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Development of a Traditional Chinese Aromatic Sachet Compound for Primary Dysmenorrhea in University Students: A Three-Round Delphi Consensus Study

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Abstract

Background: *Primary dysmenorrhea is highly prevalent among university women and negatively affects quality of life, study performance, and mental health. While NSAIDs are effective, adverse effects and recurrence motivate interest in noninvasive complementary approaches. Aromatherapy and traditional Chinese aromatic therapies show promise but suffer from heterogeneous formulations and limited standardization.*

Objective: *To establish an expert consensus on a standardized, pattern-specific traditional Chinese medicinal (TCM) aromatic sachet compound specifically for university students with cold coagulation and blood stasis type dysmenorrhea.*

Methods: *A formal three-round Delphi study was conducted with 15 senior TCM clinicians in Guangzhou (Class III Grade A hospitals). An initial herb list and dosage ranges were generated from a structured literature review and TCM pattern rationale. Experts rated each herb's agreement (5-point Likert) and recommended dosage; rounds iteratively refined the list with controlled feedback. Decision criteria were mean agreement ≥ 4.0and coefficient of variation ≤ 0.25; coordination was assessed by Kendall's W withp < 0.05. Expert authority was quantified by Cr = (Ca + Cs)/2, where Ca is the judgment basis coefficient and Cs familiarity. We also updated the evidence base via recent high-indexed literature (2017–2025) on aromatherapy/TCM for dysmenorrhea.*

Results: *Across three rounds, 100% questionnaires were validly returned. Round-level authority was high (e.g., Ca 0.95–0.97; Cs 0.70–0.81; Cr0.82–0.89). Expert coordination was statistically significant: Kendall's W 0.125, 0.451, and 0.278, all p < 0.05. The final consensus yielded a 13-herb aromatic sachet compound tailored to cold coagulation and blood stasis pattern: Bai Zhi (5 g), Ding Xiang (5 g), Ai Ye (5 g), Xiao Hui Xiang (5 g), Shan Nai (5 g), Rou Gui (10 g), Dang Gui (10 g), Chuanxiong (10 g), Xiang Fu (10 g), Mu Xiang (10 g), Mei Gui Hua (15 g), Gui Hua (15 g), Su He Xiang (0.1 g), total 105.1 g per sachet. The formulation integrates aromatic warm-through (温通), transform dampness (化湿), and open-the-orifices (开窍) categories to warm channels, move blood, regulate qi, soothe mood, and mitigate gastrointestinal discomfort during menses.*

Conclusion: *The Delphi process produced a scientifically grounded, pattern-specific, and practical TCM aromatic sachet formula with strong expert consensus and authority. Standardization of components and dosing addresses prior heterogeneity in aromatic interventions. The resulting standardized formula provides a robust foundation for future clinical trials to evaluate its efficacy and safety as a noninvasive modality for university students.*

Keywords: *primary dysmenorrhea; university students; Delphi method; traditional Chinese medicine; aromatherapy; aromatic sachet; self-care*

1. INTRODUCTION

Primary dysmenorrhea (PD) is a widespread gynecological issue, and it is particularly burdensome among university students, where prevalence commonly exceeds 60%, contributing to academic absenteeism, sleep disturbance, mood symptoms, and diminished overall functioning (Al-Diwan, 2025; Hu et al., 2020). This significant health concern is not limited to one region, as studies globally report similar challenges in managing its impact on young women's lives (Itani et al., 2022; Armour et al., 2019). While pharmacologic management is effective, limitations related to adverse effects and symptom recurrence have fueled a search for safer, noninvasive alternatives.

Complementary and alternative medicine (CAM), especially aromatherapy, has gained popularity (Caballero-Gallardo et al., 2025). The therapeutic rationale is increasingly understood to involve not only psychological relaxation but also direct physiological effects, potentially through the modulation of

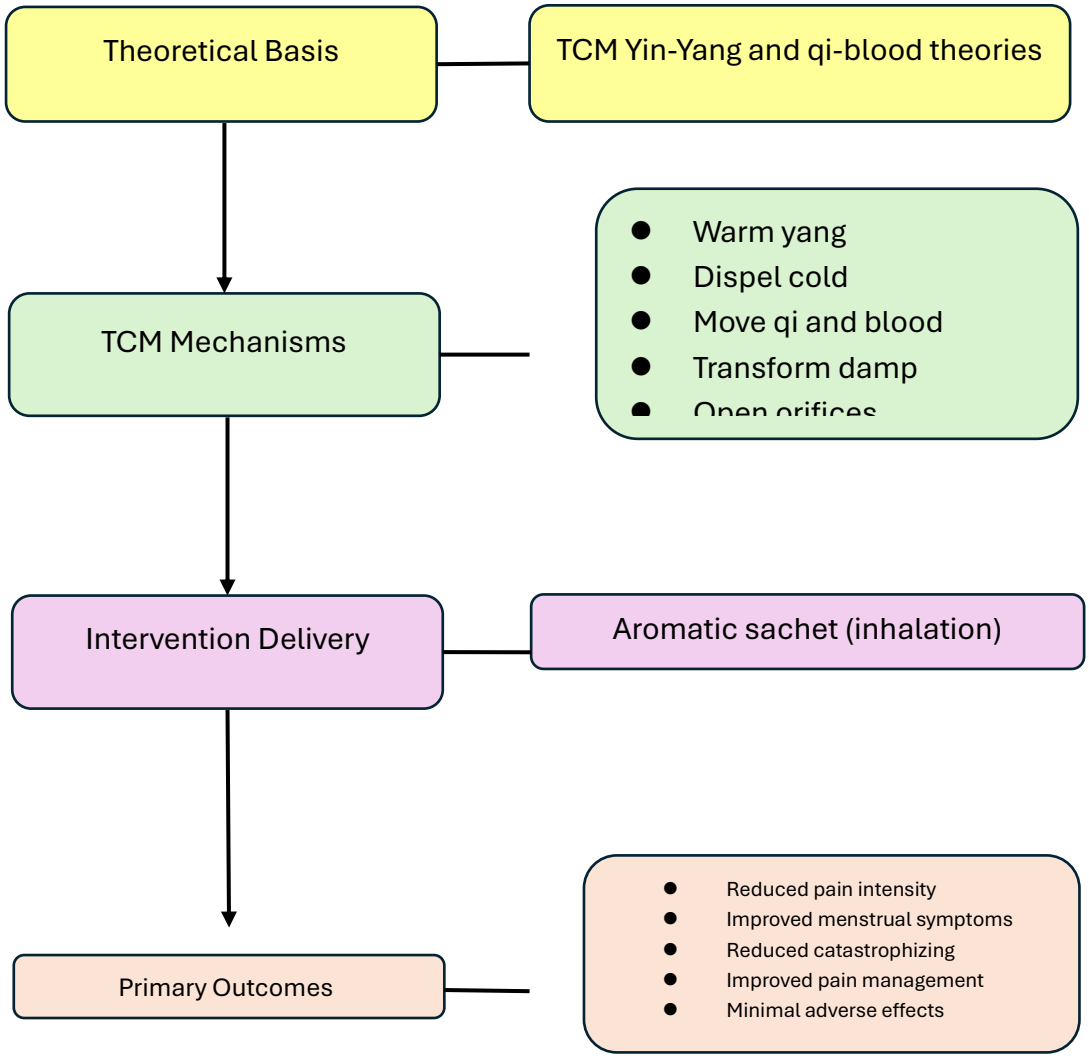
prostaglandin synthesis or the interaction between olfactory pathways and the brain's pain-processing centers (Mihailov et al., 2023; Lötsch et al., 2016). Multiple high-indexed systematic reviews confirm that aromatherapy reduces PD pain compared to placebo (Lee et al., 2018; Song et al., 2018; Sut &Kahyaoglu-Sut, 2017).

Despite this, clinical application is hampered by a lack of standardization and safety considerations (e.g., phototoxicity, dermal sensitization, and neurotoxicity with improper use) (Ali et al., 2015). Traditional Chinese aromatic therapy (香药外治) offers a historically grounded approach using whole herbs in sachets, minimizing direct skin contact (Han & Kay, 2024). Crucially, TCM emphasizes pattern differentiation, a cornerstone of personalized medicine (Wang, 2023; Zhang et al., 2021). University students frequently present with a pattern of cold coagulation and blood stasis (Xuxin et al., 2025). Therefore, developing a standardized, expert-derived aromatic formula for this specific pattern is essential for enabling consistent useself-care and facilitating rigorous clinical evaluation.

The primary aim of this study was to construct, via a three-round Delphi method, an expert consensus TCM aromatic sachet compound specifically for university students with cold coagulation and blood stasis PD. To achieve this, we integrated evidence from the classical TCM literature, modern clinical expertise, and recent high-indexed studies (2017–2025) supporting aromatherapy and TCM approaches for PD.

Theoretical framework: The intervention is grounded in TCM Yin-Yang and qi-blood theory—warming yang to dispel cold, moving qi and blood to relieve pain, transforming dampness to soothe the middle, and opening orifices to calm the shen—and in Orem's self-care theory, which posits that enhancing self-care agency and providing simple tools (e.g., sachets, education) can improve health outcomes. We hypothesize that a standardized aromatic sachet can reduce pain severity, alleviate associated gastrointestinal and mood symptoms, and improve a student's ability to manage pain.

Figure 1. Theoretical Framework for the Aromatic Sachet Intervention



2. METHODS

2.1 Design

We conducted a structured three-round Delphi consensus with senior TCM gynecologists. This structured communication technique is well-established for building consensus in health research where evidence is complex or emerging (Humphrey-Murto et al., 2017). The process preserved anonymity and used controlled statistical feedback to guide refinement.

2.2 Research group

The research team comprised one chief TCM physician, one associate chief TCM physician, one associate professor, and two master's students. The team defined scope, synthesized literature on PD patterning in university students, drafted candidate aromatic herbs with rationales and initial dosages, designed and administered questionnaires, and analyzed Delphi data.

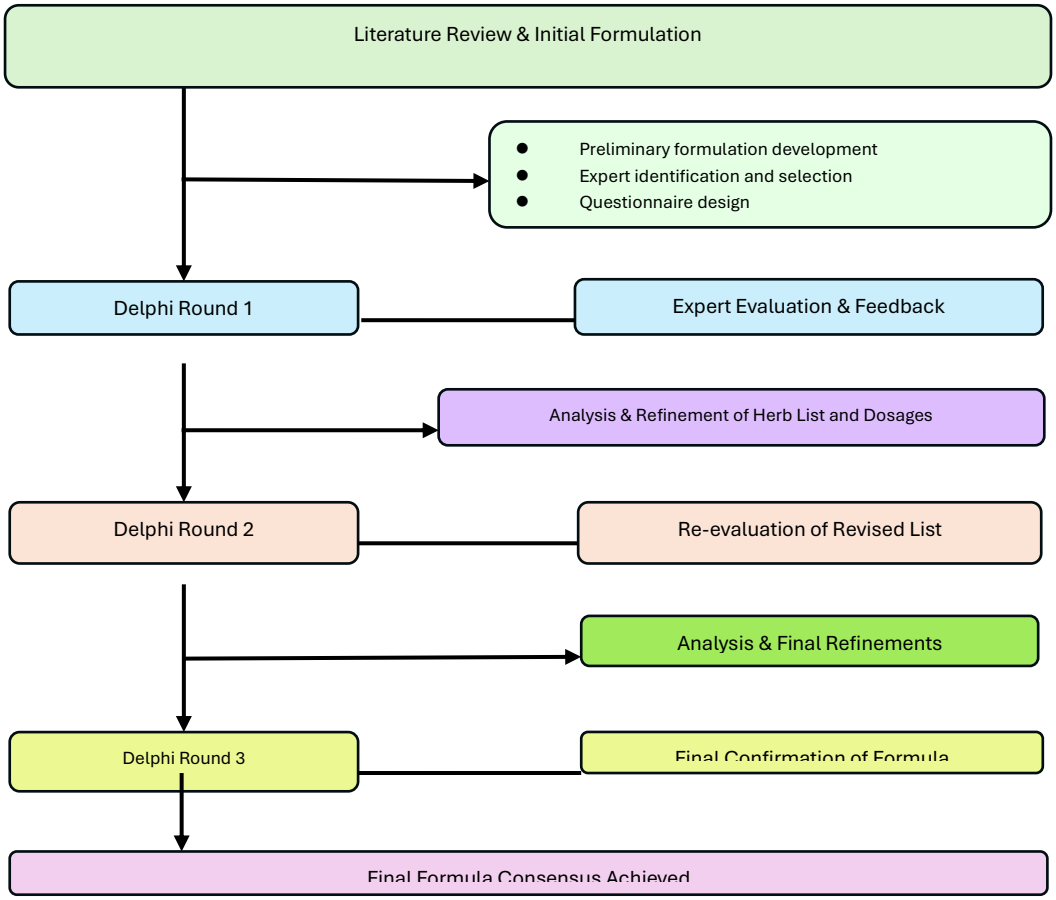
2.3 Expert panel selection

Fifteen TCM experts were purposively recruited from two tertiary Class III Grade A hospitals in Guangzhou. Inclusion criteria: (1) bachelor's degree or higher; (2) associate senior title or higher; (3) ≥10 years of clinical TCM gynecology practice; (4) willingness and availability to complete all rounds. Panel demographics: mean age 52.07 ± 3.08 years; mean experience 28.87 ± 2.95 years; five chiefs and ten associate chiefs; 100% actively practicing in TCM gynecology.

Table 1. Weighting Schema for Expert Judgment Basis (Ca)

Basis of Judgment	Large (Weight)	Medium (Weight)	Small (Weight)
Working experience	0.5	0.4	0.3
Theoretical knowledge	0.3	0.2	0.1
Reference to materials	0.1	0.1	0.1
Intuitive choice	0.1	0.1	0.1

Figure 2. Technical Route of the Study



2.4 Questionnaire development and Delphi rounds

The round-1 questionnaire contained three parts: (1) study overview and instructions; (2) herb evaluation (composition items with 5-point agreement scale, 1 = "strongly disagree" to 5 = "strongly agree", plus fields for suggested dosage and alternatives); and (3) expert background, familiarity levelCs, and basis-of-judgment weighting Ca (Table 1). Candidates prioritized fragrant herbs with warming, blood-moving, qi-regulating, damp-transforming, and orifice-opening actions aligned to cold coagulation and blood stasis PD. Herbs with known phototoxicity or high sensitization potential as essential oils were given lower priority if a fragrant whole-herb alternative existed.

After each round, we computed item means, standard deviations, and coefficients of variation (CV), summarized group feedback, and revised the list (retain, adjust dose, replace) for the next round.

2.5 Decision rules and statistical analysis

- **Retention threshold:** mean agreement $\bar{x} \geq 4.0$ and CV ≤ 0.25.
- **Expert positive coefficient:** effective return rate (target >70%).
- **Authority coefficient:**Cr = (Ca + Cs)/2with Cr > 0.7 indicating high authority.
- **Coordination:** Kendall's W∈ [0,1]; significance by chi-square test at $p < 0.05$.

Formulas:

- Coefficient of variation: $CV = \sigma / \bar{x}$
- Authority coefficient: Cr = (Ca + Cs)/2.

Data were double-entered and analyzed in SPSS 25.0.

2.6 Safety and quality considerations

Given potential essential oil phototoxicity and dermal sensitization, we prioritized aromatic whole herbs in a sachet for inhalation exposure, minimized inclusion of highly sensitizing resins, and limited Su He Xiang to a microdose (0.1 g) to contribute aroma without overwhelming exposure. The final formula was constrained to ≤13 herbs to streamline sourcing and quality control. A standard per-sachet mass was targeted around 100 g to ensure reproducible aroma intensity.

3. RESULTS

3.1 Expert engagement, authority, and coordination

All three rounds achieved a 100% effective recovery rate, indicating strong engagement. The authority and coordination metrics, summarized in Table 2, confirmed the robustness of the consensus process.

Table 2. Expert Coordination and Authority Across Delphi Rounds

Delphi Round	Kendall's W	χ^2	p-value	Judgment Basis (Ca)	Familiarity (Cs)	Authority (Cr)
Round 1	0.125	26.17	<0.05	0.97	0.75	0.86
Round 2	0.451	20.31	<0.05	0.95	0.70	0.82
Round 3	0.278	12.50	<0.05	0.96	0.81	0.89

3.2 Item progression and final formula

Round-1 retained 10 herbs (high agreement and low CV): Bai Zhi, Dang Gui, Gui Zhi, Xiang Fu, Mei Gui Hua, Ru Xiang, Mu Xiang, Su He Xiang, Ding Xiang, and Ai Ye; four items with low means/high CV (Hong Hua, Yue Ji, Zi Su Geng, She Xiang) were removed; Jiang Xiang was flagged for reassessment. Based on expert feedback and literature, we proposed additions (e.g., Mo Yao for pain; Gao Liang Jiang for warming; Gui Hua for aroma/mood).

Round-2 integrated changes: Ru Xiang and Gui Zhi were reconsidered due to insufficient aroma; Gui Zhi was replaced by Rou Gui to strengthen warming potency and fragrance; Ru Xiang was removed. To keep total items ≤13 and optimize synergy, Jiang Xiang, Mo Yao, and Gao Liang Jiang were replaced with Xiao Hui Xiang (qi movement), Chuanxiong (blood movement), and Shan Nai (warming, aroma). Ding Xiang and Ai Ye dosages were adjusted to 5 g each; per-sachet mass tentatively set to ~100 g.

Round-3 finalized four additional items and dosages with high consensus and low variability (e.g., Xiao Hui Xiang 5 g; Chuanxiong 10 g; Shan Nai 10 g; Rou Gui 10 g) and adjusted Bai Zhi to 5 g and Dang Gui to 10 g.

In summary, the three-round process systematically refined the initial herb list. Round 1 retained 10 herbs with high agreement and low CV. Round 2 integrated expert feedback, replacing herbs like Gui Zhi with the more aromatic Rou Gui and removing Ru Xiang. Round 3 finalized dosages and confirmed the inclusion of all 13 herbs, achieving strong consensus. The final formula is detailed in Table 3.

Table 3. Final Aromatic Sachet Formula and Doses (per sachet)

TCM Function	**Herb (Pinyin & Latin)**	**Dosage (g)**
Warm Channels & Dispel Cold	Rou Gui (Cinnamomum cassia)	10
	Ai Ye (Artemisia argyi)	5
	Ding Xiang (Syzygium aromaticum)	5
	Shan Nai (Kaempferia galanga)	5
	Xiao Hui Xiang (Foeniculum vulgare)	5
	Bai Zhi (Angelica dahurica)	5
Move Blood & Relieve Pain	Chuanxiong (Ligusticum chuanxiong)	10

	Dang Gui (Angelica sinensis)	10
	Mei Gui Hua (Rosa rugosa)	15
Regulate Qi & Reduce Distension	Xiang Fu (Cyperus rotundus)	10
	Mu Xiang (Aucklandialappa)	10
Soothe Mood & Open Orifices	Gui Hua (Osmanthus fragrans)	15
	Su He Xiang (Styrax/Storax)	0.1
Supportive Aroma & Synergy	Ding Xiang (Syzygium aromaticum)	5
Total Weight		105.1

5. DISCUSSION

5.1 Summary

This study successfully used a three-round Delphi process to establish an expert consensus on a standardized 13-herb aromatic sachet formula for PD. The process demonstrated high expert authority and coordination, resulting in a theoretically coherent and practical formulation.

5.2 Alignment with contemporary evidence

The final formula aligns well with modern research. For instance, a 2022 systematic review confirmed that lavender, a key aromatic component with properties similar to the flowers in our formula, is effective for pain relief in PD (Fasanghari et al., 2023). The inclusion of warming herbs like Rou Gui (cinnamon) is supported by evidence of its anti-inflammatory properties (Davoudi & Ramazani, 2024;Wong, 2023; Gruenwald et al., 2010). The qi-regulating herb Xiang Fu (Cyperus rotundus) has also been identified in systematic reviews as a cornerstone of herbal treatments for PD (Putra et al., 2025; Roniet al., 2024).
Our formula includes fragrant flowers (Mei Gui Hua; Gui Hua) to support anxiolytic and mood-soothing effects and aromatic warm-through herbs (Rou Gui, Shan Nai, Bai Zhi, Ai Ye) for vasodilation and pain relief consistent with TCM and potentially with decreased myometrial hypercontractility. Qi-regulating and blood-moving herbs (Xiang Fu, Mu Xiang, Chuanxiong, Dang Gui) address pelvic stagnation and cramping. The inclusion of Su He Xiang at microdose is conventional in TCM to harmonize aroma and "open orifices," likely enhancing perceived olfactory depth without significant systemic exposure.

5.3 Safety and Standardization Advantages

By prioritizing whole herbs for inhalation, this formula minimizes the risks associated with concentrated essential oils. Standardization of the 13 herbs and their dosages is a crucial step toward improving the reproducibility and reliability of aromatic therapies in clinical practice.

5.4 Adherence and Practicality

This approach aligns with findings that empowering young women with effective strategies is a key component of managing PD (Wong et al., 2016). A standardized, easy-to-use sachet can improve adherence to non-pharmacological pain management.

5.5 Implications for Future Clinical Research

This consensus-derived formula provides a strong basis for future clinical evaluation. A well-designed clinical study would be the logical next step to rigorously assess the efficacy and safety of the sachet.

5.6 Limitations

- **Expert panel:** The panel was limited to two hospitals in one city; while authority was high, geographic diversity was limited. Multicenter Delphi validation would enhance generalizability.
- **Method:** Delphi relies on expert opinion rather than direct clinical outcomes; clinical studies are required to confirm efficacy and safety.

- **Quality Control:**Future research should include chemical profiling of the sachet's volatile components.
- **Pattern specificity:**The formula is specific to one common TCM pattern.

5.7 Future directions
- Develop chemical fingerprints and stability testing for sachets.
- Compare sachet inhalation with essential oil inhalation and with adjunctive NSAID use.
- Explore digital support tools (reminders, symptom tracking) to enhance adherence.

6. CONCLUSION
A rigorous three-round Delphi process produced a consensus, pattern-specific TCM aromatic sachet compound for primary dysmenorrhea among university students. The formulation is theoretically coherent, practically standardized, and aligned with emerging evidence that aromatherapy reduces menstrual pain. This work provides the foundation for a well-designed study to confirm the clinical efficacy, safety, and implementation potential of this sachet as a low-risk adjunct or alternative to systemic analgesics in student health settings.

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Authors' contributions
JWC and CSUL were responsible for the study's conceptualization and design. JWC conducted data collection and drafted the initial manuscript. YZ and CSUL critically reviewed and revised the manuscript for essential intellectual content. All authors (JWC, YZ, WL, CSUL, WIPPand YMCC) have read, edited, and approved the final version of the manuscript for publication.

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Ethics
Ethical Approval and Consent to Participate
This research was approved by the Medical Ethnics Committee of Guangzhou Medical University (202212002).

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