and sometimes a decreased sense of smell. The nasal mucosa is reddish, and swollen sometimes. The patient suffers from dry mouth, stool stem node probably, and (or) yellow urine. The tongue is red in texture, and is thin and white, or yellow in coating, for tongue inspection. The pulse manifestation is rapid for pulse diagnosis.

4.1.3 Syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose

Patient suffers from severe nasal obstruction, and (or) a large amount of clear or sticky nasal discharge. Sometimes there is nasal itching, continuous sneezing, and (or) a decreased sense of smell. The nasal mucosa is pale or grey, and swollen slightly. The patient suffers from tiredness, fatigue, shortness of breath, poor appetite and (or) loose stool. The tongue texture is pale or also enlarged, and sometimes with teeth-marks. Meanwhile, the tongue coating is white or also thin, for tongue inspection. The pulse manifestation is soggy and moderate, or thready and weak, for pulse diagnosis.

4.1.4 Syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose

Patient suffers from perennial and paroxysmal clear nasal discharge and (or) nasal itching, sometimes with nasal obstruction, continuous sneezing, and (or) a decreased sense of smell. The nasal mucosa is purple or pale, or also swollen. The patient suffers from soreness and (or) weakness of waist and (or) knees, clear

and abundant urine, fearing of cold, or feeling cold. The tongue is pale in texture, and is white or also thin in its coating for tongue inspection. The pulse manifestation is deep and thready, or also weak, for pulse diagnosis.

4.2 Diagnosis, classification, staging and grading in western medicine

See diagnosis, classification, staging and grading of AR in western medicine at ANNEX C.

5 Treatment

5.1 Traditional Chinese medicine prescriptions

5.1.1 Syndrome of lung *qi* deficiency and wind-cold fettering exterior

5.1.1.1 Therapeutic principle

Warming lung and dissipating cold, replenishing *qi* and consolidating exterior.

5.1.1.2 Prescriptions

a) Yupingfeng San (Jade Screen Powder), from *Jiu Yuan Fang (Investigating the Essential Prescription)*: Huang Qi (Milkvetch Root, *Radix Astragaliseu Hedysari*), Bai Zhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Fang Feng (Divaricate Saposhnikovia Root, *Radix Saposhnikoviae*). (GRADE-TCM 1B^U: Strong recommendation, level of evidence: B)

b) Wenfei Zhiliu Dan (Warming Lung *Qi* and Relieving Rhinorrhea Pill), from *Bian Zheng Lu (Treatise on Syndrome Differentiation)*: Ren Shen (Ginseng, *Radix Ginseng*), He Zi (Medicine Terminalia Fruit, *Fructus Chebulae*), Shishouyu'nao'gu (Skull of Drumfish), Jing Jie (Fineleaf Schizonepeta Herb, *Herba Schizonepetae*), Jie Geng (Platycodon Root, *Radix Platycodonis*), Gan Cao (Liquorice Root, *Radix Glycyrrhizae*). (GRADE-TCM 1B^U: Strong recommendation, level of evidence: B)

5.1.1.3 Modifications

For those with severe nasal symptoms, the following supplement can be referred and added: Cang'erzi (Siberian Cocklebur Fruit, *Fructus Xanthii*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Bohe (Peppermint, *Herba Menthae*) and (or) Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*). For those with severe nasal, eye and (or) pharyngeal symptoms, especially with frequent sneezing, the following supplement can be referred and added: Wugong (Centipede, *Scolopendra*), Quaxie (Scorpion, *Scorpio*), Dilong (Earthworm, *Lumbricus*) and (or) Chantui (Cicada Slough, *Periostracum Cicadae*).

5.1.1.4 Other considerations

a) Patients of AR within seasonal, persistent and (or) onset period type is highly suggested to consider this syndrome (mainly) for prescription. Meanwhile, patients of AR within perennial, intermittent and (or) resting period type is

suggested to consider this syndrome (mainly) for prescription.

b) When subject to personal allergy, physical inapplicability, or lack of certain herbs, the following weakly recommended alternative prescriptions can be taken into consideration with modifications: Guizhi Tang (Cinnamon Twig Decoction), Mahuang Fuzi Xixin Tang (Ephedra, Aconite and Asarum Decoction), Buzhong Yiqi Tang (Middle-Tonifying Qi-Replenishing Decoction), Cang'erzi San (Fructus Xanthii Powder), Xiao Qinglong Tang (Minor Green-Blue Dragon Decoction), Chuanxiong Chatiao San (Tea-Blended Ligusticum Powder), Ling Gan Wuwei Jiang Xin Tang (Potia, Licorice, Schisandra, Ginger and Asarum Decoction). (See ANNEX D)

5.1.2 Syndrome of latent heat in lung meridian and attacking nose

5.1.2.1 Therapeutic principle

Clearing heat and dispelling wind, relieving stuffy orifices and improving sneezing.

5.1.2.2 Prescriptions

Xinyi Qingfei Yin (Flos Magnoliae Lung-Clearing Decoction), from *Wai Ke Zheng Zong (Orthodox Manual of External Medicine)*: Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Shanzhi (Cape Jasmine Fruit, *Fructus Gardeniae*), Huangqin (Baical Skullcap Root, *Radix Scutellariae*), Baihe (Lily Bulb, *Bulbus Lili*), Maimendong (Dwarf Lilyturf Tuber, *Radix Ophiopogonis*), Zhimu (Common Anemarrhena Rhizome, *Rhizoma Anemarrhenae*), Shigao (Gypsum, *Gypsum Fibrosum*), Shengma (Largetrifolious Bugbane Rhizome, *Rhizoma Cimicifugae*), Pipaye (Loquat Leaf, *Folium Eriobotryae*), Gancao (Licorice Root, *Radix Glycyrrhizae*). (GRADE-TCM 1C: Strong recommendation, level of evidence: C)

5.1.2.3 Modifications

For those with severe latent heat, the following supplement can be referred and added: Zhimu (Common Anemarrhena Rhizome, *Rhizoma Anemarrhenae*), Huangbai (Amur Cork Tree, *Cortex Phellodendri*) and (or) Mudanpi (Tree Peony Root Bark, *Cortex Moutan Radicis*). For those with latent heat due to *qi* (or *yang*) deficiency, the following supplement can be referred and added: Huangqi (Milkvetc.h Root, *Radix Astragaliseu Hedysari*), Renshen (Ginseng, *Radix Ginseng*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Zhigancao (Licorice Root, *Radix Glycyrrhizae*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*), Chenpi (Dried Tangerine Peel, *Pericarpium Citri Reticulatae*), Shengma (Largetrifolious Bugbane Rhizome, *Rhizoma Cimicifugae*), Chaihu (Chinese Thorowax Root, *Radix Bupleuri*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*) and (or) Dazao (Chinese Date, *Fructus, Jujubae*).

5.1.2.4 Other considerations

a) Patients of AR within seasonal, intermittent and (or) onset period type is suggested to consider this syndrome (mainly) for prescription. Meanwhile,

patients of AR within perennial, persistent and (or) resting period type is suggested not to consider this syndrome (mainly) for prescription.

b) When subject to personal allergy, physical inapplicability, or lack of certain herbs, the following weakly recommended alternative prescriptions can be taken into consideration with modifications: Cang'erzi San (Fructus Xanthii Powder). (See ANNEX D)

5.1.3 Syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose

5.1.3.1 Therapeutic principle

Replenishing *qi* and invigorating spleen, elevating *yang* and resolving dampness.

5.1.3.2 Prescriptions

a) Buzhong Yiqi Tang (Middle-Tonifying *Qi*-Replenishing Decoction), from *Nei Wai Shang Bian Huo Lun (Clarifying Doubts about Damage from Internal and External Causes)*: Huangqi (Milkvetch Root, *Radix Astragaliseu Hedysari*), Renshen (Ginseng, *Radix Ginseng*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Zhigancao (Liquorice Root, *Radix Glycyrrhizae*), Shengma (Large-trifolious Bugbane Rhizome, *Rhizoma Cimicifugae*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*), Chenpi (Dried Tangerine Peel, *Pericarpium Citri Reticulatae*), Chaihu (Chinese Thorowax Root, *Radix Bupleuri*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Dazao (Chinese Date, *Fructus Jujubae*). (GRADE-TCM 1B^U: Strong recommendation, level of evidence: B)

(b) Shen Ling Baizhu San (Ginseng, Poria and White Atractylodes Powder), from *Tai Ping Hui Min He Ji Ju Fang (Formulary of the Bureau of Taiping People's Welfare Pharmacy)*: Renshen (Ginseng, *Radix Ginseng*), Fuling (Indian Bread, *Poria*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Baibiandou (Hyacinth Bean, *Semen Dolichoris Album*), Jiegeng (Platycodon Root, *Radix Platycodonis*), Lianzi (Lotus Seed, *Semen Nelumbinis*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Sharen (Villous Amomum Fruit, *Fructus Amomi Villosi*), Yiyiren (Coix Seed, *Semen Coicis*). (GRADE-TCM 1B^U: Strong recommendation, level of evidence: B)

5.1.3.3 Modifications

For those of onset period type, the following supplement can be referred and added: Xixin (Manchurian Wildginger, *Herba Asari*), Wuweizi (Chinese Magnoliavine Fruit, *Fructus Schisandrae Chinensis*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*) and (or) Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*). For those with continuous and (or) a large amount of clear nasal discharge, the following supplement can be referred and added: Wumei (Smoked Plum, *Fructus Mume*) and (or) Hezi (Medicine Terminalia Fruit, *Fructus Chebulae*). For those suffer from severe swollen of nasal mucosa, the following supplement

can be referred and added: Cheqianzi (Plantain Seed, *Semen Plantaginis*), Zexie (Oriental Waterplantain Rhizome, *Rhizoma Alismatis*), Zhebeimu (Thunberg Fritillary Bulb, *Bulbus Fritillariae Thunbergii*) and (or) Banxia (Pinellia Tuber, *Rhizoma Pinelliae*).

5.1.3.4 Other considerations

a) Patients of AR within seasonal, perennial, persistent and (or) onset period type is highly suggested to consider this syndrome (mainly) for prescription. Meanwhile, patients of AR within intermittent and (or) resting period type is suggested to consider this syndrome (mainly) for prescription.

b) When subject to personal allergy, physical inapplicability, or lack of certain herbs, the following weakly recommended alternative prescriptions can be taken into consideration with modifications: Lizhong Tang (Middle-Regulating Decoction), Yupingfeng San (Jade Screen Powder), Sijunzi Tang (Four Gentlemen Decoction), and Suoquan Wan (Urination-Reducing Pill). (See ANNEX D)

5.1.4 Syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose

5.1.4.1 Therapeutic principle

Tonifying kidney *yang* and replenishing *qi*, warming *yang* and consolidating exterior

5.1.4.2 Prescriptions

a) Jin Gui Shen Qi Wan (Kidney Qi Pill of the Golden Chamber), from *Jin Gui Yao Lue (Synopsis of the Golden Chamber)*: Shudihuang (Prepared Rehmannia Root, *Radix Rehmanniae Preparata*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Shanzhuyu (Asiatic Cornelian Cherry Fruit, *Fructus Corni*), Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Fuzi (Prepared Common Monkshood Daughter Root, *Radix Aconiti Lateralis Preparata*), Zexie (Oriental Waterplantain Rhizome, *Rhizoma Alismatis*), Fuling (Indian Bread, *Poria*), Mudanpi (Tree Peony Root Bark, *Cortex Moutan Radicis*), Niuxi (Medicinal Cyathula Root, *Radix Cyathulae*), Cheqianzi (Plantain Seed, *Semen Plantaginis*). (GRADE-TCM 1D^u: Strong recommendation, level of evidence: D)

b) You Gui Wan (Right-Restoring Pill), from *Jing Yue Quan Shu (Jing Yue's Collected Works)*: Fuzi (Prepared Common Monkshood Daughter Root, *Radix Aconiti Lateralis Preparata*), Rougui (Cinnamon Bark, *Cortex Cinnamomi*), Shudihuang (Prepared Rehmannia Root, *Radix Rehmanniae Preparata*), Shanzhuyu (Asiatic Cornelian Cherry Fruit, *Fructus Corni*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Tusizi (Dodder Seed, *Semen Cuscutae*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*), Duzhong (Eucommia Bark, *Cortex Eucommiae*), Gouqizi (Barbary Wolfberry Fruit, *Fructus Lycii*), Lujiao (Deer-Horn Glue, *Colla Corni Cervi*). (GRADE-TCM 1B^u: Strong recommendation, level of evidence: B)

5.1.4.3 Modifications

For those with long course of disease, *yang* deficiency and blood stasis, the following supplement can be referred and added: Dangguiwei (Chinese Angelica, *Radix Angelicae Sinensis*), Chishao (Red Peony Root, *Radix Paeoniae Rubra*) and (or) Chuanxiong (Sichuan Lovage Rhizome, *Rhizoma Ligustici Chuanxiong*). For those with kidney-*yin* deficiency, the following supplement can be referred and added: Shudihuang (Prepared Rehmannia Root, *Radix Rehmanniae Preparata*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Shanzhuyu (Asiatic Cornelian Cherry Fruit, *Fructus Corni*), Tusizi (Dodder Seed, *Semen Cuscutae*), Gouqizi (Barbary Wolfberry Fruit, *Fructus Lycii*), Lujiaojiao (Deer-Horn Glue, *Colla Corni Cervi*), Guibanjiao (Tortoise Carapace and Plastron, *Carapax et Plastrum Testudinis*) and (or) Chuan'niuxi (Medicinal Cyathula Root, *Radix Cyathulae*).

5.1.4.4 Other considerations

a) Patients of AR within perennial and (or) persistent type is highly suggested to consider this syndrome (mainly) for prescription. Meanwhile, patients of AR within intermittent, seasonal, resting period and (or) onset period type is suggested to consider this syndrome (mainly) for prescription.

b) When subject to personal allergy, physical inapplicability, or lack of certain herbs, the following weakly recommended alternative prescriptions can be taken into consideration with modifications: Zhenwu Tang (True Warrior Decoction), Guizhi Jia Fuzi Tang (Cinnamon Twig Decoction Plus Aconite), and Suoquan Wan (Urination-Reducing Pill). (See ANNEX D)

5.2 Chinese patent medicine

5.2.1 Syndrome of lung *qi* deficiency and wind-cold fettering exterior

Xinqin Granule (Capsule/ Tablet) (GRADE-TCM 1C: Strong recommendation, level of evidence: C)

5.2.2 Syndrome of latent heat in lung meridian and attacking nose

Tongqiao Biyan Granule (Capsule/ Tablet) (GRADE-TCM 1C: Strong recommendation, level of evidence: C), Xiangju Capsule (Granule/ Tablet) (GRADE-TCM 2C: Weak recommendation, level of evidence: C), Biyankang Tablet (GRADE-TCM 2C: Weak recommendation, level of evidence: C), Cang'erzi Biyan Dripping Pill (Capsule) (GRADE-TCM 2C: Weak recommendation, level of evidence: C), Xinyi Biyan Pill (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

5.2.3 Syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose

Fuzi Lizhong Pill (Tablet) (GRADE-TCM 2E: Weak recommendation, level of evidence: E).

5.2.4 Other syndrome

Biyuan Tongqiao Granule (for syndrome of external pathogen invading lung) (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

Note: Please choose appropriate method of administration and course of treatment according to the INSTRUCTIONS and clinical situation.

5.3 TCM external treatment - Acupuncture

5.3.1 Conventional acupuncture with filiform needles (GRADE-TCM 1A^U: Strong recommendation, level of evidence: A)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior; The intervention is suggested for patients with AR in 1) syndrome of latent heat in lung meridian and attacking nose, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial, seasonal, persistent and (or) onset period type; The intervention is suggested for patients with AR within intermittent and (or) resting period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8), Yintang (EX-HN 3) and (or) Kouheliao (LI 19), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Feishu (BL 13), Fengchi (GB 20), Shenshu (BL 23), Baihui (GV 20), Pishu (BL 20), Lieque (LU 7), Dazhui (GV 14) and (or) Quchi (LI 11), etc.. Consideration on reinforcement and reduction of acupuncture manipulation is suggested.

5.3.2 Sphenopalatine ganglion acupuncture (GRADE-TCM 2B: Weak recommendation, level of evidence: B)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is highly suggested for patients with AR within onset period type; The intervention is suggested for patients with AR within perennial, seasonal and (or) persistent type.

During treatment, additional adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8), Yintang (EX-HN 3) and (or) Kouheliao (LI 19), etc.; Meanwhile, additional point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Feishu (BL 13), Fengchi (GB 20), Shenshu (BL 23), Baihui (GV 20), Pishu (BL 20), Lieque (LU 7), Dazhui (GV 14) and (or) Quchi (LI 11), etc..

5.3.3 Electric acupuncture with filiform needles (GRADE-TCM 2C: Weak

recommendation, level of evidence: C)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within perennial, seasonal, intermittent, persistent and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Feishu (BL 13), Fengchi (GB 20), Shenshu (BL 23), Baihui (GV 20), Pishu (BL 20), and (or) Quchi (LI 11), etc.. Consideration on reinforcement and reduction of acupuncture manipulation is suggested; Meanwhile, selection of electric stimulation degree and frequency according to state of the disease is suggested.

5.3.4 Warming needle (with filiform needles) moxibustion (GRADE-TCM 2C: Weak recommendation, level of evidence: C)

This intervention is suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6) and (or) Quchi (LI 11), etc.. Consideration of (moxibustion light) shining on skin of acupoint directly and sufficiently from burning end of moxa stick or cone is suggested; Meanwhile, consideration of reducing moxibustion smoke (for possible adverse effects on patients) is suggested.

5.4 TCM external treatment – Moxibustion

5.4.1 Heat-sensitive moxibustion (GRADE-TCM 1C: Strong recommendation, level of evidence: C)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial, seasonal, intermittent, persistent and (or) onset period type; The intervention is suggested

for patients with AR within resting period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Yintang (EX-HN 3), Shangyingxiang (EX-HN 8), and (or) Shangyintang (Upper Yintang), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Feishu (BL 13), Tongtian (BL 7), Shenque (CV 8), Shangxing (GV 23), Fengchi (GB 20), Xiwu Point (Sphenopalatine Ganglion Point), Dazhui (GV 14) and (or) Zusanli (ST 36), etc.. Consideration of (moxibustion light) shining on skin of acupoint directly and sufficiently from burning end of moxa stick is suggested; Meanwhile, consideration of reducing moxibustion smoke (for possible adverse effects on patients) is suggested.

This intervention is suggested for children.

5.4.2 Conventional and suspended moxibustion (GRADE-TCM 2B^u: Weak recommendation, level of evidence: B)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose; The intervention is suggested for patients with AR in syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial, persistent and (or) resting period type; The intervention is suggested for patients with AR within seasonal, intermittent and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Baihui (GV 20), Geshu (BL 17), Shangxing (GV 23), Xuanzhong (GB 39), Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Yongquan (KI 1), Neiguan (PC 6), Fengchi (GB 20), Dazhui (GV 14), Feishu (BL 13), Danshu (BL 19), Shenshu (BL 23), etc.. Consideration of (moxibustion light) shining on skin of acupoint directly and sufficiently from burning end of moxa stick is suggested; Meanwhile, consideration of reducing moxibustion smoke (for possible adverse effects on patients) is suggested.

This intervention is suggested for children and pregnant women.

5.4.3 Thunder-fire moxibustion (suspended) (GRADE-TCM 2C: Weak recommendation, level of evidence: C)

This intervention is suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of

kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yintang (EX-HN 3), Yingxiang (LI 20), Shangyingxiang (EX-HN 8), Suliao (GV 25), Jingming (BL 1), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Shangxing (GV 23), Hegu (LI 4), Lieque (LU 7), Feishu (BL 13), Dazhui (GV 14), Fengmen (BL 12), Gaohuang (BL 43), Cuanzhu (BL 2), Shenshu (BL 23), Zhongwan (CV 12), Guanyuan (CV 4), Qihai (CV 6), etc.. Consideration of (moxibustion light) shining on skin of acupoint directly and sufficiently from burning end of moxa stick is suggested; Meanwhile, consideration of reducing moxibustion smoke (for possible adverse effects on patients) is highly suggested.

This intervention is suggested for children.

5.4.4 Separated* moxibustion

(Separated*: Including ginger, salt or materia medica cake-separated moxibustion) (GRADE-TCM 2C: Weak recommendation, level of evidence: C)

This intervention is highly suggested for patients with AR in 1) spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 2) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose; The intervention is suggested for patients with AR in syndrome of lung *qi* deficiency and wind-cold fettering exterior. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Yintang (EX-HN 3), Shangyingxiang (EX-HN 8), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Lieque (LU 7), Hegu (LI 4), Chize (LU 5), Zusanli (ST 36), Sanyinjiao (SP 6), Shenque (CV 8), Guanyuan (CV 4), Dazhui (GV 14), Feishu (BL 13), Fengmen (BL 12), Pishu (BL 20), Shenshu (BL 23), etc.. Selection of item for separation (such as ginger slice, garlic slice, aconite cake or salt, etc.) according to state of the disease and (or) the TCM syndrome individually is highly suggested; Meanwhile, consideration of reducing moxibustion smoke (for possible adverse effects on patients) is highly suggested.

5.4.5 Governor vessel (GV) moxibustion (GRADE-TCM 2C: Weak recommendation, level of evidence: C)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of

kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial and (or) seasonal type; The intervention is suggested for patients with AR within intermittent, persistent, resting period and (or) onset period type.

During treatment, additional adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, additional point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Lieque (LU 7), Hegu (LI 4), Chize (LU 5), Zusanli (ST 36), Sanyinjiao (SP 6), Shenque (CV 8) and (or) Guanyuan (CV 4), etc.. Consideration of reducing moxibustion smoke (for possible adverse effects on patients) is highly suggested.

5.5 Other TCM external treatment

5.5.1 Acupoint injection therapy with materia medica extracts (GRADE-TCM 1B^U: Strong recommendation, level of evidence: B)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior; The intervention is suggested for patients with AR in 1) syndrome of latent heat in lung meridian and attacking nose, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial, seasonal, persistent and (or) onset period type; The intervention is suggested for patients with AR within intermittent and (or) resting period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Feishu (BL 13), Fengchi (GB 20), Shenshu (BL 23), Pishu (BL 20), Lieque (LU 7), etc.. Selection of materia medica (extracts) injection based on syndrome differentiation is suggested, such as Huangqi (Milkvetch Root, *Radix Astragaliseu Hedysari*) Injection, Danggui (Chinese Angelica, *Radix Angelicae Sinensis*) Injection, Chuanxiong (Sichuan Lovage Rhizome, *Rhizoma Ligustici Chuanxiong*) Injection, Yuxingcao (Heartleaf Houltuynia Herb, *Herba Houltuyniae*) Injection, Chaihu (Chinese Thorowax Root, *Radix Bupleuri*) Injection, Danshen (Salvia Root, *Radix Salviae Miltiorrhizae*) Injection and (or) Honghua (Safflower, *Flos Carthami*) Injection, etc..

5.5.2 Intradermal needle therapy (GRADE-TCM 2B: Weak recommendation, level of evidence: B)

This intervention is suggested for patients with AR in either of the four

syndromes. Meanwhile, the intervention is suggested for patients with AR within seasonal, intermittent, persistent, and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Shangyingxiang (EX-HN 8), Yingxiang (LI 20), Kouheliao (LI 19) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Hegu (LI 4), Zusanli (ST 36), Sanyinjiao (SP 6), Feishu (BL 13), Fengchi (GB 20), Shenshu (BL 23), Baihui (GV 20), Pishu (BL 20), Lieque (LU 7), Dazhui (GV 14) and (or) Quchi (LI 11), etc..

This intervention is suggested for children.

5.5.3 Catgut embedment in acupoint therapy (GRADE-TCM 2B: Weak recommendation, level of evidence: B)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within perennial, seasonal, persistent, and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is suggested, including Yingxiang (LI 20) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Feishu (BL 13), Zusanli (ST 36), Dazhui (GV 14), Shenshu (BL 23), Pishu (BL 20), Guanyuan (CV 4) and (or) Quchi (LI 11), etc..

5.5.4 Acupoint application therapy with materia medica (GRADE-TCM 1B: Strong recommendation, level of evidence: B)

This intervention is highly suggested for patients with AR in 1) syndrome of lung *qi* deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose; The intervention is suggested for patients with AR in 1) syndrome of latent heat in lung meridian and attacking nose. Meanwhile, the intervention is highly suggested for patients with AR within perennial and (or) seasonal type; the intervention is suggested for patients with AR within intermittent, persistent, resting period and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yingxiang (LI 20) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Fengmen (BL 12), Zusanli (ST 36), Feishu (BL 13), Pishu (BL 20), Geshu (BL 17), Gaohuang (BL 43), Dazhui (GV 14), Shenzhu (GV 12), Qihai (CV 6), Guanyuan (CV 4), Shenshu (BL 23) and (or) Dingchuan (EX-B1),

etc.. In addition to irritant herbs for stimulation of acupoint [including Baijiezi (White Mustard Seed, *Semen Sinapis Albae*), Xixin (Manchurian Wildginger, *Herba Asari*), Gansui (Gansui Root, *Radix Euphorbiae Kansui*) and Yanhusuo (Yanhusuo, *Rhizoma Corydalis*), conventionally], selection of additional Chinese materia medica based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Huangqi (Milkvetch Root, *Radix Astragaliseu Hedysari*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Fangfeng (Divaricate Saposhnikovia Root, *Radix Saposhnikoviae*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Jingjie (Fineleaf Schizonepeta Herb, *Herba Schizonepetae*), Renshen (Ginseng, *Radix Ginseng*), Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Huangqin (Baical Skullcap Root, *Radix Scutellariae*), Shanzhi (Cape Jasmine Fruit, *Fructus Gardeniae*), Zhimu (Common Anemarrhena Rhizome, *Rhizoma Anemarrhenae*), Pipaye (Loquat Leaf, *Folium Eriobotryae*), Huangbai (Amur Cork Tree, *Cortex Phellodendri*), Mudanpi (Tree Peony Root Bark, *Cortex Moutan Radicis*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*) and (or) Fuling (Indian Bread, *Poria*), etc..

This intervention is highly suggested for children and is suggested for pregnant women.

5.5.5 Ear point pressure with pills (GRADE-TCM 2B: Weak recommendation, level of evidence: B)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

During treatment, point selection according to the disease for relieving stuffy nose is highly suggested, including Neibi (Internal nose: TG 4) and (or) Waibi (External nose: TG 1, 2i), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, including Fei (Lung: CO 14), Shen (Kidney: CO 10), Pi (Spleen: CO 13), Shenshangxian (Adrenal gland: TG 2p), Fengxi (Wind stream: SF 1, 2i), Shenmen (Shenmen: TF 4), Neifenmi (Endocrine: CO 18) and (or) Pizhixia (Subcortex: AT 4), etc.. In addition to selecting point according to the disease and (or) based on syndrome differentiation, detecting and selecting ashi (ear) point in combination of local tenderness and (or) ear point detector is highly suggested.

This intervention is highly suggested for children and is suggested for pregnant women.

5.5.6 Tuina (massage) (GRADE-TCM 2B^u: Weak recommendation, level of evidence: B)

This intervention is suggested for patients with AR in 1) syndrome of lung *qi*

deficiency and wind-cold fettering exterior, 2) syndrome of spleen *qi* deficiency, clear *yang* failing to ascend, and dampness attacking nose, and 3) syndrome of kidney-*yang* deficiency and deficiency-cold attacking nose. Meanwhile, the intervention is suggested for patients with AR within perennial, seasonal, intermittent, persistent and (or) onset period type.

During treatment, adjacent point selection according to the disease for relieving stuffy nose is highly suggested, including Yingxiang (LI 20), Shangyingxiang (EX-HN 8) and (or) Yintang (EX-HN 3), etc.; Meanwhile, point selection based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is highly suggested, including Shangxing (GV 23), Xinhui (GV 22), Hegu (LI 4), Quchi (LI 11), Fengchi (GB 20), Zusanli (ST 36), Dazhui (GV 14), Feishu (BL 13), Geshu (BL 17) and (or) Jiaji (EX-B 2), etc.. Consideration on reinforcement and reduction of tuina (massage) manipulation is highly suggested.

This intervention is highly suggested for children and is suggested for pregnant women.

5.5.7 Nasal drops of materia medica extracts (GRADE-TCM 2C: Weak recommendation, level of evidence: C)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

The following nasal drops of materia medica extracts are suggested: Congbai Nasal Drop, Dibiling Nasal Drop, Xinyi Nasal Drop, Zicao Cang'erzi You Nasal Drop. During treatment, selection of nasal drops with materia medica extracts according to the disease for relieving stuffy nose is suggested, such as Cang'erzi (Siberian Cocklebur Fruit, *Fructus Xanthii*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Bohe (Peppermint, *Herba Menthae*), Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*), Lulutong (Beautiful Sweetgum Fruit, *Fructus Liquidambaris*), Ebushicao (Small Centipeda Herb, *Herba Centipedae*) and (or) Huoxiang (Cablin Patchouli Herb, *Herba PogoStemonis*), etc..

5.5.8 Nasal fumigation with materia medica liquid (or extracts) (GRADE-TCM 2D: Weak recommendation, level of evidence: D)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

During treatment, selection of materia medica liquid (or extracts) according to the disease for relieving stuffy nose is suggested, such as Cang'erzi (Siberian Cocklebur Fruit, *Fructus Xanthii*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Bohe (Peppermint, *Herba Menthae*), Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*), Lulutong (Beautiful Sweetgum Fruit, *Fructus*

Liquidambaris), Ebushicao (Small Centipeda Herb, *Herba Centipedae*) and (or) Huoxiang (Cablín Patchouli Herb, *Herba PogoStemonis*), etc.; Meanwhile, selection of materia medica liquid (or extracts) based on syndrome differentiation for balancing the constitution, reinforcing healthy *qi* and eliminating pathogen is suggested, such as Huangqi (Milkvetc.h Root, *Radix Astragaliseu Hedysari*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Fangfeng (Divaricate Saposhnikovia Root, *Radix Saposhnikoviae*), Jingjie (Fineleaf Schizonepeta Herb, *Herba Schizonepetae*), Renshen (Ginseng, *Radix Ginseng*), Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Huangqin (Baical Skullcap Root, *Radix Scutellariae*), Shanzhi (Cape Jasmine Fruit, *Fructus Gardeniae*), Zhimu (Common Anemarrhena Rhizome, *Rhizoma Anemarrhenae*), Pipaye (Loquat Leaf, *Folium Eriobotryae*), Huangbai (Amur Cork Tree, *Cortex Phellodendri*), Mudanpi (Tree Peony Root Bark, *Cortex Moutan Radicis*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*) and (or) Fuling (Indian Bread, *Poria*), etc..

This intervention is suggested for children and pregnant women.

5.6 Traditional Chinese medicine gong fa

5.6.1 Tai ji quan (GRADE-TCM 2E: Weak recommendation, level of evidence: E)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

5.6.2 Ba duan jin (GRADE-TCM 2E: Weak recommendation, level of evidence: E)

This intervention is suggested for patients with AR in either of the four syndromes. Meanwhile, the intervention is suggested for patients with AR within either of the four classifications and the two staging.

6 Effects and outcomes

See “Core Outcome Set for Allergic Rhinitis in Traditional Chinese Medicine (COS-AR-TCM)” at ANNEX G.

ANNEX A
Informative
International Grading of Recommendations Assessment, Development and
Evaluation Standard for Traditional Chinese Medicine (GRADE-TCM)

A.1 GRADE evidence-based evaluation standards

GRADE evidence-based evaluation standards follow the GRADE Collaborative Group’s evidence-based quality evaluation guidelines, including four grades: ⊕⊕⊕⊕ (High level/4 scores), ⊕⊕⊕○ (Moderate level/3 scores), ⊕⊕○○ (Low level/2 scores) and ⊕○○○ (Very low level/1 score). The initial grade is “High level/4 scores”, and a score reduction system is adopted. Details are shown in Table A.1.

Table A.1: GRADE evidence-based evaluation standards

| Factors of downgrading/upgrading | Scores |
|--|----------------|
| Factors that may reduce the grade of evidence | |
| 1. Risk of bias | |
| · Serious | Minus 1 score |
| · Very serious | Minus 2 scores |
| 2. Inconsistency | |
| · Serious | Minus 1 score |
| · Very serious | Minus 2 scores |
| 3. Indirectness | |
| · Serious | Minus 1 score |
| · Very serious | Minus 2 scores |
| 4. Imprecision | |
| · Serious | Minus 1 score |
| · Very serious | Minus 2 scores |
| 5. Publication bias | |
| · Serious | Minus 1 score |
| · Very serious | Minus 2 scores |
| Factors that may increase the grade of evidence | |
| 1. Large effect | |
| · Large: Evidence from two or more studies consistently shows RR>2 or RR<0.5, with almost no confounding factors | Add 1 score |
| · Very large: Direct evidence shows RR>5 or RR<0.2, and does not affect its authenticity | Add 2 scores |
| 2. Plausible confounding | Add 1 score |
| 3. Dose-response gradient | Add 1 score |

A.2 GRADE-TCM evidence-based upgrading criteria

The selection of GRADE-TCM evidence-based upgrading criteria is based on expert group discussion and consensus of this document, with comprehensive reference to *The Composition of Evidence Body of Traditional Medicine and Recommendation for Its Evidence Grading* compiled by Professor Jian-Ping Liu and *Methodological Study on Integrating the Ancient and Modern Doctor's Experience into Evidence-based Clinical Practice Guidelines of Traditional Chinese Medicine* compiled by Professor Shou-Chuan Wang. Diversity of clinical evidence in TCM guidelines were fully considered in the GRADE-TCM evidence-based upgrading criteria, as well as heritage of ancient TCM literature and experience of famous TCM scholars. In the upgrading criteria, the following principles were emphasized — “maintaining internationalization with GRADE as main focus, reducing evidence bias with authoritative and objective data as a supplement, and highlighting inheritance with ancient literature as reference”. The criteria are shown in Table A.2.

Table A.2: GRADE-TCM evidence-based upgrading criteria

| No. | Criteria | Demonstration of upgrading principles |
|-----|---|--|
| I | Inclusion of published textbooks | <p>Based on the inclusion of 29 published textbooks, clear records of relevant TCM interventions for AR were found.</p> <p>On this basis, it was necessary to comply with the frequency ranking of the interventions clearly recorded in the textbooks. For interventions with B-level evidence intended to be upgraded to A-level evidence, the frequency should be in the top 25% of the frequency rankings among all of the interventions. Similarly, for C-level evidence intended to be upgraded to B-level evidence, it needs to be in the top 50% of the frequency rankings. For D-level evidence to be upgraded to C-level evidence, it needs to be in the top 75% of the frequency rankings. For E-level evidence to be upgraded to D-level evidence, it needs to be clearly recorded in at least one published textbook.</p> |
| II | Recommendation from previous guidelines, consensus, standards, and specifications | <p>Based on the 50 included guidelines, consensus, standards, and specifications, clear recommendations of the TCM interventions for AR were found.</p> |
| III | Records in ancient literature | <p>Based on computer retrieval of a database consisting of 1156 ancient medical literature and manual retrieval of relevant ancient medical literature, clear records of the TCM interventions for AR were found.</p> |

| | | |
|----|---|--|
| | | <p>Ancient names of the TCM interventions were obtained by searching the literature database and consulting relevant materials. The name of AR corresponds to the “<i>Bi Qiu</i>” in ancient literature, as well as some diseases represented by “<i>Ti</i>” (runny nose) and “<i>Ti</i>” (sneezing) in Chinese.</p> |
| IV | Validated medical records of famous TCM Masters in modern times | <p>Based on online medical records databases (Cloud Platform for Ancient and Modern TCM Cases, National Service Platform for Academic Experience of Famous TCM Doctor, Medical Records Database of Ancient TCM Literature) and relevant literature reports, as well as manual retrieval of related medical record collections and academic experience collections, we found clear and validated cases of the interventions for AR.</p> <p>The famous TCM Masters here include: National TCM Master, National Famous TCM Doctor, the Top Ten Provincial Famous TCM Doctor, Provincial Famous TCM Doctor, National Instructor of Inheriting the Academic Experience of Famous TCM Expert, Provincial Academic and Technology Leader, National <i>Qihuang</i> Scholar, TCM expert with the State Department special allowance, and modern TCM master who do not meet the above criteria but enjoy a high recognized reputation.</p> |

A.3 GRADE-TCM evidence-based evaluation standards

The development of GRADE-TCM evidence-based evaluation standards is based on expert group discussion and consensus of this document, with comprehensive reference to *Research on Clinical Evidence Grading and Scoring System of TCM* compiled by Professor Qing-Yong He and Professor Jie Wang, *Suggestions for Establishing Evidence Evaluation Methods Suitable for Clinical Diagnosis and Treatment of Traditional Chinese Medicine* compiled by Professor Jing-Bai Zhong, and *Research on the Evaluation Method and Application of Literature Quality in Traditional Chinese Medicine Treatment* compiled by Professor Jing-Hua Li. At the same time, by sticking to the principle of “from GRADE to GRADE”, referring to the GRADE evidence-based evaluation standards, and so as to reduce the excessive impact of GRADE-TCM evidence-based upgrading criteria on GRADE ratings and ultimately improve the international recognition of this document, the expert group discussed and stipulated that one entry can and can only be upgraded by up to one level based on GRADE-TCM evidence-based evaluation standards. The criteria are shown in Table A.3.

Table A.3 GRADE-TCM evidence-based evaluation standards

| Initial GRADE rating | Upgrading criteria | | GRADE-TCM rating |
|----------------------|---|-----|--------------------------|
| GRADE A | / | | GRADE-TCM A |
| GRADE B | Does the entry comply with criteria I, II, III, and IV in GRADE-TCM evidence-based upgrading criteria | Yes | GRADE-TCM A ^u |
| GRADE B | | No | GRADE-TCM B |
| GRADE C | Does the entry comply with any three of the four criteria (I, II, III, and IV) in GRADE-TCM evidence-based upgrading criteria | Yes | GRADE-TCM B ^u |
| GRADE C | | No | GRADE-TCM C |
| GRADE D | Does the entry comply with any two of the four criteria (I, II, III, and IV) in GRADE-TCM evidence-based upgrading criteria | Yes | GRADE-TCM C ^u |
| GRADE D | | No | GRADE-TCM D |
| GRADE E | Does the entry comply with any one of the four criteria (I, II, III, and IV) in GRADE-TCM evidence-based upgrading criteria | Yes | GRADE-TCM D ^u |
| GRADE E | | No | GRADE-TCM E |

The TCM intervention that met the GRADE-TCM evidence-based evaluation standards and was upgraded will be indicated by superscribing “u” (Upgrade) (such as “GRADE-TCM 1A^u”, “GRADE-TCM 2B^u”). In addition, when no relevant randomized controlled trial was included for certain interventions, but with only non-randomized (or semi-randomized) controlled trial, case-control trial, case report, review, or other literature support searched, a GRADE-TCM E rating was given.

ANNEX B
Informative
Principles of consensus and recommendation

B.1 General principles

The Delphi method for expert consensus in this document, with online and offline approaches combined were adopted. Please referred to the “Forming Recommendation Opinions and Consensus Suggestions” of the China Association of Chinese Medicine for achievement and judgment of consensus recommendations.

Consensus experts weighed the benefits and harms based on clinical and/or research experience, theoretical analysis, literature records, etc., and voted each entry in the questionnaire to be very important (certain benefits outweigh harms), relatively important (possible benefits outweigh harms), average (uncertain or no significant difference in benefits and harms), relatively unimportant (possible harms outweigh benefits), and very unimportant (certain harms outweigh benefits). The above 5 options were scored 5, 4, 3, 2, and 1 points respectively, and blank options were recorded as waivers. Percentages of “very important”, “relatively important”, “high importance”, “average”, “relatively unimportant”, “very unimportant”, and “low importance” for each entry were calculated.

B.2 Recommendation or suggestion in consensus

If the entry was supported by GRADE evidence (TCM interventions), expert recommendation will be formed based on results of GRADE-TCM evidence. If the entry was not supported by GRADE evidence (Diagnosis, GRADE-TCM methodology, COS-AR-TCM outcomes), expert suggestion will be formed based on relevant data. When any option other than the “average” option, namely “very important”, “relatively important”, “relatively unimportant”, or “very unimportant”, received a vote percentage greater than 50%, the consensus was reached concerning this entry. In addition, when either side, namely “high importance” (“very important” + “relatively important”) or “low importance” (“relatively unimportant” + “very unimportant”), received a vote percentage of 70% or more, it could also reach a consensus, correspondingly (“weak recommendation/ suggested” or “weak objection/ not suggested”). Otherwise, it would be considered “consensus not reached”.

There were four levels of expert recommendations, corresponding to each importance (i.e. “very important”, “relatively important”, “relatively unimportant”, “very unimportant”), which are “strong recommendation”, “weak recommendation”, “weak objection”, and “strong objection”.

There were four levels of expert suggestions, corresponding to each importance (i.e. “very important”, “relatively important”, “relatively unimportant”, “very unimportant”), which are “highly suggested”, “suggested”, “not suggested”, and “highly suggested not”.

B.3 Coefficient of variation and multiple rounds of questionnaires

Number of votes, mean of scores, standard deviation (SD) of scores, and coefficient of variation (CV) of scores for each entry were calculated. Recommendation or suggestion that did not reach consensus would be deleted after confirmation by the expert group of this document. Entry with a consensus and a CV of 0.3 or less would be included after confirmation by the expert group. For entry that had reached consensus but had a CV greater than 0.3, after discussion or necessary modifications by the expert group, another round of consensus voting or deletion will be carried out.

In addition, in development of the *Core Outcome Set for Allergic Rhinitis in Traditional Chinese Medicine (COS-AR-TCM)*, in order to improve the accuracy of consensus, the second round of consensus was made on the entries participating in the first round of voting. At the same time, in the second round of expert consensus, voting and consensus on the newly proposed entries in the first round of questionnaire were also conducted.

ANNEX C

Informative

Diagnosis, classification, staging and grading of AR in western medicine

C.1 Clinical manifestations

C.1.1 Medical history

Diagnosis of AR should focus on personal and (or) family history of relative allergic diseases. In addition, asking about history of overdose or long-term usage of nasal decongestants, if appropriate, is helpful for excluding the symptoms related to rhinitis medicamentosa (rebound nasal obstruction, mainly).

C.1.2 Symptoms

Main symptoms of AR include nasal obstruction, itching, runny nose, and continuous sneezing. In some patients, eye itching, sand-like foreign body sensation on eye, and redness, tears due to rubbing can be observed. In severe cases of allergy, frequent throat clearing and even coughing can be seen without other obvious cause.

C.1.3 Signs

Main signs of AR include abnormal color (e.g., pale, dark red) and (or) morphology (e.g., swelling) of nasal mucosa. Further, other abnormal signs (e.g., hypertrophy) on inferior turbinate, middle turbinate, nasal septum, inferior and (or) middle nasal passages can also be seen. In addition, abnormality in quantity and (or) quality of nasal discharge may also be seen.

C.2 Laboratory examinations

C.2.1 Allergen test

- a) Skin prick test (SPT) for common allergens: Specificity and sensitivity are high, and both of them can reach above 80%, generally. The test can provide valuable evidence for diagnosis of AR, and upon which, can measure whether allergic to a certain allergen, and evaluate intensity of the reaction quantitatively.
- b) Intradermal test for common allergens: This is less commonly applied in clinic, which shows weak correlation with symptoms, and is possible for false-positive reactions or even systemic adverse reactions.
- c) Allergen challenge test (including allergen provocation test and local allergen provocation test): This is the “golden standard” for diagnosis of AR and can be used for searching for key allergens. It is particularly suitable for patients with localized AR who have a high suspicion of AR on medical history and clinical manifestations, but are negative in SPT and serum-specific IgE test.

C.2.2 IgE test

- a) Serum allergen-specific IgE test: Specificity and sensitivity are high, and the test is widely used for diagnosis of AR. However, its test value does not necessarily correlate with severity of the disease, while positive specific IgE may not necessarily cause clinical symptoms.
- b) Serum total IgE test: This is less used in clinic because its sensitivity and specificity are poor.
- c) Nasal discharge allergen-specific IgE test: There are some clinical value in this test concerning differential diagnosis of AR.

C.2.3 Other laboratory tests

Other laboratory tests are usually not recommended routinely, and should only be considered as appropriate when there is doubt in other tests, such as medical history, clinical manifestation, allergen test, IgE test, etc.. These tests include nasal discharge eosinophil test, mucus cilia function test, nasal acoustic reflex, olfactory test, microarray testing, and nasal nitric oxide (NO) testing, etc..

C.3 Pediatric allergic rhinitis

Diagnosis of pediatric AR is generally similar to that of adults. In addition, a dark gray-blue suborbital ring and folds may be seen in children with AR, these are known as allergic shiners.

C.4 Differential diagnosis

If the patient suffers from bilateral nasal congestion, it is necessary to exclude nasal polyps and deflection of nasal septum, mainly; Unilateral nasal congestion mainly requires the exclusion of deviated nasal septum, foreign bodies, posterior nostril polyps and tumors.

Unilateral nasal discharge is rare, and if the patient has a recent history of external head injury, the skull base imaging examination should be considered on the basis of brief screening (such as “sitting forward test”) to exclude cerebrospinal fluid leakage. If the patient has nasal discharge and yellow nasal discharge, it can be seen in both infection and AR, but attention should be paid to whether to rule out the combination of acute and chronic sinusitis; In case of unilateral light blood colored mucus, unilateral tumor, foreign body, nose digging or overuse of nasal spray should be excluded.

C.5 Classification in western medicine

- a) Classification according to type of allergen:

——For perennial AR, the symptoms are perennial. The common allergens are dust mites, cockroaches, animal dander, etc., which are also perennial and

inhalation of indoor allergens, and some occupational allergens, mainly.

—For seasonal AR, the symptoms are seasonal. The common allergens are pollen and fungus, etc., which are also seasonal and inhalation of allergens, mainly, and with regional characteristics.

b) Classification according to onset time of the symptoms:

—For intermittent AR, duration of the symptoms is less than 4 days per week, or continuous duration of the symptoms is less than 4 weeks.

—For persistent AR, duration of the symptoms is more than 4 days per week, or continuous duration of the symptoms is more than 4 weeks.

c) Classification according to main symptoms:

—For the type of sneezing and clear nasal discharge, the main symptoms are sneezing and clear nasal discharge, which are induced by histamine effect, mainly.

—For nasal obstruction type, the main symptom is nasal obstruction, which is induced by leukotriene or other lipid mediators, mainly.

—For combined type, superiorities of different AR symptoms are between the two types above.

C.6 Staging in western medicine

AR is divided into onset period type and resting period type according to state of AR.

C.7 Grading in western medicine

Grading according to severity of clinical manifestations of AR and their impact on quality of life:

a) For mild type, the symptoms of AR are mild generally, which doesn't cause significant impact on quality of routine life of the patients.

b) For moderate-to-severe type, the symptoms of AR are moderate or severe, generally, which cause significant impact on quality of routine life of the patients.

ANNEX D
Informative
Chinese medicine prescriptions with weak recommendation

D.1 Syndrome of lung qi deficiency and wind-cold fettering exterior

- a) Guizhi Tang (Cinnamon Twig Decoction), from *Shang Han Lun (Treatise on Cold Damage Diseases)*: Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Baishao (Debark Peony Root, *Radix Paeoniae Alba*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Dazao (Chinese Date, *Fructus, Jujubae*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*). (GRADE-TCM 2B^U: Weak recommendation, level of evidence: B).
- b) Mahuang Fuzi Xixin Tang (Ephedra, Aconite and Asarum Decoction), from *San Yin Ji Yi Bing Zheng Fang Lun (Treatise on Diseases, Patterns, and Prescriptions Related to Unification of the Three Etiologies)*: Mahuang (Ephedra, *Herba Ephedrae*), Fuzi (Prepared Common Monkshood Daughter Root, *Radix Aconiti Lateralis Preparata*), Xixin (Manchurian Wildginger, *Herba Asari*). (GRADE-TCM 2C^U: Weak recommendation, level of evidence: C).
- c) Buzhong Yiqi Tang (Middle-Tonifying Qi-Replenishing Decoction), from *Nei Wai Shang Bian Huo Lun (Clarifying Doubts about Damage from Internal and External Causes)*: Huangqi (Milkvetch Root, *Radix Astragaliseu Hedysari*), Renshen (Ginseng, *Radix Ginseng*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Zhigancao (Liquorice Root, *Radix Glycyrrhizae*), Shengma (Large-trifolious Bugbane Rhizome, *Rhizoma Cimicifugae*), Danggui (Chinese Angelica, *Radix Angelicae Sinensis*), Chenpi (Dried Tangerine Peel, *Pericarpium Citri Reticulatae*), Chaihu (Chinese Thorowax Root, *Radix Bupleuri*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Dazao (Chinese Date, *Fructus, Jujubae*). (GRADE-TCM 2B^U: Weak recommendation, level of evidence: B)
- d) Cang'erzi San (Fructus Xanthii Powder), from *Chong Din Yan Shi Ji Sheng Fang (Revised Yan's Prescription for Aid and Living)*: Cang'erzi (Siberian Cocklebur Fruit, *Fructus Xanthii*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Bohe (Peppermint, *Herba Menthae*), Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*). (GRADE-TCM 2B^U: Weak recommendation, level of evidence: B).
- e) Xiao Qinglong Tang (Minor Green-Blue Dragon Decoction), from *Tai Ping Hui Min He Ji Ju Fang (Formulary of the Bureau of Taiping People's Welfare Pharmacy)*: Mahuang (Ephedra, *Herba Ephedrae*), Baishao (Debark Peony Root, *Radix Paeoniae Alba*), Xixin (Manchurian Wildginger, *Herba Asari*), Ganjiang (Dried Ginger, *Rhizoma Zingiberis*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Wuweizi (Chinese Magnoliavine Fruit, *Fructus Schisandrae Chinensis*), Banxia (Pinellia Tuber,

Rhizoma Pinelliae). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

- f) Chuanxiong Chatiao San (Tea-Blended Ligusticum Powder), from *Tai Ping Hui Min He Ji Ju Fang (Formulary of the Bureau of Taiping People's Welfare Pharmacy)*: Chuanxiong (Sichuan Lovage Rhizome, *Rhizoma Ligustici Chuanxiong*), Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*), Qianghuo (Incised Notopterygium Rhizome and Root, *Rhizoma et Radix Notopterygii*), Xixin (Manchurian Wildginger, *Herba Asari*), Fangfeng (Divaricate Saposhnikovia Root, *Radix Saposhnikoviae*), Jingjie (Fineleaf Schizonepeta Herb, *Herba Schizonepetae*), Bohe (Peppermint, *Herba Menthae*), Gancao (Liquorice Root, *Radix Glycyrrhizae*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).
- g) Ling Gan Wuwei Jiang Xin Tang (Potia, Licorice, Schisandra, Ginger and Asarum Decoction), from *Jin Gui Yao Lue (Synopsis of the Golden Chamber)*: Fuling (Indian Bread, *Poria*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Wuweizi (Chinese Magnoliavine Fruit, *Fructus Schisandrae Chinensis*), Ganjiang (Dried Ginger, *Rhizoma Zingiberis*), Xixin (Manchurian Wildginger, *Herba Asari*). (GRADE-TCM 2E: Weak recommendation, level of evidence: E).

D.2 Syndrome of latent heat in lung meridian and attacking nose

Cang'erzi San (Fructus Xanthii Powder), from *Chong Din Yan Shi Ji Sheng Fang (Revised Yan's Prescription for Aid and Living)*: Cang'erzi (Siberian Cocklebur Fruit, *Fructus Xanthii*), Xinyi (Biond Magnolia Flower, *Flos Magnoliae*), Bohe (Peppermint, *Herba Menthae*), Baizhi (Dahurian Angelica Root, *Radix Angelicae Dahuricae*). (GRADE-TCM 2B^U: Weak recommendation, level of evidence: B)

D.3 Syndrome of spleen qi deficiency, clear yang failing to ascend, and dampness attacking nose

- a) Lizhong Tang (Middle-Regulating Decoction), from *Shang Han Lun (Treatise on Cold Damage Diseases)*: Renshen (Ginseng, *Radix Ginseng*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Zhigancao (Liquorice Root, *Radix Glycyrrhizae*), Ganjiang (Dried Ginger, *Rhizoma Zingiberis*). (GRADE-TCM 2D^U: Weak recommendation, level of evidence: D).
- b) Yupingfeng San (Jade Screen Powder), from *Jiu Yuan Fang (Investigating the Essential Prescription)*: Huang Qi (Milkvetch Root, *Radix Astragaliseu Hedysari*), Bai Zhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Fang Feng (Divaricate Saposhnikovia Root, *Radix Saposhnikoviae*) (GRADE-TCM 2B^U: Weak recommendation, level of evidence: B)
- c) Sijunzi Tang (Four Gentlemen Decoction), from *Tai Ping Hui Min He Ji Ju Fang*

(*Formulary of the Bureau of Taiping People's Welfare Pharmacy*): Renshen (Ginseng, *Radix Ginseng*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*), Fuling (Indian Bread, *Poria*), Zhigancao (Liquorice Root, *Radix Glycyrrhizae*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

d) Suoquan Wan (Urination-Reducing Pill), from *Yi Fang Kao (Investigation of Medical Prescriptions)*: Wuyao (Lindera Root, *Radix Linderae*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Yizhiren (Fruit Sharpleaf Calangal, *Fructus Alpiniae Oxyphyllae*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

D.4 Syndrome of kidney-yang deficiency and deficiency-cold attacking nose

a) Zhenwu Tang (True Warrior Decoction), from *Shang Han Lun (Treatise on Cold Damage Diseases)*: Fuling (Indian Bread, *Poria*), Baishao (Debark Peony Root, *Radix Paeoniae Alba*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Fuzi (Prepared Common Monkshood Daughter Root, *Radix Aconiti Lateralis Preparata*), Baizhu (White Atractylodes Rhizome, *Rhizoma Atractylodis Macrocephalae*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

b) Guizhi Jia Fuzi Tang (Cinnamon Twig Decoction Plus Aconite), from *Shang Han Lun (Treatise on Cold Damage Diseases)*: Guizhi (Cassia Twig, *Ramulus Cinnamomi*), Baishao (Debark Peony Root, *Radix Paeoniae Alba*), Gancao (Liquorice Root, *Radix Glycyrrhizae*), Shengjiang (Ginger, *Zingiber Officinale Roscoe*), Dazao (Chinese Date, *Fructus Jujubae*), Fuzi (Prepared Common Monkshood Daughter Root, *Radix Aconiti Lateralis Preparata*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

c) Suoquan Wan (Urination-Reducing Pill), from *Yi Fang Kao (Investigation of Medical Prescriptions)*: Wuyao (Lindera Root, *Radix Linderae*), Shanyao (Common Yam Rhizome, *Rhizoma Dioscoreae*), Yizhiren (Fruit Sharpleaf Calangal, *Fructus Alpiniae Oxyphyllae*). (GRADE-TCM 2C: Weak recommendation, level of evidence: C).

ANNEX E

Informative

Summary for Rapid recommendation table

Table E.1 TCM treatment with strong recommendation for AR

| Recommendation | Type | Treatment | |
|-----------------|--|---|---|
| GRADE-TCM 1A | / | Conventional acupuncture with filiform needles ^U | |
| GRADE-TCM 1B | Traditional Chinese medicine prescriptions | Syndrome of lung <i>qi</i> deficiency and wind-cold fettering exterior | Yupingfeng San ^U (form <i>Jiu Yuan Fang</i>), Wenfei Zhiliu Dan ^U (form <i>Bian Zheng Lu</i>) |
| | | Syndrome of spleen <i>qi</i> deficiency, clear <i>yang</i> failing to ascend, and dampness attacking nose | Buzhong Yiqi Tang ^U (form <i>Nei Wai Shang Bian Huo Lun</i>), Shen Ling Baizhu San ^U (from <i>Tai Ping Hui Min He Ji Ju Fang</i>) |
| | | Syndrome of kidney- <i>yang</i> deficiency and deficiency-cold attacking nose | You Gui Wan ^U (form <i>Jing Yue Quan Shu</i>) |
| | TCM external treatment | Acupoint injection therapy with materia medica extracts ^U , Acupoint application therapy with materia medica | |
| GRADE-TCM 1C | Traditional Chinese medicine prescriptions | Syndrome of latent heat in lung meridian and attacking nose | Xinyi Qingfei Yin (form <i>Wai Ke Zheng Zong</i>) |
| | Chinese patent medicine | Xinqin Granule (Capsule/ Tablet), Tongqiao Biyan Granule (Capsule/ Tablet) | |
| | TCM external treatment | Heat-sensitive moxibustion | |
| GRADE-TCM 1D/1E | Traditional Chinese medicine prescriptions | Syndrome of kidney- <i>yang</i> deficiency and deficiency-cold attacking nose | Jin Gui Shen Qi Wan (from <i>Jin Gui Yao Lue</i>) GRADE-TCM 1D ^U |

Table E.2 TCM treatment with weak recommendation for AR

| Recommendation | Type | Treatment | |
|----------------|---------------------|---|---|
| GRADE-TCM 2B | Traditional Chinese | Syndrome of lung <i>qi</i> deficiency and | Guizhi Tang ^U (from <i>Shang Han Lun</i>), Buzhong Yiqi |

| | | | |
|--------------|--|---|---|
| | medicine prescriptions | wind-cold fettering exterior | Tang ^U (from <i>Nei Wai Shang Bian Huo Lun</i>), Cang'erzi San ^U (from <i>Chong Din Yan Shi Ji Sheng Fang</i>) |
| | | Syndrome of latent heat in lung meridian and attacking nose | Cang'erzi San ^U (from <i>Chong Din Yan Shi Ji Sheng Fang</i>) |
| | | Syndrome of spleen <i>qi</i> deficiency, clear <i>yang</i> failing to ascend, and dampness attacking nose | Yupingfeng San ^U (from <i>Jiu Yuan Fang</i>) |
| | TCM external treatment | Sphenopalatine ganglion acupuncture, Conventional and suspended moxibustion ^U , Intradermal needle therapy, Catgut embedment in acupoint therapy, Ear point pressure with pills, Tuina (massage) ^U | |
| GRADE-TCM 2C | Traditional Chinese medicine prescriptions | Syndrome of lung <i>qi</i> deficiency and wind-cold fettering exterior | Mahuang Fuzi Xixin Tang ^U (from <i>San Yin Ji Yi Bing Zheng Fang Lun</i>), Xiao Qinglong Tang (from <i>Tai Ping Hui Min He Ji Ju Fang</i>), Chuanxiong Chatiao San (from <i>Tai Ping Hui Min He Ji Ju Fang</i>) |
| | | Syndrome of spleen <i>qi</i> deficiency, clear <i>yang</i> failing to ascend, and dampness attacking nose | Sijunzi Tang (from <i>Tai Ping Hui Min He Ji Ju Fang</i>), Suoquan Wan (from <i>Yi Fang Kao</i>) |
| | | Syndrome of kidney- <i>yang</i> deficiency and deficiency-cold attacking nose | Zhenwu Tang (from <i>Shang Han Lun</i>), Guizhi Jia Fuzi Tang (from <i>Shang Han Lun</i>), Suoquan Wan (from <i>Yi Fang Kao</i>) |
| | Chinese patent medicine | Xiangju Capsule (Granule/ Tablet), Biyankang Tablet, Cang'erzi Biyan Dripping Pill (Capsule), Xinyi Biyan Pill, Biyuan Tongqiao Granule | |
| | TCM external treatment | Electric acupuncture with filiform needles, Warming needle (with filiform needles) moxibustion, Thunder-fire moxibustion (suspended), Separated moxibustion, Governor vessel (GV) moxibustion, Nasal drops of materia medica extracts | |

| | | | |
|--------------------|---|---|---|
| GRADE-TCM 2D/2E | Traditional Chinese medicine prescriptions | Syndrome of lung <i>qi</i> deficiency and wind-cold fettering exterior | Ling Gan Wuwei Jiang Xin Tang (from <i>Jin Gui Yao Lue</i>) GRADE-TCM 2E |
| | | Syndrome of spleen <i>qi</i> deficiency, clear <i>yang</i> failing to ascend, and dampness attacking nose | Li Zhong Tang ^u (from <i>Shang Han Lun</i>) |
| | Chinese patent medicine | Fuzi Lizhong Pill (Tablet) GRADE-TCM 2E | |
| | TCM external treatment | Nasal fumigation with materia medica liquid (or extracts) GRADE-TCM 2D | |
| | TCM gong fa | Tai ji quan GRADE-TCM 2E, Ba duan jin GRADE-TCM 2E | |

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ANNEX F
Informative
Consensus on TCM gong fa and TCM external treatment for special populations with AR

Table F.1 For pediatric patients

| Strength | Treatment |
|------------------|---|
| Highly suggested | Acupoint application therapy with materia medica, Ear point pressure with pills, Tuina (massage) |
| Suggested | Heat-sensitive moxibustion, Conventional and suspended moxibustion, Thunder-fire moxibustion (suspended), Intradermal needle therapy, Nasal fumigation with materia medica liquid (or extracts) |

Table F.2 For woman patients during pregnancy

| Strength | Treatment |
|-----------|---|
| Suggested | Conventional and suspended moxibustion, Acupoint application therapy with materia medica, Ear point pressure with pills, Tuina (massage), Nasal fumigation with materia medica liquid (or extracts) |

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ANNEX G
Informative

Core Outcome Set for Allergic Rhinitis in Traditional Chinese Medicine (COS-AR-TCM)

The COS-AR-TCM is shown in Table G.1.

Table G.1 Core Outcome Set for Allergic Rhinitis in Traditional Chinese Medicine (COS-AR-TCM)

| Outcomes | | Significance |
|---------------------------|---|------------------------------|
| Symptoms | Changes on nasal obstruction | Critical |
| | Changes on nasal itching | Critical |
| | Changes on runny nose | Critical |
| | Changes on sneezing | Critical |
| | Changes on eye itching | Significant but not critical |
| | Changes on impaired sense of smell | Significant but not critical |
| | Changes on pharyngeal itching | Significant but not critical |
| | Changes on photophobia | Moderate and not significant |
| | Changes on ophthalmic burning sensation | Moderate and not significant |
| | Changes on nasal pain | Moderate and not significant |
| TCM characteristic | Changes on scores of TCM Syndrome Factors Notes: Evaluating conversion between the eight biased constitutions and the balanced constitution (ideal healthy constitution) quantitatively by using the TCM constitution and classification scores (nine constitutions). Its significance lies in evaluating improvement of the overall constitution (syndrome) bias in patients with AR treated with TCM intervention. | Critical |
| | Changes on total score of the western medicine usage ("the three-step method") Notes: Used for evaluating TCM therapy (or auxiliary usage) in reducing dosage, frequency, and/or duration of the Western medicine usage. Using oral and/or local antihistamines (nasal or ocular), 1 point per day; Nasal glucocorticoids, 2 points per day; Oral corticosteroids, 3 points per day. If combined with asthma and using β 2 receptor agonists, 1 point per day; Inhalation of glucocorticoids counts 2 points per day. Score of all | Critical |

| | | |
|------------------|--|------------------------------|
| | medication records is the total score of drug usage. | |
| Signs | Changes on swelling of nasal mucosa | Critical |
| | Changes on pale of nasal mucosa | Critical |
| | Changes on hyperemia of nasal mucosa | Critical |
| | Changes on amount of nasal discharge | Critical |
| | Changes on nature of nasal discharge | Critical |
| Allergen-focused | Results of skin prick test (SPT) for common allergens | Critical |
| | Changes on serum specific IgE of common allergens | Critical |
| | Results of intradermal test for common allergens | Significant but not critical |
| | Changes on total serum IgE | Significant but not critical |
| | Results of provocation test for common allergens | Significant but not critical |
| Laboratory | Changes on serum Th1/Th2 ratio | Critical |
| | Changes on serum IL-4 | Significant but not critical |
| | Changes on serum IL-5 | Significant but not critical |
| | Changes on serum IL-10 | Significant but not critical |
| | Changes on serum IL-17 | Significant but not critical |
| | Changes on serum Th1 | Significant but not critical |
| | Changes on serum Th2 | Significant but not critical |
| | Changes on serum IFN- γ | Significant but not critical |
| | Changes on serum TGF- β | Significant but not critical |
| | Changes on serum TNF- α | Significant but not critical |
| | Changes on serum EOS | Significant but not critical |
| | Changes on blood T cell differentiation antigens (including CD3+, CD4+, CD8+, CD4+/CD8+) | Significant but not critical |
| | Results of cytological examination on nasal smear | Significant but not critical |
| | Changes on allergen-specific IgE in nasal lavage fluid for common allergens | Significant but not critical |
| Other tests | Results of pulmonary function test | Moderate and not significant |

| | | |
|-----------------|---|------------------------------|
| | Changes on nasal mucociliary transit time (MTT) | Moderate and not significant |
| | Changes on nasal mucociliary clearance velocity (MCV) | Moderate and not significant |
| Quality of life | Changes on scores of the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) Notes: Including nasal symptoms scores, ocular symptoms scores, non-nasal/ocular symptom scores, practical problem scores, sleeping scores, daily activity scores, and emotion scores. | Critical |
| | Changes on scores of the Mini-RQLQ | Significant but not critical |
| | Changes on scores of the Night-RQLQ (N-RQLQ) Notes: Including 16 projects in 4 fields (sleeping problems, symptoms during sleep, symptoms during day time, and practical problems). | Significant but not critical |
| | Changes on scores of the Self-rating Depression Scale (SDS) | Moderate and not significant |
| | Changes on scores of the Self-rating Anxiety Scale (SAS) | Moderate and not significant |
| | Changes on scores of the Minnesota Multiphasic Personality Inventory (MMPI) | Moderate and not significant |

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