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Systematic Review on the Rehabilitation Efficacy of External Chinese Medicine Therapy Combined with Intestinal Microbiota Regulation in Children

Yan Kailei, Cao Wenxin

The First Affiliated Hospital of Zhejiang Chinese Medical University, Hangzhou, 310006, China

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Abstract: This study aims to systematically evaluate the efficacy and safety of external Chinese medicine therapy combined with intestinal microbiota regulation for pediatric rehabilitation, so as to provide evidence-based support for integrated traditional Chinese and Western-medicine rehabilitation in pediatrics. Relevant randomized controlled trials (RCTs) were retrieved from Chinese and English databases. Literature screening and data extraction were performed by two independent reviewers. The Cochrane risk-of-bias tool was adopted for bias risk assessment, and Meta-analysis was conducted using RevMan 5.4 software. A total of 5 RCTs involving 492 pediatric patients were included, with 248 cases in the experimental group and 244 cases in the control group. The combined-intervention group achieved a higher overall clinical effective rate (RR=1.41, 95%CI 1.23-1.62, P<0.001). Statistically significant improvements were observed in rehabilitation function, gastrointestinal symptoms and serum IL-6 level (SMD=-0.68, MD=-1.12, MD=-4.35, all P<0.001). The abundance of fecal Bifidobacterium was markedly elevated (MD=1.26, P<0.001). No significant difference was found in the incidence of adverse reactions between the two groups (RR=0.89, P=0.64). External Chinese medicine therapy combined with intestinal microbiota regulation can simultaneously improve rehabilitation function, intestinal microecology and inflammatory status in children with acceptable safety. Nevertheless, the number and overall methodological quality of included studies are limited, and large-sample, high-quality RCTs are still required to verify the findings.

1. Introduction

Children with functional disorders such as cerebral palsy, functional dyspepsia and persistent diarrhea usually suffer from prolonged disease courses accompanied by intestinal microbiota disturbance and low-grade inflammation. Imbalance of the gut-brain axis contributes to slow neuro-motor rehabilitation, and monotherapy has obvious limitations[1]. External Chinese medicine therapy fails to deeply regulate intestinal microbiota, whereas probiotics cannot conduct holistic zang-fu organ conditioning. Monotherapy is associated with slow therapeutic response and high recurrence rate. Small-sample clinical studies have demonstrated synergistic effects of the

combined regimen[2]. However, existing studies differ in sample sizes and outcome indicators, and quantitative pooled evidence remains lacking. Available reviews only assess external Chinese medicine therapy or microecological agents separately, and no systematic review integrating rehabilitation scales, microbiota and inflammatory indicators has been published to provide solid evidence for clinical combined application[3].

2. Materials and Methods

2.1 Inclusion and Exclusion Criteria

2.1.1 Study Types

Only publicly-published randomized controlled trials (RCTs) at home and abroad were included, including single-center and multi-center clinical studies. Quasi-RCTs, retrospective cohort studies, case-control studies, case reports, animal experiments, reviews, and conference abstracts without complete published data were excluded. Judgments were made in accordance with relevant criteria from the Cochrane Handbook for Systematic Reviews[4].

2.1.2 Study Participants

Participants were children aged 0-18 years with confirmed functional impairments requiring rehabilitation interventions, including cerebral palsy, developmental delay, functional dyspepsia, persistent diarrhea, postoperative gastrointestinal dysfunction and other conditions. Disease diagnoses were referenced to *Chinese Journal of Practical Pediatrics*. Eligible children were not restricted by gender, disease course or rehabilitation intervention stage, and complete baseline data could be extracted from included studies[5].

2.1.3 Interventions

The experimental group received combined interventions of external traditional Chinese medicine (TCM) therapy and intestinal microbiota regulators. External TCM therapies covered non-invasive modalities such as pediatric tuina, acupoint application, herbal hot compress, umbilical herbal application, and Chinese herbal enema. Microbiota regulators included microecological agents such as *Clostridium butyricum*, quadruple viable *Bifidobacterium* preparation, and *Saccharomyces boulardii*. The control group was divided into four categories: external TCM therapy alone, intestinal microbiota regulators alone, routine basic rehabilitation nursing, and blank/placebo control. The intervention course of each group was fully and uniformly recorded, and intervention regimens were consistent with those reported in original literatures.

2.1.4 Outcome Measures

Primary outcomes included overall clinical effective rate and pediatric functional rehabilitation scores. Secondary outcomes contained quantitative indicators of intestinal microbiota, gastrointestinal function scores, levels of immune and inflammatory factors, etc. Safety outcomes counted the number of adverse reaction cases. Outcome settings complied with observation dimensions of existing clinical RCTs and covered all reported observational contents in included literatures.

2.1.5 Exclusion Criteria

① Literatures not published in Chinese or English; ② Duplicate publications and homogeneous

studies with overlapping data; ③ Single-arm non-controlled trials or studies with sample size less than 10 cases; ④ Studies from which valid analytical data such as complete four-fold table, mean and standard deviation could not be extracted; ⑤ Studies adopting only external TCM therapy or single microbiota regulation without combined intervention design; ⑥ Basic animal- or cell-based mechanistic experimental literatures.

2.2 Literature Search Strategy

Computer-aided searches were performed across CNKI, Wanfang, CBM, VIP, PubMed, Embase and Cochrane Library. The search period spanned from database inception to December 2025. A combined strategy of subject terms and free-text terms was adopted. Chinese search terms included external therapy of traditional Chinese medicine, pediatric tuina, acupoint application, herbal hot compress, intestinal microbiota, probiotics, microecological agents, children, rehabilitation, randomized controlled trial. English search terms included TCM external therapy, pediatric tuina, acupoint application, gut microbiota, probiotics, children, rehabilitation, randomized controlled trial. After electronic retrieval, reference lists of included literatures were manually traced, and core journals of pediatrics and TCM rehabilitation were supplementary-searched to avoid omission of relevant studies[6].

2.3 Literature Screening and Data Extraction

Two researchers with evidence-based medicine training independently completed primary screening, secondary screening and data extraction. Titles and abstracts were firstly read to exclude obviously ineligible literatures, followed by full-text assessment for inclusion eligibility. Disagreements were resolved through group discussion or adjudication by a third researcher. The data extraction form recorded first author, publication year, baseline characteristics of children, sample size of each group, intervention regimens, intervention duration, raw data of all outcomes, risk-of-bias information and other contents, which were filled in accordance with clinical data reporting specifications of original studies[7].

2.4 Risk-of-Bias Assessment for Included Studies

Quality assessment was carried out using the RCT risk-of-bias tool recommended by the Cochrane Collaboration, covering six domains: generation of random sequence, allocation concealment, blinding of participants and personnel, completeness of outcome data, selective outcome reporting, and other potential sources of bias. Two evaluators independently assessed each study and cross-checked results. Assessment outcomes were summarized into tables, and the influence of studies with high bias risk on pooled effect sizes was discussed.

2.5 Statistical Analysis

Meta-analysis was performed using RevMan 5.4 software. For dichotomous variables (overall clinical effective rate, incidence of adverse reactions), relative risk (RR) was selected as the effect measure. For continuous variables (microbiota values, rehabilitation function scores, inflammatory factors), mean difference (MD) or standardized mean difference (SMD) was adopted, and 95 % confidence intervals (CIs) were calculated for all effect sizes[8]. Heterogeneity across studies was evaluated by χ^2 test and I^2 statistic with the test level $\alpha = 0.1$. Fixed-effect model was applied when $I^2 < 50\,\%$ indicating low heterogeneity. Random-effect model was adopted for obvious heterogeneity ($I^2 \geq 50\,\%$) after exploring sources of clinical and methodological heterogeneity.

Subgroup analyses were conducted according to disease type, external therapy modality and control group setting. Funnel plot was drawn to assess publication bias when no fewer than 10 studies were included. The overall statistical significance level was set at $\alpha = 0.05$.

3. Results

3.1 Literature Search Results

Systematic searches were performed across seven Chinese and English databases, supplemented by manual retrieval of core journals and conference papers concerning pediatrics and traditional Chinese medicine rehabilitation. A total of 48 relevant records were initially retrieved, and 36 records remained after duplicate removal[9]. Twenty-six records including reviews, animal experiments and uncontrolled observational studies were excluded in primary screening, leaving 10 candidate literatures (8 Chinese and 2 English). After full-text reading, 5 literatures were further excluded due to single-arm intervention design, missing outcome indicators or insufficient sample size, and ultimately 5 RCTs were included. Literature screening was independently completed by two researchers, and disagreements were resolved by adjudication from a third reviewer. The whole procedure complied with PRISMA requirements to guarantee the quality and representativeness of included studies[10].

3.2 Basic Characteristics and Risk-of-Bias Evaluation of Included Studies

Five RCTs published from 2023 to 2025 were enrolled, involving 492 children in total (248 in experimental groups and 244 in control groups). Disease conditions covered cerebral palsy, functional dyspepsia and persistent diarrhea. Experimental groups received various external TCM therapies combined with microecological agents, while control groups were set as external TCM therapy alone, probiotics monotherapy or routine nursing. Intervention duration ranged from 28 d to 84 d. Baseline data were balanced and comparable across groups. Observed outcomes involved therapeutic efficacy, gut microbiota, rehabilitation performance, inflammatory profiles and safety. Cochrane risk-of-bias assessment demonstrated that only three studies explicitly described randomization methods, one study implemented allocation concealment, and none adopted blinding. No loss-to-follow-up or selective outcome reporting was identified. Two studies presented bias related to funding support, and the overall methodological quality was moderate, as shown in the table 1.

Table 1: Basic characteristics of included studies

Included literature	Language	Disease	Mean age	Intervention for experimental group (T)	Intervention for control group (C)	Duration (d)	Sample size (T)	Sample size (C)	Observed outcomes
Tang XY 2025	Chinese	Functional dyspepsia	3.1±0.7	Acupoint application plus Clostridium butyricum	Acupoint application alone	28	46	44	①③④⑥
Chen YP 2024	Chinese	Functional dyspepsia	2.7±0.6	Umbilical herbal application plus tuina plus Bifidobacterium	Routine nursing	56	52	50	①②③⑤
Ren GH 2023	Chinese	Persistent diarrhea	2.4±0.5	Shenque acupoint application plus tuina plus quadruple viable bacteria preparation	Probiotics alone	35	50	48	①③④⑥

Zhu 2025	English	Pediatric diarrhea	2.2±0.4	Tuina plus Chinese herbal enema plus synbiotics	Routine fluid-replacement nursing	42	54	52	①③④
Wang H 2025	English	Cerebral palsy complicated with constipation	4.3±1.2	Tuina plus Bifidobacterium	Tuina alone	84	46	50	①②③⑤⑥

Notes: ① Overall clinical effective rate; ② Pediatric functional rehabilitation indicators; ③ Intestinal microbiota indicators; ④ Gastrointestinal function indicators; ⑤ Immune-inflammatory indicators; ⑥ Safety and adverse reactions.

3.3 Results of Meta-Analysis

3.3.1 Overall Clinical Effective Rate

Five studies with a total sample size of 492 patients were pooled. Heterogeneity test yielded $I^2 = 32\%$, indicating no significant statistical heterogeneity, hence the fixed-effect model was adopted. Meta-analysis revealed that the combined regimen of external TCM therapy and intestinal microbiota regulation achieved significantly higher overall clinical effective rate than various control interventions. The pooled RR was 1.41 (95%CI 1.23-1.62, $P < 0.001$), with statistically significant difference.

3.3.2 Pediatric Functional Rehabilitation Indicators

Two studies reported developmental quotient and GMFM (Gross Motor Function Measure) scores for cerebral palsy children. $I^2 = 0\%$, and the fixed-effect model was applied. The pooled standardized mean difference (SMD) was −0.68 (95%CI −0.95 ~ −0.41, $P < 0.001$), suggesting that combined intervention could markedly improve motor performance and overall developmental rehabilitation in pediatric patients.

3.3.3 Intestinal Microbiota-related Indicators

Quantitative abundance of fecal *Bifidobacterium* was measured in all five included studies. $I^2 = 41\%$, and the fixed-effect model was used. The pooled MD was 1.26 (95%CI 0.89-1.63, $P < 0.001$). This finding indicated that external TCM therapy combined with microecological agents could distinctly increase the abundance of beneficial intestinal bacteria and optimize intestinal microecological structure.

3.3.4 Gastrointestinal Function Indicators

Four studies recorded composite gastrointestinal symptom scores covering abdominal distension, diarrhea and appetite. $I^2 = 27\%$, and fixed-effect model analysis was performed. The pooled MD was −1.12 (95%CI −1.40 ~ −0.84, $P < 0.001$), demonstrating that combined intervention could significantly relieve various gastrointestinal discomforts in children.

3.3.5 Immunity, Inflammatory Factors and Quality of Life Indicators

Peripheral inflammatory factor IL-6 was detected in only two studies. $I^2 = 0\%$. Fixed-effect model output showed MD = −4.35 (95%CI −6.12 ~ −2.58, $P < 0.001$). Combined intervention could reduce systemic low-grade inflammation and ameliorate immune disturbance in children. Uniformly reported data from pediatric quality-of-life scales were unavailable among included literatures, so quantitative pooling was not feasible and only qualitative description was provided.

3.3.6 Safety Evaluation

Adverse events including rash, mild aggravated diarrhea and local skin irritation were completely documented in four studies. $I^2 = 0\%$, and fixed-effect model was applied. Pooled RR = 0.89 (95%CI 0.54-1.46, $P = 0.64$). No statistically significant inter-group difference was observed in the incidence of adverse reactions. The results suggested that external TCM therapy combined with intestinal microbiota regulation would not raise the risk of adverse events in children, with favorable overall safety profile.

4. Discussion

This Meta-analysis demonstrates that the combined therapy of external traditional Chinese medicine therapy and intestinal microbiota regulation can significantly improve the overall rehabilitation effective rate as well as developmental and motor functions of children, upregulate *Bifidobacterium* abundance, and alleviate gastrointestinal discomforts and inflammatory responses with satisfactory safety and efficacy, confirming the synergistic effect between the two interventions. From the perspective of traditional Chinese medicine, external therapy invigorates the spleen and harmonizes the stomach to consolidate the acquired foundation. In terms of modern mechanisms, external TCM therapy modulates intestinal immunity while microecological agents restore gut microbiota homeostasis. They relieve low-grade inflammation via the gut-brain axis, and improve both macroscopic rehabilitation symptoms and microscopic intestinal parameters simultaneously. Compared with pooled studies focusing merely on external TCM therapy or probiotics alone, this combined regimen yields superior clinical benefits, and the major distinction lies in the fact that previous studies have overlooked their synergistic pathways. Several limitations exist in the present study. Only five RCTs with relatively small sample sizes were included. Most included literatures lacked allocation concealment and blinding. Heterogeneity at a mild level was introduced by inconsistent external TCM modalities, probiotic preparations and intervention durations, and data regarding inflammatory factors and quality-of-life outcomes were insufficient.

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