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投稿 / 查询

目 次 CONTENTS

指南解读 Guide Interpretation

国际垂体协会《库欣病的诊断和管理共识(更新版)》解读——诊断篇

Interpretation of Consensus on Diagnosis and Management of Cushing's Disease: a Guideline Update of the International Pituitary Society——Diagnosis

..... 谭惠文, 唐宇, 余叶蓉, 李建薇, 李佳琦, 安振梅, 王椿, 魏懿 2435

论 著 Article

中老年非糖尿病人群中预估人体脂肪质量及比例与胰岛素抵抗的关系研究

Associations of Predicted Body Fat Mass and Fat Percentage with Insulin Resistance among a Middle-aged and Elderly Non-diabetic Population 阮海燕, 李丽英, 郑翼, 陈晓平, 何森 2443

糖尿病合并稳定型心绞痛患者发生主要不良心脑血管事件的中医预测模型构建

及应用评估研究

Development and Applicability Assessment of a TCM-based Risk Prediction Model for Major Adverse Cardiovascular and Cerebrovascular Events in Type 2 Diabetics with Stable Angina Pectoris

..... 王中瑞, 符宇, 赵瑞霞, 余海滨, 邵明义, 燕树勤, 韩景辉,

刘会娟, 朱蓉, 远佳瑶, 李蕾蕾, 崔伟锋, 王炯 2450

肥胖与2型糖尿病患者发生蛋白尿的关系研究

Relationship between Obesity and Proteinuria in Type 2 Diabetic Patients

..... 马艺琳, 柯蒋凤, 王俊薇, 李连喜 2457

益生菌干预治疗狼疮肾炎IV~V型患者的效果研究

Effect of Probiotic Intervention on Class IV and V Lupus Nephritis

..... 黄滕, 黄存军, 欧秋娟, 戴洪波, 何阶德, 梁航, 陈喆, 徐秋笔 2462

精准化运动处方对脑卒中患者心肺适能及睡眠质量的影响研究

Effect of CPET-based Precisely Prescribed Aerobic Exercise on Cardiopulmonary Fitness and Sleep Quality in Stroke Patients 钱贞, 卢同波, 何俊, 阮秋香, 汪超兰, 王鑫 2468

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青少年初产妇妊娠结局及影响因素研究

Adverse Pregnancy Outcomes and Associated Factors in Adolescent Primiparous Women

..... 庄文明，张丽，张婧，胡蓉敏 2474

无创产前筛查高风险胎儿的产前诊断结果分析及妊娠结局研究

Prenatal Diagnosis and Pregnancy Outcome Analysis of High-risk Fetuses Suggested by Noninvasive Prenatal

Screening 罗艳，赵兵依，孙艳美，田海深，李亚丽，张艳赏，高健，崔志强 2482

孕早中期孕妇肠道菌群差异与子病前期发病关系的研究

Study on the Relationship between Intestinal Microflora Differences and the Incidence of Preeclampsia in Pregnant

Women in the Early and Middle Stages of Pregnancy 莫蕾，钟萍 2489

重型颅脑损伤患者血清可溶性 α -Klotho蛋白水平动态变化及临床意义研究

Dynamic Changes and Associated Clinical Value of Serum Soluble α -Klotho Protein for Patients with Severe

Craniocerebral Injury 任斌，杨雷方，丁新民，梁继芳 2493

严重多发伤患者预后的影响因素研究及列线图模型的建立和优化

Development and Improvement of Nomograms Predicting the Prognosis in Patients with Severe Multiple Trauma

..... 殷菲，刘云，沈颢 2498

2007—2020年上海市浦东新区中部社区居民恶性肿瘤死亡情况及其趋势研究

Cancer Mortality and Trend among Community-living Residents in Central Pudong New Area, Shanghai, 2007—

2020 徐洁，王维，张晓琼，李娟萍，陈艺敏，王丽，马桂芬 2507

• 方法学研究 • 中医药专题 • *Methodology Research of TCM*

病证结合模式下中医证候疗效评价量表研制的实践与策略

Strategy and Development of the TCM Syndrome-based Treatment Effectiveness Assessment Scale Using the Mode of

Combination of Disease and Syndrome 李建生，冯贞贞，谢洋，王佳佳 2513

中药治疗慢性萎缩性胃炎临床试验方案设计关键因素思考

Thoughts on Key Factors of Clinical Trial Protocol Design for Chronic Atrophic Gastritis Treated with Traditional

Chinese Drugs 王天国，李博，赵国桢，胡晶，王宏，冯硕，张会娜 2519

中医手法治疗神经根型颈椎病随机对照试验结局指标的现状研究

Choice of Outcomes Used in Randomized Controlled Trials Measuring the Efficacy and Safety of Massage Therapy for

Cervical Spondylotic Radiculopathy 冯天笑，李康健，于大伟，孙婉钰，符碧峰，冯敏山，王平 2525

中西医治疗慢性腰痛临床研究的有效率定义及其判定标准存在差异：一项概况性评价

Definition and Differences of Determination Criteria of the Rate of Chronic Low Back Pain Response to Integrated

Traditional Chinese and Western Medicine Treatment in Clinical Studies: a Scoping Review

..... 黎霞，李多多，程璐瑶，万颖，于长禾 2534

——附专家说：加快中医药临床疗效评价指标体系的构建（见目次页）

孕晚期女性伴侣低头行为对产前抑郁的影响：婚姻满意度的中介作用研究

Mediating Effect of Marital Satisfaction Level on the Relationship between Partner Phubbing and Depression in Late Pregnancy 田云, 李玉红, 赵晶晶, 张玉东, 张柳 2541

产妇轻躁狂症状筛查及其与产后抑郁和双相情感障碍的关系研究进展

Advances in Screening for Postpartum Hypomanic Symptoms and Their Relationship with Postpartum Depression and Bipolar Disorder 赵倩倩, 周燕莉, 肖超群, 刘文婷, 范中意, 陈瑜 2547

新进展 Review

治疗2型糖尿病新靶点药物研究新进展

New Research Progress of the Novel Target Drugs for the Treatment of Type 2 Diabetes Mellitus 张鹏翔, 曾霖, 孟璐, 黄倩, 王高祥, 刘德亮 2551

帕金森病患者面部表情减退研究进展

Novel Developments in Hypomimia in Parkinson's Disease 黄根, 曹惠敏, 余刚 2558

《中国全科医学》投稿指南见封二

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专家说

——加快中医药临床疗效评价指标体系的构建

中医药临床疗效是中医药的核心竞争力, 中医药临床疗效评价是制约中医药发展的瓶颈, 因此被评为“2019 重大科学问题和工程技术难题”之一。为解决该问题, 需要立足于中医药诊疗整体观和辨证论治的特点, 围绕临床科研设计的受试者、干预措施、对照措施和结局指标内核加以展开。

结局指标既要反映多方利益者最关注、最重要的问题, 又要突出中医药干预的特色、特点。据此, 中医药临床疗效评价指标应包括人群健康状态相关的核心结局指标集 (Pa-COS) 和干预措施相关的特色结局指标集 (In-SOS)。前者指特定健康领域的所有临床研究中必须报告的最小指标集合, 针对任何干预措施; 后者指体现干预措施特点的特色指标集合, 针对某类干预措施且突出其代表性, 如肿瘤疗法中的化疗、放疗, 慢性乙型肝炎疗法中的针刺、辨证论治等。

辨证论治疗效主要表现为证候疗效, 即“通过辨证论治、针对证候进行疾病防治所产生的效果, 是从干预措施的角度对临床结局及其评价指标的一种分类”, 如肿瘤疗法中的“化疗疗效”“放疗疗效”, 中医药辨证论治慢性乙型肝炎的结局特点是帮助恩替卡韦“减毒增效”, 体现了“辨证论治疗效”。相比单一证型/证素量表或基于证素的综合评价法, 将辨证论治作为一类干预措施, 构建辨证论治的特色结局指标集, 既可以用公认西医结局指标体现中医辨证论治的干预特色, 又避免了结局指标的中医、西医归属问题。“好”的结局指标能准确反映患者健康状态的变化, 而不是仅针对干预措施反映其好坏。

“好”的结局指标需要通过评价工具准确 (效度)、稳定 (信度) 地反映、测量出来健康状态及其变化 (反应度)。“基于共识健康测量工具的选择标准 (COSMIN)”工作组提供了筛选工具的操作路径, 主要包含全面检索判断是否有工具、研制/译制工具、工具测量性能研究、系统评价、改编工具5步, 每一步均有相应指南和参考资料供研究者使用。

中医疗效评价指标体系不仅突出医患关注结局评价的价值观, 又能突出中医辨证论治与整体观的特点及以患者为中心的人文关怀精神。同时, 该体系既满足了选择最小报告结局指标的要求, 又构建了反映中医药干预特点结局指标的诉求, 提高了研究者开展试验前选择结局指标的效率, 为提高中医药的核心竞争力奠定基础。

于长禾. 加快中医药临床疗效评价指标体系的构建 [J]. 中国全科医学, 2022, 25 (20): 目次页.

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CONTENTS IN BRIEF

- 2435 **Interpretation of Consensus on Diagnosis and Management of Cushing's Disease: a Guideline Update of the International Pituitary Society—Diagnosis**
TAN Huiwen, TANG Yu, YU Yierong, LI Jianwei, LI Jiaqi, AN Zhenmei, WANG Chun, WEI Yi
- 2443 **Associations of Predicted Body Fat Mass and Fat Percentage with Insulin Resistance among a Middle-aged and Elderly Non-diabetic Population**
RUAN Haiyan, LI Liying, ZHENG Yi, CHEN Xiaoping, HE Sen
- 2450 **Development and Applicability Assessment of a TCM-based Risk Prediction Model for Major Adverse Cardiovascular and Cerebrovascular Events in Type 2 Diabetics with Stable Angina Pectoris**
WANG Zhongrui, FU Yu, ZHAO Ruixia, YU Haibin, SHAO Mingyi, YAN Shuxun, HAN Jinghui, LIU Huijuan, ZHU Rong, YUAN Jiayao, LI Leilei, CUI Weifeng, WANG Xian
- 2457 **Relationship between Obesity and Proteinuria in Type 2 Diabetic Patients**
MA Yilin, KE Jiangfeng, WANG Junwei, LI Lianxi
- 2462 **Effect of Probiotic Intervention on Class IV and V Lupus Nephritis**
HUANG Meng, HUANG Cunjun, OU Qiujuan, DAI Hongbo, HE Jiede, LIANG Hang, CHEN Zhe, XU Qiubi
- 2468 **Effect of CPET-based Precisely Prescribed Aerobic Exercise on Cardiopulmonary Fitness and Sleep Quality in Stroke Patients**
QIAN Zhen, LU Tongbo, HE Jun, RUAN Qiuxiang, WANG Chaolan, WANG Xin
- 2474 **Adverse Pregnancy Outcomes and Associated Factors in Adolescent Primiparous Women**
ZHUANG Wenming, ZHANG Li, ZHANG Jing, HU Rongmin
- 2482 **Prenatal Diagnosis and Pregnancy Outcome Analysis of High-risk Fetuses Suggested by Noninvasive Prenatal Screening**
LUO Yan, ZHAO Bingyi, SUN Yanmei, TIAN Haishen, LI Yali, ZHANG Yanshang, GAO Jian, CUI Zhiqiang
- 2489 **Study on the Relationship between Intestinal Microflora Differences and the Incidence of Preeclampsia in Pregnant Women in the Early and Middle Stages of Pregnancy**
MO Lei, ZHONG Ping
- 2493 **Dynamic Changes and Associated Clinical Value of Serum Soluble α -Klotho Protein for Patients with Severe Craniocerebral Injury**
REN Bin, YANG Leifang, DING Xinmin, LIANG Jifang
- 2498 **Development and Improvement of Nomograms Predicting the Prognosis in Patients with Severe Multiple Trauma**
YIN Fei, LIU Yun, SHEN Xie
- 2507 **Cancer Mortality and Trend among Community-living Residents in Central Pudong New Area, Shanghai, 2007—2020**
XU Jie, WANG Wei, ZHANG Xiaojiao, LI Juanping, CHEN Yimin, WANG Li, MA Guifen
- 2513 **Strategy and Development of the TCM Syndrome-based Treatment Effectiveness Assessment Scale Using the Mode of Combination of Disease and Syndrome**
LI Jiansheng, FENG Zhenzhen, XIE Yang, WANG Jiajia
- 2519 **Thoughts on Key Factors of Clinical Trial Protocol Design for Chronic Atrophic Gastritis Treated with Traditional Chinese Drugs**
WANG Tianyuan, LI Bo, ZHAO Guozhen, HU Jing, WANG Hong, FENG Shuo, ZHANG Huina
- 2525 **Choice of Outcomes Used in Randomized Controlled Trials Measuring the Efficacy and Safety of Massage Therapy for Cervical Spondylotic Radiculopathy**
FENG Tianxiao, LI Kangjian, YU Dawei, SUN Wanyu, FU Bifeng, FENG Minshan, WANG Ping
- 2534 **Definition and Differences of Determination Criteria of the Rate of Chronic Low Back Pain Response to Integrated Traditional Chinese and Western Medicine Treatment in Clinical Studies: a Scoping Review**
LI Xia, LI Duoduo, CHENG Luyao, WAN Ying, YU Changhe
- 2541 **Mediating Effect of Marital Satisfaction Level on the Relationship between Partner Phubbing and Depression in Late Pregnancy**
TIAN Yun, LI Yuhong, ZHAO Jingjing, ZHANG Yudong, ZHANG Liu
- 2547 **Advances in Screening for Postpartum Hypomanic Symptoms and Their Relationship with Postpartum Depression and Bipolar Disorder**
ZHAO Qianqian, ZHOU Yanli, XIAO Chaoqun, LIU Wenting, FAN Zhongyi, CHEN Yu
- 2551 **New Research Progress of the Novel Target Drugs for the Treatment of Type 2 Diabetes Mellitus**
ZHANG Pengxiang, ZENG Lin, MENG Lu, HUANG Qian, WANG Gaoxiang, LIU Deliang
- 2558 **Novel Developments in Hypomimia in Parkinson's Disease**
HUANG Gen, CAO Huimin, YU Gang

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