



### RESEARCH ARTICLE

## PREPARATION OF AN EFFECTIVE TRADITIONAL CHINESE MEDICINAL COMPOUND FOR SLEEP-AID SACS IN THE TREATMENT OF INSOMNIA IN OLDER PEOPLE: A DELPHI METHOD STUDY

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### Abstract

**Objective:** To establish an expert consensus on an optimal Traditional Chinese Medicine (TCM) compound for use in sleep-aid sacs to treat insomnia in older adults.

**Methods:** A three-round Delphi study was conducted with 12 TCM experts from a Class Three Grade A hospital in Guangzhou, China, from April to July 2021. An initial list of herbs was developed based on a literature review. Experts rated the importance of each herb on a 5-point Likert scale over three successive questionnaire rounds. Statistical analysis, including mean scores, coefficient of variation (CV), and Kendall's W coefficient, was used to assess the concentration and coordination of expert opinions.

**Results:** The effective questionnaire recovery rate was 100% across all three rounds. The final expert authority coefficient (Cr) was high at 0.94. The Kendall's W coefficients for the three rounds were 0.196, 0.341, and 0.158, respectively ( $p < .05$ ), indicating strong and statistically significant coordination among experts. The CV for all selected herbs was less than 0.25, showing high opinion consistency. The final consensus process yielded a 10-herb compound: Dalbergia odorifera, Semen ziziphi spinosae, Chinese Eaglewood, Rose, Polygala, Radix Aucklandiae, Cassia Obtusifolia, Jasmine, Albiziae Cortex, and Polygoni Multiflori Caulis.

**Conclusion:** The Delphi method successfully facilitated a consensus among TCM experts, resulting in a scientifically derived and reliable herbal compound for treating insomnia in older people via sleep-aid sacs. This study provides a validated, non-invasive therapeutic option and a methodological reference for future research in TCM-based quality of life interventions.

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## Introduction:-

Insomnia in older adults is a prevalent and significant public health issue, affecting daily function and diminishing quality of life. National surveys in China indicate an insomnia rate as high as 74.1% among the elderly, with rates in nursing homes reaching between 54.5% and 64.9%.<sup>1-4</sup> This condition is more than a subjective feeling of insufficient sleep; it is a risk factor for chronic diseases, falls, depression, and increased mortality, with a natural history that often leads to persistent symptoms if left untreated.<sup>5-8</sup> The aging global population underscores the urgent need for effective, safe, and accessible treatments for senile insomnia.<sup>9</sup>

From a Traditional Chinese Medicine (TCM) perspective, insomnia often stems from a disharmony of Yin and Yang, deficiency of qi and blood, and a lack of shen (a stable mental state).<sup>10</sup> While conventional pharmacology is a common treatment route, there is growing patient preference for TCM therapies due to their perceived milder side effects and holistic approach, a trend supported by systematic reviews showing the potential efficacy of TCM for primary insomnia.<sup>11-13</sup> Among these, sleep-aid aromatherapy and herbal sacs have gained popularity as non-invasive alternatives, with studies noting the positive effects of characteristic fragrances on sleep quality.<sup>14, 15</sup> However, the preparation of these remedies often lacks standardization and rigorous expert validation, posing risks to efficacy and safety. This gap highlights the need for a core outcome set for clinical trials in this area to ensure consistency and comparability of research.<sup>16</sup>

To address this gap, this study aimed to develop and validate an optimal TCM herbal compound specifically for use in sleep-aid sacs for older adults. The Delphi method was selected as a structured communication technique to systematically solicit expert opinions and achieve a reliable consensus.<sup>17, 18</sup> This approach is increasingly used in healthcare to establish clinical guidelines and standardize practices where evidence is emerging or complex, including the development of nursing programs and clinical management models.<sup>19-21</sup> By leveraging the collective knowledge of experienced TCM practitioners, this study sought to formulate a safe, effective, and scientifically grounded prescription to improve sleep quality and overall well-being in the geriatric population.

## Methods:-

### Study Design

This study employed a formal Delphi method to systematically gather and synthesize opinions from a panel of TCM experts. The process consisted of three iterative rounds of questionnaires administered between April 2021 and July 2021. Data were analyzed using SPSS Version 25.0. The study protocol was designed to ensure anonymity among experts while providing controlled feedback between rounds to guide the panel toward a final consensus, a key feature of the Delphi technique.<sup>22-23</sup>

### Research Group

A research group comprising seven members was established to oversee the study. The group included experts in geriatric nursing, clinical nursing management, and nursing education, as well as four postgraduate nursing students with experience in TCM. The group's responsibilities included defining the research topic, selecting the expert panel, designing the questionnaires, managing distribution and collection, establishing screening criteria for the herbal compound, and analyzing the results of each consultation round.

### Expert Panel Selection

A panel of 12 TCM experts was recruited from a Class Three Grade A general hospital in Guangzhou, a tertiary-level institution serving as a major medical hub. This ensured the experts possessed a high degree of authority and representativeness. The inclusion criteria were designed to select for deep expertise, following best practices for Delphi panel formation.<sup>17, 24</sup> The criteria were: (1) over 10 years of experience in TCM diagnosis and treatment of older people; (2) a bachelor's degree or higher; (3) a middle or senior professional title; (4) recognized professional knowledge and rigorous academic work; and (5) commitment to participating in all three rounds of the study.

### Delphi Process and Questionnaire

The Delphi process began with the research group conducting a literature review to identify the common pathogenesis of insomnia in older adults and to compile a draft list of frequently used Chinese herbs. This initial step is critical for grounding the first-round questionnaire in existing evidence, a common practice in Delphi studies

aimed at developing clinical guidelines or evaluation systems.<sup>16-25,26</sup> This initial list formed the basis of the first-round questionnaire.

The expert questionnaire contained three parts:

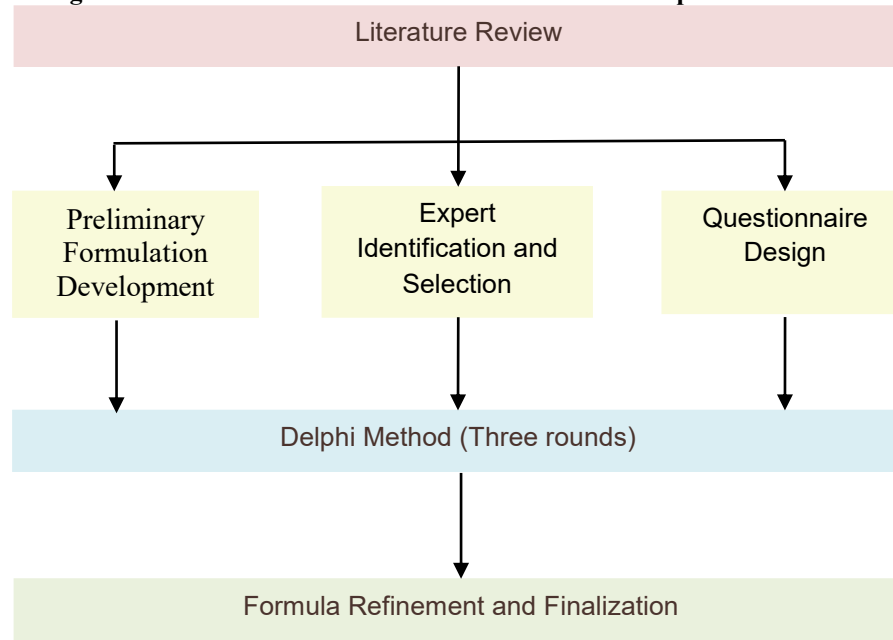
1. **Introduction:** Outlined the study's purpose, background, and significance, with instructions for completion.
2. **Herb Evaluation:** Listed TCM herbs for evaluation. Experts rated the importance of each herb for treating insomnia in the elderly using a 5-point Likert scale (1 = "not important" to 5 = "very important"). This section also included columns for recommended dosage and a suggestion field for experts to propose adding, removing, or modifying herbs.
3. **Expert Information:** Collected demographic data, professional experience, and self-rated familiarity with the topic (Cs) and the basis for their judgments (Ca). The basis of judgment (Ca) was weighted based on four factors: working experience, theoretical knowledge, reference to materials, and intuitive choice (Table 1).

**Table 1. Assigned Weightings of Expert Judgment**

| Reasons of Judgment                         | Large | Medium | Small |
|---|-------|--------|-------|
| Working experience                          | 0.5   | 0.4    | 0.3   |
| Theoretical knowledge                       | 0.3   | 0.2    | 0.1   |
| Reference to domestic and foreign materials | 0.1   | 0.1    | 0.1   |
| Intuitive choice                            | 0.1   | 0.1    | 0.1   |

After each round, the research group analyzed the responses. A new questionnaire was then compiled for the subsequent round, which included a statistical summary of the previous round's results (mean scores, standard deviation) and a list of the revised herbs. This iterative feedback process continued until a stable consensus was achieved.

**Figure 1 Traditional Chinese Medicine Formula Development Process**



### Statistical Analysis and Screening Criteria

Descriptive statistics were used to analyze the experts' background information. The reliability and validity of the Delphi process were assessed using several standard indicators widely accepted in survey research and Delphi methodology.<sup>27-28</sup>

1. **Expert Positive Coefficient:** The questionnaire recovery rate, with >70% considered very good.
2. **Expert Authority Coefficient (Cr):** Calculated as the arithmetic mean of the familiarity score (Cs) and the judgment basis score (Ca). A Cr > 0.7 indicates high authority.
3. **Concentration of Expert Opinions:** Measured by the mean importance score and the full score rate (K) for each herb.
4. **Coordination of Expert Opinions:** Measured by the coefficient of variation (CV) for each herb and Kendall's W for the overall expert panel. A CV ≤ 0.25 indicates good consistency. Kendall's W, with a significance level of  $p < 0.05$ , measures the concordance of the experts' rankings.

The screening criteria for retaining a herb in the prescription were a mean importance score > 4.0 and a CV ≤ 0.25, thresholds commonly used in similar Delphi-based construction studies to ensure consensus and relevance.<sup>29-30</sup>

### Results:-

#### Background Information of the Experts

The 12 TCM experts who participated had an average age of 47 years and an average of 22 years of work experience. All experts were actively engaged in the clinical treatment of older people. Of the panel, 75% (n=9) had ≥15 years of work seniority, and 66.7% (n=8) held senior professional titles. The panel's educational background included one doctorate, three master's degrees, and eight bachelor's degrees. Detailed demographic data are presented in Table 2.

**Table 2. Background Information of Experts (n=12)**

| Project            | Group                   | Number of people | Constituent ratio |
|--------------------|-------------------------|------------------|-------------------|
| Gender             | Male                    | 7                | 58.3%             |
|                    | Female                  | 5                | 41.7%             |
| Age                | 30 to 39 years old      | 2                | 16.7%             |
|                    | 40 to 49 years old      | 3                | 25.0%             |
|                    | 50 or higher            | 7                | 58.3%             |
| Education          | Bachelor's degree       | 8                | 66.7%             |
|                    | Master's degree         | 3                | 25.0%             |
|                    | Doctoral degree         | 1                | 8.3%              |
| Professional title | Attending physician     | 4                | 33.3%             |
|                    | Associate senior doctor | 6                | 50.0%             |
|                    | Chief physician         | 2                | 16.7%             |
| Work seniority     | <15 years               | 3                | 25.0%             |
|                    | ≥15 years               | 9                | 75.0%             |

|  |     |    |        |
|--|-----|----|--------|
| Clinical diagnosis and treatment of older people | Yes | 12 | 100.0% |
|--|-----|----|--------|

#### Expert Positive Coefficient and Degree of Authority

The study achieved a 100% effective recovery rate for the questionnaires in all three rounds (Table 3), indicating a high level of engagement and motivation from the expert panel. The degree of expert authority was calculated after the first round. The judgment basis coefficient (Ca) was 0.96, and the familiarity coefficient (Cs) was 0.92. The overall expert authority coefficient (Cr) was 0.94, demonstrating that the panel possessed a high level of expertise and authority on the research topic (Tables 4 and 5).

**Table 3. Effective Recovery Rates of Expert Consultation Questionnaires**

| Consultation phase | Number of questionnaires issued | Number recovered | Response rate (%) | Effective recovery rate (%) |
|--------------------|---------------------------------|------------------|-------------------|-----------------------------|
| First round        | 12                              | 12               | 100               | 100                         |
| Second round       | 12                              | 12               | 100               | 100                         |
| Third Round        | 12                              | 12               | 100               | 100                         |

**Table 4. Frequency Distribution of Expert Judgment**

| Reasons of judgment                         | Large | Medium | Small |
|---|-------|--------|-------|
| Working experience                          | 10    | 2      | 0     |
| Theoretical knowledge                       | 9     | 3      | 0     |
| Reference to domestic and foreign materials | 4     | 4      | 4     |
| Intuitive choice                            | 2     | 4      | 6     |

Note:  $Ca = (10 \times 0.5 + 2 \times 0.4 + 9 \times 0.3 + 3 \times 0.2 + 0.4 + 0.4 + 0.4 + 0.2 + 0.4 + 0.6) \div 12 = 0.96$

**Table 5. Frequency Distribution of Experts' Familiarity with the Consultation Contents**

| Degree of familiarity | Very familiar | Quite familiar | Generally familiar | Unfamiliar | Very unfamiliar |
|-----------------------|---------------|----------------|--------------------|------------|-----------------|
| Headcount             | 7             | 5              | 0                  | 0          | 0               |

Note:  $Cs = (7 + 5 \times 0.8) \div 12 = 0.92$

#### Coordination and Concentration of Expert Opinions

The coordination of expert opinions was robust. The CV values for all herbs included in the final prescription ranged from 0.081 to 0.220, well below the threshold of 0.25, indicating strong agreement on the importance of individual herbs. The Kendall's W coefficients for the three rounds were 0.196, 0.341, and 0.158, and the  $\chi^2$  test was statistically significant ( $p < 0.05$ ) for each round (Table 6). This confirms a high degree of overall coordination among the experts' evaluations.

**Table 6. Degree of Coordination of Expert's Opinion**

| Consultation phase | Kendall's W | $\chi^2$ | p     |
|--------------------|-------------|----------|-------|
| First round        | 0.196       | 23.531   | <0.05 |
| Second round       | 0.341       | 40.972   | <0.05 |
| Third Round        | 0.158       | 17.094   | <0.05 |

The concentration of expert opinions, reflected by the mean importance scores, increased with each round. In the final round, mean scores for the selected herbs ranged from 4.08 to 4.83. Herbs such as Rose, Chinese Eaglewood, *Dalbergia odorifera*, and *Semen ziziphi spinosae* received full score rates (K) of  $\geq 50\%$ , indicating a very high degree of consensus on their importance (Table 7).

**Table 7. Expert's Herb Content and Importance Scores (Final Round)**

| Herb                              | Mean $\pm$ Standard Deviation | CV    | K     |
|-----------------------------------|-------------------------------|-------|-------|
| <i>Dalbergia odorifera</i>        | 4.42 $\pm$ 0.79               | 0.179 | 58.3% |
| <i>Semen ziziphi spinosae</i>     | 4.42 $\pm$ 0.79               | 0.179 | 58.3% |
| Chinese Eaglewood                 | 4.67 $\pm$ 0.49               | 0.105 | 66.7% |
| Rose                              | 4.83 $\pm$ 0.39               | 0.081 | 83.3% |
| <i>Polygala</i>                   | 4.25 $\pm$ 0.87               | 0.204 | 50.0% |
| <i>Radix Aucklandiae</i>          | 4.08 $\pm$ 0.90               | 0.220 | 33.3% |
| <i>Cassia Obtusifolia</i>         | 4.17 $\pm$ 0.58               | 0.138 | 25.0% |
| Jasmine                           | 4.42 $\pm$ 0.52               | 0.116 | 41.6% |
| <i>Albiziae Cortex</i>            | 4.50 $\pm$ 0.52               | 0.116 | 50.0% |
| <i>Polygoni Multiflori Caulis</i> | 4.33 $\pm$ 0.65               | 0.150 | 41.6% |

#### **Modification and Finalization of the TCM Compound**

Based on the screening criteria and expert feedback, the initial list of herbs was systematically refined over the three rounds. Herbs with a mean score  $< 4.0$  or a CV  $> 0.25$  were removed. In the first and second rounds, experts suggested replacements for several herbs to better align with the therapeutic goal, which were adopted after group discussion (Table 8). For example, Borneol was replaced by *Dalbergia Odorifera*. After three rounds of consultation, a final 10-herb compound was established (Table 7).

**Table 8. Details of Expert Opinions on Herb Modification**

| Consultation phase | Expert opinion   | Whether to adopt |
|--------------------|--|------------------|
| First round        | Light Bamboo Leaves was replaced by Polygoni Multiflori Caulis | Yes              |
| First round        | Borneol was replaced by Dalbergia Odorifera                    | Yes              |
| First round        | Huanglian was replaced by Semen Ziziphi Spinosae               | Yes              |
| First round        | Cinnamon was replaced by Agarwood                              | Yes              |
| First round        | Kaempferi was replaced by Roses                                | Yes              |
| First round        | Xinyi was replaced by Polygala                                 | Yes              |
| Second round       | White Cardamom was replaced by Radix Aucklandiae               | Yes              |
| Second round       | The dose of Ganoderma atrum should be reduced                  | Yes              |
| Second round       | Xiangfu was replaced by Cassia Obtusifolia                     | Yes              |
| Second round       | Atractylodes was replaced by Jasmine                           | Yes              |
| Second round       | Acorus tatarinowii was replaced by Albizia Julibrissin         | Yes              |
| Second round       | Polygoni Multiflori Caulis was replaced by Angelica sinensis   | No               |
| Second round       | The Polygala was changed to Frangipani or Mint                 | No               |

### Discussion:-

This study successfully utilized the Delphi method to establish an expert consensus on a TCM compound for treating insomnia in older adults via sleep-aid sacs. The high questionnaire recovery rate (100%), strong expert authority coefficient (0.94), and significant coordination coefficients (Kendall's W,  $p < 0.05$ ) confirm the reliability and scientific validity of the process. The findings demonstrate that the Delphi technique is a robust tool for standardizing TCM practices and enhancing the quality of care for conditions where individualized treatment is paramount, a conclusion supported by its use in developing other complex healthcare models.<sup>27,31,32</sup>

The final 10-herb prescription represents a synthesis of classical TCM theory, modern literature, and extensive clinical experience. The selection process, guided by iterative expert feedback, ensured that the chosen herbs were not only considered effective but also safe for the geriatric population, who are often vulnerable to adverse drug reactions. The resulting compound aims to restore the balance of Yin and Yang and pacify the shen (spirit), addressing the root pathogenesis of insomnia in TCM. This aligns with modern research suggesting that multi-herb, multi-target TCM formulas, such as the classic Suanzaoren decoction, can be effective for complex conditions like insomnia.<sup>33,34</sup>

The development of a non-invasive therapy like a sleep-aid sac is a significant step in improving the quality of life for older adults. It avoids the systemic side effects associated with oral medications and offers a gentle, patient-friendly treatment modality, which is particularly important in geriatric care where polypharmacy is a concern.<sup>14,35</sup> This approach is consistent with a broader shift in healthcare toward patient-centered and minimally invasive interventions. The finalized compound has since been tested in a nursing home setting in Guangzhou, achieving good clinical efficacy and demonstrating the practical value of this research, similar to other TCM-based clinical studies.<sup>36-38</sup>

**Limitations:-**

This study has several limitations. First, the expert panel was recruited from a single hospital in Guangzhou, China. While the experts were highly qualified, this may limit the generalizability of the findings to other regions of China or internationally, where TCM practices may differ. Future research should involve a more geographically diverse panel of experts to validate and potentially refine the compound. Second, the Delphi method is based on expert opinion, not a randomized controlled trial. While the consensus provides a strong foundation, the clinical efficacy and safety of the final compound must be rigorously evaluated in large-scale, multi-center clinical trials. Finally, this study focused on formulating the compound using the TCM inheritance assistance platform; further research is needed to standardize the dosage and preparation of the sleep-aid sacs themselves.<sup>39</sup>

**Conclusion:-**

With the global population aging, the incidence of insomnia among older adults is a growing concern that significantly impacts healthcare quality. This study successfully applied the Delphi method to formulate a reliable, scientifically-grounded TCM herbal compound for use in sleep-aid sacs. The process demonstrated high levels of expert consensus, authority, and coordination. The resulting 10-herb prescription offers a promising, non-invasive therapeutic option for managing insomnia in older people. These findings provide a valuable reference for the clinical application of TCM in geriatric care and establish a methodological framework for developing other evidence-based TCM interventions aimed at improving patient quality of life.

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**Conflict of Interest**

All authors declare no conflicts of interest.

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