

Research Article

Standardizing TCM External Therapies and Time-Based Acupuncture-Moxibustion: Theory, Evidence, and Digital Translation

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Abstract: This paper explores the theoretical and methodological foundations for standardizing traditional Chinese medicine external therapies, with particular attention to time-based moxibustion, Lingui Bafa, and integrated acupuncture-tuina-moxibustion approaches in mild cognitive impairment and chronic musculoskeletal pain. Drawing on recent theoretical analyses, multicenter observational studies, and randomized controlled trial designs, the discussion considers how meridian time sequences, qi transformation rhythms, and standardized operational protocols may be mutually informative rather than reducible to a single explanatory model. To some extent, standardization may improve reproducibility and clinical communication, yet it may also obscure individualized diagnostic reasoning and contextual therapeutic factors. The paper further examines the construction of smart wellness models that integrate industrial standards with digital systems, suggesting that such integration could support data-informed decision-making while requiring critical attention to validity, bias, and implementation barriers. Considering the above factors, this work does not aim to resolve all tensions between tradition and standardization; rather, it proposes a reflective framework in which theoretical coherence, empirical verification, and digital translation are treated as interdependent and provisional. Further research is needed to clarify which elements of external therapy are most amenable to standardization and which should remain flexible in practice.

Keywords: *Traditional Chinese Medicine External Therapy; Time-Based Moxibustion; Lingui Bafa; Mild Cognitive Impairment; Chronic Musculoskeletal Pain;*

1. Introduction

The standardization of traditional Chinese medicine external therapies has become an increasingly prominent topic in both clinical research and health service governance. This prominence is not simply a response to bureaucratic demands for measurable protocols; it also reflects a deeper theoretical question about whether therapeutic practices rooted in meridian theory, qi transformation, and time-sensitive diagnostic reasoning can be rendered sufficiently explicit to permit multicenter evaluation without losing their interpretive flexibility. Recent work on time-based moxibustion with Lingui Bafa for mild cognitive impairment, for example, has attempted to articulate a theoretical bridge between time-based qi transformation and meridian time sequence, suggesting that treatment timing may be understood as a substantive clinical variable rather than a merely administrative scheduling preference ^[1]. Such a claim is ambitious, and to some extent it remains at the level of theoretical analysis rather than confirmatory evidence. Yet it opens a useful line of inquiry: if timing matters, then standardization must decide whether to standardize the timing rule, the operational procedure, or both^[21].

Parallel to this theoretical discussion, empirical studies on traditional Chinese medicine external therapy for chronic soft tissue pain have adopted multicenter observational designs to examine whether standardized protocols can be implemented across

heterogeneous clinical settings ^[2]. The value of such studies lies not only in their findings but also in their methodological compromises. Multicenter observational research can capture real-world variation, but it may also introduce selection bias, inconsistent outcome ascertainment, and practitioner-level heterogeneity that are difficult to fully control. The construction and application of a standard system for traditional external therapy in health preservation further illustrates the institutional dimension of standardization, where clinical protocols, service standards, and health preservation guidelines intersect ^[3]. This leads us to further thinking about whether standardization should be understood as a fixed endpoint or as a dynamic process of negotiated consensus.

The integration of industrial standards with digital systems has added another layer of complexity. The construction and practice of a smart wellness model suggest that traditional Chinese medicine health preservation standards may be embedded in digital platforms, enabling data collection, feedback, and personalized recommendations ^[4]. This development is promising, but it also raises questions about algorithmic reductionism, data quality, and the risk of treating standardized indicators as substitutes for clinical judgment. In parallel, randomized controlled trial designs have been used to evaluate integrated acupuncture, tuina, and moxibustion for chronic multisite musculoskeletal pain, incorporating biomarker and pressure pain threshold assessments ^[5]. Such trials represent a more rigorous attempt to link traditional interventions with objective outcome measures, yet the choice of biomarkers and the interpretation of pressure pain thresholds are not self-evident; they require theoretical justification and cautious validation. A theoretical analysis of combined acupuncture, tuina, and moxibustion for elderly chronic musculoskeletal pain, guided by meridian examination and framed through tendon excess-deficiency and qi-blood stasis, offers a complementary perspective that emphasizes pattern differentiation over fixed protocol ^[6]. Considering the above factors, the introduction of this paper does not assume that standardization is inherently beneficial or inherently reductive. Instead, it treats standardization as a contested and context-dependent process that must be examined through theoretical, empirical, and digital lenses.

Historical and comparative perspectives further complicate any straightforward narrative of standardization. A comparative study of Chinese and European medical history through the lens of “sympathetic understanding” suggests that medical systems are not merely technical assemblages but are embedded in cultural assumptions about the body, causality, and therapeutic authority ^[7]. This observation is relevant to contemporary standardization debates because it warns against treating traditional Chinese medicine external therapies as if they were pre-modern practices awaiting modernization. Rather, standardization itself is a historical product, and its categories may reflect particular institutional priorities. A related analysis of the European Renaissance and the New Culture Movement in relation to the modernity of medical history further suggests that medical modernity is not a single trajectory but a contested field of reinterpretation ^[8]. Considering the above factors, the introduction of this paper acknowledges that standardization is not a neutral container; it shapes what counts as evidence, what counts as fidelity, and what counts as therapeutic success.

The evidence base for traditional Chinese medicine interventions also includes data-mining studies of classical formulas and clinical patterns, which may inform standardized decision-making without prescribing fixed protocols. Research on the Menghe medical school’s treatment of warm diseases, for instance, has used data mining to identify medication patterns that may support pattern-based prescribing ^[9]. Such studies are valuable for clarifying the internal logic of traditional formulae, but they also have limitations: data mining can identify frequency and association without establishing causality, and the results may be sensitive to source selection and coding decisions. Similar methodological considerations apply to studies on the Menghe four schools’ treatment of insomnia ^[19] and on the Menghe medical school’s treatment of damp-heat warm diseases ^[20]. These studies suggest that standardization may be informed by historical prescribing patterns, but they also indicate that such patterns require critical interpretation rather than mechanical replication.

Beyond clinical and historical domains, the standardization of traditional Chinese medicine external therapies is inseparable from education, professional identity, and research training. Discussions on cultivating socialist core values among traditional Chinese medicine graduate students emphasize the importance of integrating professional education with ethical and ideological formation ^[10]. While this topic may appear distant from clinical standardization, it is relevant because standardized practice depends on

practitioners who can internalize both technical protocols and professional values. A related discussion on moral education for traditional Chinese medicine graduate students further suggests that the formation of clinical judgment is not merely a matter of acquiring knowledge but also of developing reflective responsibility ^[11]. Considering the above factors, standardization should be understood as an educational and ethical project, not only a technical one.

The implementation of standardized external therapies also depends on the dissemination and adoption of appropriate technologies, particularly in regional and resource-limited settings. A survey on the promotion and application of appropriate traditional Chinese medicine technologies in Pingliang City, Gansu Province, provides useful insight into the gap between policy intention and local practice ^[12]. Such surveys often reveal that adoption is shaped by training opportunities, reimbursement structures, patient acceptance, and practitioner workload. These factors are not peripheral to standardization; they may determine whether a standard is used, adapted, or abandoned. This leads us to further thinking about whether standardization should be evaluated not only by internal validity but also by implementability and equity.

Preclinical research on cognitive impairment and related conditions provides another layer of evidence that may inform, but not directly determine, clinical standardization. Studies on the effects of naofuming dripping pills on learning and memory in vascular dementia rats, for example, have explored potential neuroprotective mechanisms ^[13]. Such studies are valuable for generating hypotheses, but their translation to human clinical practice is uncertain because of species differences, dosage scaling, and outcome measurement. Behavioral comparisons of SAMR1 and C57BL/6 mouse strains in Alzheimer's disease models further illustrate the importance of model selection and the difficulty of generalizing across experimental systems ^[14]. Research on Semaphorin 3A expression in focal cerebral ischemia and the protective effects of Tongluo Jiunao injection similarly suggests that molecular mechanisms may be relevant to cognitive and neurological outcomes, but the clinical implications remain provisional ^[15]. Comparative studies of different Chinese herbal compound formulas in dementia-like mouse models also indicate that therapeutic effects may vary by formula composition and model characteristics ^[16]. Considering the above factors, preclinical evidence should be treated as hypothesis-generating rather than confirmatory in the context of standardization.

Mental health and psychosocial factors among traditional Chinese medicine graduate students may also indirectly affect the implementation and evaluation of standardized therapies. A survey of mental health status and influencing factors among incoming graduate students at the China Academy of Chinese Medical Sciences suggests that psychological distress is not uncommon and may affect learning, research productivity, and clinical training ^[17]. While this finding does not directly address external therapy standardization, it highlights the human context in which standardization is enacted. Standardized protocols may be formally adopted but inconsistently implemented if practitioners are stressed, overburdened, or insufficiently supported. This leads us to further thinking about whether implementation research should include practitioner well-being as a relevant variable.

Finally, experimental studies on memory acquisition and related cognitive processes may inform the theoretical rationale for interventions targeting mild cognitive impairment. Research on the effects of maca extract on scopolamine-induced memory acquisition impairment in mice, for example, has explored potential nootropic or protective effects ^[18]. Such studies are preliminary and should not be overinterpreted, but they contribute to a broader literature on cognitive enhancement and neuroprotection. Considering the above factors, the introduction of this paper situates standardization within a wider evidentiary and institutional landscape that includes historical, educational, preclinical, and psychosocial dimensions.

2. Theoretical Foundations and Methodological Tensions

The theoretical foundations of time-based moxibustion and Linggui Bafa rest on the assumption that meridian time sequence and qi transformation rhythms are clinically meaningful. This assumption is not unique to contemporary practice; it resonates with classical discussions of chronobiology in Chinese medicine. However, the translation of such assumptions into standardized protocols is not straightforward. The theoretical analysis mentioned earlier proposes a framework in which time-based qi transformation and meridian time sequence guide intervention for mild cognitive impairment, but the framework itself does not

specify how to handle individual variation in chronotype, sleep-wake cycle, or comorbid conditions. To some extent, this omission is not a flaw but a boundary condition: theoretical analysis can clarify conceptual relationships without resolving operational questions. Further research is needed to determine whether the proposed timing rules are clinically superior to conventional timing or whether they function primarily as a structuring device for practitioner attention.

The methodological tensions become more visible when considering multicenter observational studies. The aforementioned study on standardized traditional Chinese medicine external therapy for chronic soft tissue pain reports feasibility and short-term outcomes, but the observational design necessarily limits causal inference. It may demonstrate symptom improvement, yet it cannot rule out regression to the mean, placebo effects, or concurrent treatments. The construction of a standard system for traditional external therapy in health preservation attempts to address this limitation by specifying service processes, practitioner qualifications, and outcome indicators. Such specification can improve consistency, but it may also impose a false sense of uniformity on practices that are inherently individualized. This leads us to further thinking about whether standardization should aim for procedural fidelity or for principled flexibility. A possible middle ground is to standardize the decision-making process rather than the exact intervention content, but this approach requires clear documentation of reasoning steps and remains difficult to validate.

The smart wellness model mentioned earlier introduces digital systems as a potential solution to the scalability problem. By integrating industrial standards with digital platforms, the model may enable real-time monitoring, personalized feedback, and data-driven quality improvement. However, digital translation also introduces new biases. Data collected through wearable devices or mobile applications may overrepresent younger, technologically literate, or urban populations. Moreover, algorithmic recommendations may prioritize measurable outcomes over patient-reported experiences or practitioner insights. Considering the above factors, the theoretical foundations of standardization cannot be separated from the methodological choices that operationalize them. The integration of acupuncture, tuina, and moxibustion for chronic multisite musculoskeletal pain, as evaluated in the previously noted randomized controlled trial, offers a useful case in point. The trial design includes biomarker and pressure pain threshold assessments, which may strengthen internal validity but may also narrow the definition of therapeutic success. The complementary theoretical analysis guided by meridian examination suggests that tendon excess-deficiency and qi-blood stasis patterns may not be fully captured by biomarkers alone. This divergence is not necessarily a contradiction; it may indicate that different research questions require different levels of standardization and different outcome domains.

Historical and comparative studies further complicate the theoretical foundations of standardization. The comparative analysis of Chinese and European medical history through “sympathetic understanding” suggests that medical systems are shaped by cultural assumptions about the body and therapeutic authority. This perspective implies that standardization is not simply a technical procedure but a cultural translation. Similarly, the analysis of the European Renaissance and the New Culture Movement in relation to medical modernity suggests that medical progress is not linear and that different traditions may develop incommensurable criteria for validity. Considering the above factors, theoretical foundations should be treated as historically situated and open to reinterpretation rather than as fixed axioms.

Data-mining studies of classical formulae and clinical patterns offer another theoretical resource. Research on the Menghe medical school’s treatment of warm diseases has identified medication patterns that may inform pattern-based prescribing. Such studies are useful for generating hypotheses about effective combinations, but they do not establish clinical efficacy. Similar limitations apply to studies on the Menghe four schools’ treatment of insomnia and on the Menghe medical school’s treatment of damp-heat warm diseases. These studies suggest that historical prescribing patterns may inform standardized decision support, but they also indicate that such patterns require validation in contemporary clinical contexts. This leads us to further thinking about whether standardization should incorporate historical pattern knowledge as a heuristic rather than as a rule.

Preclinical research provides additional theoretical grounding for interventions targeting cognitive impairment. Studies on naofuming dripping pills in vascular dementia rats, behavioral comparisons of SAMR1 and C57BL/6 mouse strains, Semaphorin

3A expression in focal cerebral ischemia, and different Chinese herbal compound formulas in dementia-like mouse models collectively suggest that multiple mechanisms may be involved in cognitive protection. However, these studies also highlight the problem of translation: animal models cannot fully replicate human mild cognitive impairment, and molecular outcomes may not correspond to clinical improvement. Research on maca extract and scopolamine-induced memory impairment further illustrates the preliminary nature of preclinical evidence. Considering the above factors, theoretical foundations should be constructed with awareness of the gap between mechanism and clinical effect.

3. Evidence Assessment and Interpretive Pluralism

Assessing the evidence for standardized traditional Chinese medicine external therapies requires more than cataloging study results. It requires attention to the fit between research design, clinical question, and interpretive framework. The multicenter observational study discussed earlier provides useful data on feasibility and short-term outcomes, but its lack of randomization and blinding limits its ability to support claims of efficacy. The standard system construction is primarily a normative contribution, offering categories and procedures rather than causal evidence. The smart wellness model is similarly programmatic, describing an integrated approach that may be evaluated through implementation research rather than through conventional clinical trials. This leads us to further thinking about whether the field needs a broader evidentiary hierarchy that includes theoretical coherence, expert consensus, and implementation feasibility alongside randomized controlled trial evidence.

The randomized controlled trial on integrated acupuncture, tuina, and moxibustion for chronic multisite musculoskeletal pain represents a more rigorous attempt to evaluate these interventions. The three-arm assessor-blinded design with biomarker and pressure pain threshold assessments is methodologically stronger than an observational study, but it is not without limitations. Biomarkers may not fully reflect the subjective and functional dimensions of pain, and pressure pain thresholds may vary with measurement site, operator technique, and patient expectation. The theoretical analysis based on meridian examination offers a complementary interpretation, suggesting that therapeutic effects may be mediated by changes in tendon excess-deficiency and qi-blood stasis. This interpretation is plausible but not yet empirically confirmed. Considering the above factors, evidence assessment should avoid treating one methodological approach as inherently superior. Instead, it should ask which claims are supported by which designs and under what conditions.

The theoretical analysis on time-based moxibustion with Lingui Bafa for mild cognitive impairment is particularly relevant here because it explicitly links timing to qi transformation and meridian time sequence. If this link is valid, then standardization must incorporate temporal variables that are often ignored in conventional clinical trials. However, the theoretical analysis does not provide empirical validation, and the translation from theory to protocol remains underspecified. Further research is needed to determine whether time-based moxibustion produces measurable changes in cognitive outcomes and whether those changes are attributable to timing, needling or moxibustion technique, or nonspecific therapeutic factors. This leads us to further thinking about the role of interpretive pluralism in evidence assessment. Different stakeholders may prioritize different outcomes: patients may value symptom relief and quality of life, practitioners may value pattern differentiation and clinical coherence, and policymakers may value cost-effectiveness and scalability. Standardization that ignores this plurality may achieve consistency at the expense of relevance.

Historical and comparative evidence also contributes to interpretive pluralism. The comparative study of Chinese and European medical history through “sympathetic understanding” suggests that different medical traditions may have different criteria for what counts as evidence and what counts as therapeutic success. The analysis of the European Renaissance and the New Culture Movement in relation to medical modernity further suggests that medical knowledge is historically contingent and subject to reinterpretation. Considering the above factors, evidence assessment should be reflexive about its own assumptions rather than treating standardization as a neutral benchmark.

Data-mining studies of classical formulae provide another form of evidence that is often overlooked in conventional hierarchies. Research on the Menghe medical school's treatment of warm diseases, the Menghe four schools' treatment of insomnia, and the Menghe medical school's treatment of damp-heat warm diseases offer pattern-level insights that may inform standardized decision support. However, these studies are limited by source selection, coding decisions, and the absence of clinical outcome data. They should be treated as hypothesis-generating rather than confirmatory. This leads us to further thinking about whether evidence assessment should include historical and textual analysis as a legitimate form of knowledge synthesis.

Preclinical studies provide mechanistic evidence that may support theoretical plausibility but cannot establish clinical efficacy. Studies on naofuming dripping pills in vascular dementia rats, behavioral comparisons of SAMR1 and C57BL/6 mouse strains, Semaphorin 3A expression in focal cerebral ischemia, different Chinese herbal compound formulas in dementia-like mouse models, and maca extract in scopolamine-induced memory impairment collectively suggest that multiple pathways may be involved in cognitive protection. However, these studies also highlight the problem of translation and the need for cautious interpretation. Considering the above factors, evidence assessment should integrate preclinical, historical, observational, and experimental evidence without collapsing them into a single hierarchy.

Psychosocial and educational evidence may also inform implementation and standardization. The survey on mental health status among incoming graduate students at the China Academy of Chinese Medical Sciences suggests that practitioner well-being may affect clinical training and implementation. Discussions on cultivating socialist core values and moral education further suggest that standardization is not only a technical process but also an educational and ethical one. The survey on the promotion and application of appropriate traditional Chinese medicine technologies in Pingliang City illustrates the gap between policy and local practice. This leads us to further thinking about whether evidence assessment should include implementation and educational outcomes as legitimate domains.

4. Digital Translation, Implementation, and Critical Reflections

The digital translation of traditional Chinese medicine external therapy standards is both an opportunity and a risk. The smart wellness model mentioned earlier suggests that industrial standards can be integrated with digital systems to support personalized health preservation. This integration may enable continuous data collection, remote monitoring, and adaptive recommendations. However, it also raises critical questions about data validity, algorithmic transparency, and the risk of reinforcing existing inequalities. To some extent, digital systems may improve access for patients who cannot attend in-person sessions, but they may also exclude those with limited digital literacy or unreliable internet access. This leads us to further thinking about whether digital translation should be guided by equity-oriented design principles rather than by technological feasibility alone.

The construction of a standard system for traditional external therapy in health preservation provides a useful starting point for implementation research. Such a system can specify training requirements, safety protocols, and outcome measures, but it cannot guarantee that practitioners will adhere to them in practice. Implementation barriers may include time constraints, lack of institutional support, and resistance to standardized documentation. The multicenter observational study discussed earlier illustrates some of these barriers, as variation across sites may reflect differences in patient populations, practitioner experience, and organizational culture. Considering the above factors, implementation should be understood as a continuous process of adaptation rather than a one-time adoption of a fixed protocol.

The randomized controlled trial on integrated acupuncture, tuina, and moxibustion for chronic musculoskeletal pain and the theoretical analysis based on meridian examination offer complementary perspectives. The trial provides evidence on short-term outcomes, while the theoretical analysis provides a framework for interpreting those outcomes through meridian examination and pattern differentiation. This complementarity suggests that standardization need not be reduced to a single epistemic model. Instead, it may be possible to develop a layered standard in which core safety and procedural elements are fixed, while diagnostic reasoning and treatment selection remain flexible. Further research is needed to test whether such layered standards improve

clinical outcomes without compromising practitioner autonomy. The theoretical analysis on time-based moxibustion with Linggui Bafa for mild cognitive impairment adds another layer, suggesting that temporal variables may need to be incorporated into both standardized protocols and digital systems. This leads us to further thinking about whether the field is ready for such complexity or whether it should first establish basic feasibility and safety data.

Historical and comparative perspectives may also inform digital translation. The comparative study of Chinese and European medical history through “sympathetic understanding” suggests that medical systems are embedded in cultural assumptions that may not be easily digitized. The analysis of the European Renaissance and the New Culture Movement in relation to medical modernity further suggests that digital translation is not a neutral process but a reinterpretation of tradition. Considering the above factors, digital systems should be designed with cultural sensitivity and historical awareness.

Data-mining studies of classical formulae may inform digital decision support. Research on the Menghe medical school’s treatment of warm diseases, the Menghe four schools’ treatment of insomnia, and the Menghe medical school’s treatment of damp-heat warm diseases suggest that historical prescribing patterns can be encoded as heuristics. However, such encoding risks oversimplification and may obscure the contextual reasoning that originally guided formula selection. This leads us to further thinking about whether digital systems should represent uncertainty and variation rather than only point estimates or fixed rules.

Preclinical evidence may inform digital translation by identifying potential biomarkers or mechanisms. Studies on naofuming dripping pills in vascular dementia rats, behavioral comparisons of SAMR1 and C57BL/6 mouse strains, Semaphorin 3A expression in focal cerebral ischemia, different Chinese herbal compound formulas in dementia-like mouse models, and maca extract in scopolamine-induced memory impairment collectively suggest that multiple mechanisms may be relevant. However, these studies also highlight the gap between animal models and human clinical practice. Considering the above factors, digital translation should be cautious about overinterpreting preclinical evidence.

Educational and psychosocial factors may also affect implementation. Discussions on cultivating socialist core values and moral education suggest that standardization requires practitioners who can integrate technical protocols with ethical reflection. The survey on mental health status among incoming graduate students suggests that psychological distress may affect learning and implementation. The survey on the promotion and application of appropriate traditional Chinese medicine technologies in Pingliang City illustrates the importance of local context. This leads us to further thinking about whether digital translation should include training, support, and well-being as core components rather than add-ons.

5. Conclusion

Considering the above factors, the standardization of traditional Chinese medicine external therapies and time-based acupuncture-moxibustion should be approached as a reflective and iterative endeavor rather than a linear progression from theory to protocol to digital implementation, and the evidence base examined here—ranging from theoretical analyses of time-based moxibustion with Linggui Bafa for mild cognitive impairment, multicenter observational studies of standardized external therapy for chronic soft tissue pain, standard system construction for traditional external therapy in health preservation, smart wellness models integrating industrial standards with digital systems, randomized controlled trials of integrated acupuncture, tuina, and moxibustion for chronic multisite musculoskeletal pain, and theoretical analyses guided by meridian examination, alongside historical-comparative studies, data-mining studies of Menghe medical school patterns, educational and ethical discussions, regional technology adoption surveys, preclinical studies on cognitive impairment, and psychosocial surveys—collectively illustrates both the promise and the tension of standardization, suggesting that possible directions for future research include developing layered standards that distinguish core safety elements from flexible diagnostic reasoning, validating temporal variables in time-based moxibustion through adequately powered trials, evaluating digital translation through equity-oriented implementation research, and examining how historical, educational, and psychosocial factors shape adoption and fidelity, so that to some extent the value of standardization may lie not in producing uniform interventions but in making clinical reasoning more transparent, comparable, and open to revision.

Data Availability Statement

Data will be made available on request.

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Conflicts of Interest

The author(s) declare no conflicts of interest.

Ethical Approval and Consent to Participate

Not applicable.

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