Paradigm Academic Press
Journal of Innovations in Medical Research
ISSN 2788-7022
JUN. 2026 VOL.5, NO.2

Construction and Application of Standard System for Traditional External Therapy in Traditional Chinese Medicine Health Preservation

Yao Chen[1]

[1] Beijing Tongrentang TCM Culture Research Association, Beijing 100009, China

Correspondence: Yao Chen, Beijing Tongrentang TCM Culture Research Association, Beijing 100009, China.

doi:10.63593/JIMR.2788-7022.2026.06.004

Abstract

Against the backdrop of a growing global burden of chronic non-communicable diseases and sub-health issues, traditional Chinese medicine (TCM) external therapies serve as core techniques for TCM health preservation. However, inconsistent operational norms and lack of quantitative parameters have resulted in high clinical heterogeneity, hindering their clinical application and international development. This study constructed a four-layer hierarchical standard system for TCM external therapies by integrating literature analysis and three rounds of Delphi expert consultation, and extracted 17 core quantitative operational parameters for cupping, scraping, moxibustion and other therapies. A multicenter stratified randomized controlled trial involving 384 participants was further conducted to validate the system. The subjects were divided into four groups: control group, standardized TCM external therapy group, therapy combined with TCM constitution conditioning group, and therapy combined with digital health management group. After 12 weeks of intervention and 12 weeks of follow-up, relevant biomarkers, clinical scales and safety indicators were assessed. The overall expert consensus rate of the standard system reached 83.2%. All intervention groups exhibited significant increases in BDNF levels and decreases in inflammatory factors, along with notable improvements in fatigue and sleep status. The combination of standardized therapy and constitution conditioning delivered the best therapeutic effect. Operation standardization was positively correlated with clinical efficacy and negatively correlated with adverse event incidence. All adverse reactions were mild, and participants maintained high treatment compliance. This standard system fills the gaps in existing industry specifications. Standardized TCM external therapies are effective and safe for intervening sub-health and mild chronic diseases. It is suggested to promote the implementation of this system, conduct in-depth mechanism research and accelerate its international popularization.

Keywords: traditional Chinese medicine health preservation, traditional Chinese medicine external therapy, standard system, quantitative operation, Delphi method, randomized controlled trial, sub-health state, safety evaluation

1. Introduction

1.1 Research Background and Current Situation

Chronic non-communicable diseases (NCDs) have become the leading burden of global health. The World Health Organization (WHO) reported that NCDs account for 71% of the total global disease burden in 2019, and evidence from *The Lancet* demonstrated that standardized preventive interventions could reduce medical costs by 30%–40%. Traditional Chinese medicine (TCM) based preventive care, guided by the concept of “treating disease before its onset”, has shown unique advantages in sub-health and chronic disease management.

Clinical real-world data from Beijing Ditan Hospital (2018–2022) indicated that TCM preventive interventions increased early intervention rate by 35%–45% and patient compliance by 52%, while the incidence of adverse

reactions decreased by 68% compared with oral chemical drugs. Traditional external therapies (TETs), including cupping, scraping, moxibustion and tuina, are the core techniques of TCM health preservation. However, the lack of unified operational specifications has become a major bottleneck restricting clinical popularization and international promotion.

At present, existing national standards such as GB/T 12346-2015 only cover acupuncture, without unified norms for mainstream external therapies. Regional guidelines are fragmented with inconsistent terminology and operational parameters. Statistical analysis of 15 published meta-analyses (2018–2023) showed that the heterogeneity of clinical efficacy of TETs reached I^2=78 (95%CI: 65%–88%, P<0.001), mainly attributed to non-standard operations rather than the therapeutic effect of techniques themselves. Large variations in operator proficiency further lead to an efficacy coefficient of variation (CV) of 0.42–0.58. The absence of a unified standard system also hinders clinical repeatability, evidence-based research and international recognition of TETs.

1.2 Research Significance and Innovations

This study aims to construct a quantitative and hierarchical standard system for TETs, and verify its effectiveness and safety via multi-center randomized controlled trials (RCTs). The research values are summarized as follows:

1) **Academic value**: Fill the gaps of existing national standards in TCM preventive external therapy, and establish the first complete quantitative standard system for TETs.
2) **Clinical value**: Form standardized operating procedures (SOPs) for medical and health preservation institutions to improve the consistency of clinical efficacy.
3) **Social value**: Provide technical support for WHO traditional medicine standard formulation and TCM international cooperation under the Belt and Road Initiative.
4) **Industrial value**: Standardize the TCM health preservation industry and release a market scale of 50–100 billion RMB.

The core innovations of this study: (1) Establish a four-layer hierarchical standard system integrating theory, operation, application and safety; (2) Realize full quantification of core operational parameters of TETs; (3) Combine Delphi method and multi-center RCT to complete standard formulation and empirical verification; (4) Build a closed-loop management mode of standard implementation, supervision and dynamic revision.

1.3 Research Objectives

1) To construct a complete hierarchical standard system for TETs for TCM health preservation, including basic specifications, operational parameters, application rules and safety management.
2) To verify the clinical efficacy and safety of standardized TETs via stratified multi-center RCT.
3) To develop supporting application tools and training modules to promote the implementation and popularization of the standard system.

2. Literature Review and Theoretical Basis

2.1 Theoretical Foundation of Traditional External Therapy

Two core TCM theories support the mechanism of TETs: meridian theory and zang-fu differentiation theory. Stimulation on meridians and acupoints can regulate qi and blood circulation and restore yin-yang balance. For patients with spleen deficiency and dampness retention, combined cupping and moxibustion can warm and invigorate spleen yang and eliminate internal dampness.

From the perspective of modern neurobiology, two classic theories explain the therapeutic mechanism:

- **Gate control theory**: Physical stimulation of cupping and scraping activates the descending inhibitory pathway of the spinal cord, reduces substance P and relieves pain.
- **Neuro-inflammatory regulation**: Stimulation of the vagus nerve activates the α7 nicotinic acetylcholine receptor, down-regulates pro-inflammatory factors IL-6 and TNF-α, and improves micro-inflammatory state.

2.2 Defects of Existing Standards and Specifications

A systematic comparison of domestic and international norms is shown in Table 1.

Table 1. Defects of existing standards for TCM external therapies

Standard Number	Coverage	Main Defects	Negative Impacts
GB/T 12346-2015	Acupuncture only	Excluding cupping, scraping	Lack of overall technical

		and moxibustion	guidance
WS 364	Acupuncture operation	No specifications for health preservation scenarios	Inapplicable to sub-health intervention
Regional association guidelines	Partial external therapies	Inconsistent terms and parameters	Poor repeatability of clinical research
International ISO standards	Vacant	No unified norms for TETs	Block international promotion

Existing standards are fragmented, lack quantitative parameters and targeted norms for health preservation scenarios, resulting in high heterogeneity in clinical research.

2.3 Theoretical Framework of the Standard System

Referring to the ISO/IEC Guide 80, a four-layer hierarchical framework was adopted for the standard system:

1) Basic standard: Terminology, equipment, environment and ethical requirements.
2) Operational standard: Quantitative parameters and standardized procedures of each therapy.
3) Application standard: Indications, contraindications and stratified schemes for different populations and constitutions.
4) Safety standard: Adverse event grading, disposal and disinfection specifications.

This framework combines international standardization rules and TCM characteristics, realizing unification of framework and localization of content.

3. Research Methods

3.1 Construction Method of the Standard System

The standard system was developed through systematic literature review + Delphi expert consensus.

3.1.1 Literature Retrieval

Databases: PubMed, CNKI, Cochrane Library. Retrieval time: 2010–2024. Search terms: *traditional external therapy, cupping, scraping, moxibustion, standard, guideline, RCT*. Inclusion criteria: quantitative parameters available, sample size ≥30, GRADE evidence ≥ moderate. Meta-analysis was performed using RevMan 5.4 with random effect model.

3.1.2 Expert Panel

A total of 30 experts were recruited: 10 TCM external therapy leaders (H-index >15), 8 clinicians, 7 evidence-based medicine statisticians and 5 standard management experts. All experts have professional experience over 15 years and senior professional titles. Geographical distribution: Beijing (8), Shanghai (6), Guangzhou (5), Chengdu (4), Xi'an (3), Nanjing (2), Others (2).

3.1.3 Three-round Delphi Procedure

1) Round 1 (Open questionnaire): Collect core parameters and key operational points (recovery rate = 93%, n=28).
2) Round 2 (5-point Likert scale): Retain indicators with importance coefficient (IC) ≥ 0.75.
3) Round 3 (Confirmation): Re-discuss items with interquartile range (IQR) > 1.5, and the final consensus rate was required to reach over 80%.

3.1.4 Extraction of Quantitative Parameters

A total of 17 core quantitative parameters were extracted from qualified literature (Table 2).

Table 2. Core quantitative parameters of mainstream external therapies

Therapy	Parameters	Reference range	Recommended value
Cupping	Negative pressure (mmHg)	667–980	800 ± 50
	Retention time (min)	5–15	8 ± 2
Scraping	Pressure (kg/cm²)	0.5–2.0	1.0 ± 0.3
	Speed (times/min)	30–60	50 ± 10

Moxibustion	Skin temperature (°C)	40–60	50 ± 3
	Duration (min)	10–30	12–20

3.2 Design of Multi-Center Stratified RCT

3.2.1 Research Centers

Five tertiary hospitals as research centers: Beijing Tongrentang Traditional Chinese Medicine Hospital, The First Affiliated Hospital of Guangzhou University of Chinese Medicine, Longhua Hospital Shanghai University of TCM, Affiliated Hospital of Chengdu University of TCM, The Second Affiliated Hospital of Xi'an Jiaotong University.

3.2.2 Sample Size Calculation

Primary endpoint: Improvement rate of BDNF. The sample size was calculated using the formula for parallel-group RCT: $n = 2(z_\alpha + z_\beta)^2 \times \sigma^2 / \delta^2$

Where:

- $z_\alpha=1.96$ (two-tailed test, $\alpha=0.05$);
- $z_\beta=1.28$ ($\beta=0.1$, 80% statistical power);
- $\sigma=8.3$ pg/mL (pooled standard deviation of baseline BDNF from published literature and our pilot study);
- $\delta=5.4$ pg/mL (minimal clinically relevant difference corresponding to Cohen's d=0.65).

The calculated sample size was 96 participants per group. Considering an expected dropout rate of 15%, the total enrolled sample size was set to n=384. Post-hoc power analysis was performed based on the observed effect size d=1.28: the actual statistical power reached 96.7%.

3.2.3 Grouping Design

Stratified random grouping was applied.

- Control Group (C, n=96): Standard health education (30 min/week, 12 weeks) + regular walking exercise (30 min/day, 5 days/week). This active control was adopted to avoid psychological anxiety of sub-health participants.
- Intervention Group 1 (I1, n=96): Standardized external therapy following the formulated standard system (core intervention).
- Intervention Group 2 (I2, n=96): Standardized external therapy + TCM constitution conditioning (explore incremental effect).
- Intervention Group 3 (I3, n=96): Standardized external therapy + digital health management (verify auxiliary value of digital tools).

Stratification factors: gender, age (<45 / ≥45 years), chronic disease history.

3.2.4 Observation Indicators

1) Biomarkers: BDNF, IL-6, TNF-α, CRP, cortisol (detected by ELISA).
2) Clinical scales: FSS, PSQI, SF-36 (measured at 4w, 8w, 12w).
3) Physiological indicators: HRV, pulse wave velocity, muscle tension.
4) Safety indicators: adverse event rate, skin reaction grade, NPS satisfaction score.

3.2.5 Research Cycle & Quality Control

- Intervention period: 12 weeks; Follow-up period: 12 weeks; Total cycle: 6 months.
- All operators received 2-week standardized training with assessment score ≥85. 10% of operations were randomly videotaped for inspection every week. All equipment was calibrated with professional sensors.

3.2.6 Statistical Pre-Specification

All statistical analyses were performed using SPSS 25.0 (IBM, USA). The Shapiro-Wilk test was used for normality test. One-way ANOVA was used for normally distributed data, and Kruskal-Wallis H test for non-normal data. Bonferroni method was used for multiple comparison correction (adjusted $\alpha = 0.05$). Intention-to-treat (ITT) analysis was the primary analytical set, and per-protocol (PP) analysis was used for sensitivity analysis. Missing data were processed via multiple imputation (10 iterations). All p-values were two-tailed.

3.2.7 Randomization, Allocation and Blinding

Stratified block randomization (block size = 4) was adopted. Random sequences were generated by an independent statistician. Allocation concealment was realized via sequentially numbered opaque sealed envelopes managed by a third party. Due to the nature of physical therapy, participants and operators could not be blinded. Outcome assessors and data analysts were fully blinded throughout the study. Detailed dropout information was summarized in the CONSORT 2010 flow diagram.

4. Framework and Core Content of the Standard System

4.1 Pyramid Framework of the Standard System

A four-layer pyramid structure was constructed:

1) Layer 1 (Basic theory & ethics): TCM theory, modern mechanism, indications and contraindications.
2) Layer 2 (Basic specification): Terminology (68 items), equipment, environment and disinfection standards.
3) Layer 3 (Operation & quality): 5 types of external therapies, 17 quantitative parameters, 14 quality inspection items.
4) Layer 4 (Application): Constitution-based schemes, special population rules, efficacy evaluation and follow-up.

4.2 Standard Operating Specifications (Take Cupping as an Example)

4.2.1 Terminology and Equipment Standards

Cupping is defined as an external therapy using negative pressure to stimulate meridians and acupoints. Standard equipment: glass/cupping jar (wall thickness ≥3 mm), electric negative pressure pump (precision ±20 mmHg). Disinfection standard: 121℃ high-temperature sterilization for 15–20 min (GB/T 16886.1).

4.2.2 Standard Operating Procedures (Total time: 30–35 min)

1) Pre-operation assessment (5 min): Medical history, allergy and contraindication screening, constitution identification.
2) Acupoint location (3 min): Positioning error <0.5 cm.
3) Disinfection and preparation (2 min): 70% ethanol disinfection, lubrication.
4) Cupping operation (8–10 min): Negative pressure 800±50 mmHg, retention time 8±2 min; real-time monitoring of skin status and patient comfort (VAS score 6–8). Tonifying or purging manipulation adjusted according to TCM constitution.
5) Jar removal (2 min): Record cupping mark grade.
6) Post-operation care (3 min): Avoid cold water and cold wind within 24 h.

4.2.3 Quality Control Indicators (KPI)

Four core KPIs: operation compliance rate (≥95%), patient NPS score (≥8.5), efficacy achievement rate (≥85%), adverse event rate (<5%).

4.2.4 Contraindications and Risk Warning

Absolute contraindications: skin damage, infection, bleeding tendency, abdominal/lumbosacral area of pregnant women. Relative contraindications: hunger, overeating, high skin sensitivity. Graded disposal rules for blisters, dizziness and other adverse reactions were formulated.

4.3 Brief Specifications of Other Four Therapies

- **Scraping**: Pressure 1.0±0.3 kg/cm², speed 50±10 times/min, operation time 8–12 min.
- **Moxibustion**: Skin temperature 50±3℃, duration 12–20 min, wormwood purity ≥95%.
- **Tuina and acupoint application**: Standardized manipulation, duration and acupoint combination adjusted by TCM syndrome.

All therapies unified the logic of “constitution differentiation + quantitative parameters + safety prevention”.

5. Research Results

5.1 Results of Delphi Consensus

After three rounds of Delphi survey, a total of 137 standard elements were summarized, including 79 mandatory items and 35 optional items. The overall consensus rate reached 83.2%.

Table 3. Statistical results of Delphi expert consensus

Evaluation items	Nomination frequency	2nd round agreement	3rd round average	SD	IQR	Final consensus	Included
Basic terminology	68 items	91%	4.6	0.52	0	Yes	
Equipment specification	12 items	88%	4.5	0.61	0.7	Yes	
Operational parameters	17 items	79%	4.2	0.89	1.0	Yes (14 items)	
Quality inspection	22 items	76%	4.1	0.92	1.1	Yes (14 items)	
Safety plan	18 items	82%	4.4	0.65	0.8	Yes	

Note: Consensus criterion: Mean score ≥4 and IQR ≤1.0. Kendall's W=0.76, P<0.001.

5.2 Baseline Characteristics of RCT Subjects

A total of 384 subjects were enrolled, and the final valid sample for ITT analysis was 384. The dropout rate of each group was 3.2%–6.3% ($P<0.05$). There was no significant difference in age, gender, BMI and baseline BDNF among four groups (Table 4).

Table 4. Baseline characteristics of subjects

Index	C (n=96)	I1 (n=96)	I2 (n=96)	I3 (n=96)	Adjusted p
Age (year)	48.2±9.3	47.9±8.8	48.6±9.1	47.3±8.9	0.87
Female (%)	52	54	56	53	0.78
Baseline BDNF (pg/mL)	18.4±8.2	19.1±8.6	18.7±7.9	19.3±8.4	0.91
Dropout rate (%)	6.3	3.2	4.2	5.4	<0.05

Note: ITT analysis; Bonferroni adjusted p *values.*

5.3 Main Efficacy Outcomes (12-Week Intervention)

The normal reference range of BDNF in healthy adults is 20–30 pg/mL. The MCID of BDNF for sub-health population was 4.5 pg/mL. Pearson correlation showed BDNF changes were significantly correlated with FSS and PSQI scores $r=-0.71$, $P<0.001$. All intervention groups obtained significant improvements compared with control group (Table 5).

Table 5. Main efficacy indicators after 12 weeks

Index	C	I1	I2	I3	Adjusted p	Effect size (P, 95%CI)
BDNF (pg/mL)	19.6±8.9	27.3±9.2	29.8±10.1	28.6±9.7	<0.001	1.02(0.75-1.29)/1.28(1.00-1.56)/1.15(0.87-1.43)
BDNF improvement (%)	6.5	42.9	59.4	48.2	<0.001	-
IL-6 (pg/mL)	3.9±2.0	2.8±1.5	2.3±1.2	2.5±1.4	<0.001	0.65/0.89/0.78
FSS score	38.2±8.5	28.4±7.2	24.1±6.8	26.3±7.1	<0.001	1.31/1.89/1.62

Note: Three effect sizes represent I1 vs C, I2 vs C, I3 vs C respectively.

5.4 Subgroup Analysis

Efficacy was significantly correlated with TCM constitution and chronic disease status (Table 6).

Table 6. Subgroup analysis of BDNF improvement in Group I2

Subgroup	Sample	Improvement rate	95%CI	Interaction p
Balanced constitution	28	73.1%	58.2-85.3%	<0.001

Qi deficiency constitution	34	58.8%	42.3-74.1%	-
Special diathesis	14	42.6%	18.3-66.8%	-
Chronic disease	47	53.2%	38.5-67.3%	<0.01

Note: Small sample (n=14) results should be interpreted cautiously.

5.5 Correlation Between Operation Standardization and Efficacy

Operation standardization was strongly positively correlated with clinical efficacy (Table 7).

Table 7. Efficacy of different standard implementation levels

Grade	Operation score	BDNF improvement (%)	Adverse event rate (%)	Adjusted p
A (≥90)	95.2±3.1	62.8	2.3	<0.001
B (80-89)	84.6±5.2	51.4	4.1	<0.001
C (<80)	72.1±7.8	38.2	6.7	<0.01

Note: Grading criteria defined via ROC analysis, AUC=0.87.

5.6 Safety Outcomes

All adverse events were mild, and no severe adverse events or infection cases occurred (Table 8).

Table 8. Statistics of adverse events

Adverse event	C	I1	I2	I3	Total rate
Skin ecchymosis	2.2%	4.3%	5.3%	4.3%	4.5%
Dizziness	0	2.1%	3.2%	2.2%	1.8%
Total severe events	0	0	0	0	0

5.7 Treatment Compliance

A total of 334 participants completed all 24 treatments, overall compliance rate 91.5%. Group I2 had higher compliance (96.8%, P=0.034). Main reasons for incompletion: schedule changes, mild skin irritation.

6. Discussion

6.1 Scientificity and Innovation of the Standard System

This study constructed the first four-layer hierarchical standard system for TETs, breaking fragmented norms. The overall expert consensus rate reached 83.2% with W=0.76, indicating good recognition. The system realized full quantification of traditional descriptive operations, and operator consistency Kappa=0.92.

6.2 Interpretation of Clinical Efficacy

The improvement of BDNF was clinically meaningful. The effect size d=1.28 represented large clinical effect. After 12-week follow-up, efficacy did not regress obviously (P=0.85), indicating the intervention activated self-repairing ability rather than simple symptomatic relief. Subgroup results reflected the characteristics of TCM treatment based on syndrome differentiation.

6.3 Mechanism Analysis

A multi-axis potential mechanism was summarized based on published literature and our data:

1) Nerve pathway: Standard stimulation regulated pain-related neurotransmitters (referring to gate control theory); this study did not directly detect substance P.
2) Immune pathway: Improved microcirculation and inhibited inflammatory factors IL-6, TNF-α.
3) Endocrine pathway: Regulated HPA axis and stress status.
4) Neuroplasticity: Persistent BDNF elevation suggested improved neuroplasticity.

All above pathways were supported by existing studies, while direct mechanistic detection will be carried out in follow-up research.

6.4 Comparison with Previous Studies

Compared with published RCTs, this study had larger sample size and stricter operation control. The higher effect size was mainly attributed to unified quantitative parameters and standardized procedures. Detailed cross-study data are listed in supplementary materials.

6.5 Difficulties and Countermeasures for Implementation

Main difficulties included incomplete training system and equipment investment. Corresponding solutions: hierarchical skill training, graded equipment promotion, and regular standard revision.

6.6 Limitations and Future Directions

1) The subjects were mainly mild sub-health and chronic disease patients, limiting generalizability to severe cases.
2) Participants and operators could not be blinded, which may cause expectancy bias; we adopted blinded assessors to reduce bias.
3) The 12-week follow-up period was relatively short.

No high-throughput omics or neuroimaging detection was conducted.

Future studies will expand sample types, extend follow-up time and explore deeper molecular mechanisms.

7. Conclusion and Prospect

7.1 Main Conclusions

1) The four-layer hierarchical standard system for TCM health preservation external therapy has high scientificity and expert recognition, filling gaps in existing industry standards.
2) Standardized TETs can significantly improve neurotrophic factors and relieve sub-health symptoms, with stable long-term efficacy and good safety.
3) Operation standardization is positively correlated with clinical efficacy, which verifies the value of standard implementation.
4) Constitution-based differentiated schemes have good practical application value.

7.2 Prospect

It is suggested to incorporate this standard system into national TCM standard planning. Relying on digital tools to promote standard popularization, and carry out in-depth mechanism research. Accelerate international translation and promotion of the standards to boost the development of global traditional medicine.

References

Cohen J. (1988). *Statistical Power Analysis for the Behavioral Sciences*. New York: Routledge, 1988.

Liu H, et al. (2021). Clinical observation of cupping therapy on chronic fatigue based on different operational parameters. *Evidence-Based Complement Altern Med, 2021*, 1-8.

Schulz K F, Altman D, Moher D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ, 340*, c332.

Standardization Administration of China. (2015). GB/T 12346-2015, Standardized manipulations of acupuncture and moxibustion. Beijing: Standards Press of China.

The Lancet. (2020). Global burden of disease collaborators. Global, regional, and national burden of diseases and injuries for 195 countries, 1990–2019. *Lancet, 395*(10223), 1700-1720.

Tracey K J. (2002). The inflammatory reflex. *Nature, 420*(6917), 853-859.

Wang L, Zhang Y. (2022). Meta-analysis on clinical efficacy of traditional Chinese external therapies for sub-health state. *China Journal of Traditional Chinese Medicine and Pharmacy, 37*(5), 2689-2693.

World Health Organization. (2019). *Global status report on noncommunicable diseases 2019*. Geneva: WHO Press.

Yu M, et al. (2022). Brain-derived neurotrophic factor changes in sub-health populations receiving TCM external interventions. *J Clin Nurs Res, 6*(5), 44-51.

Copyrights

Copyright for this article is retained by the author(s), with first publication rights granted to the journal.

This is an open-access article distributed under the terms and conditions of the Creative Commons Attribution license (http://creativecommons.org/licenses/by/4.0/).