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REVIEW ARTICLE

Expert consensus on the clinical application of Tianmeng oral liquid in psychosomatic disorders

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Abstract

Psychosomatic disorders are characterized by complex interactions between psychological factors and somatic symptoms and frequently present with comorbid insomnia, anxiety, and depressive symptoms. Although conventional pharmacological treatments are widely used, their limitations highlight the need for integrative therapeutic approaches. Tianmeng oral liquid, a multi-component Chinese herbal formulation, has been increasingly used in clinical practice for the treatment of psychosomatic symptoms. This review aims to develop expert consensus on the clinical application of Tianmeng oral liquid in the treatment of psychosomatic disorders. This consensus was developed through a comprehensive review of the literature, evaluation of available clinical and experimental evidence, and structured expert panel discussions. Recommendations were formulated based on evidence strength, clinical experience, and principles of psychosomatic medicine. Tianmeng oral liquid exhibits a multi-target pharmacological profile, modulating central nervous system activity, neuroendocrine regulation, and immune homeostasis. Available evidence suggests that it may improve sleep quality, alleviate anxiety and depressive symptoms, and enhance overall well-being in patients with psychosomatic disorders. The formulation may be used as monotherapy in mild cases or as an adjunct to standard pharmacological and psychological interventions. It is generally well tolerated when administered according to recommended dosing strategies. Tianmeng oral liquid may be considered a complementary therapeutic option within a comprehensive biopsychosocial treatment framework for psychosomatic disorders. Further high-quality randomized controlled trials and mechanistic studies are warranted to strengthen the evidence base and refine clinical application strategies.

Keywords: Psychosomatic disorders; Insomnia; Tianmeng oral liquid; Integrative medicine; Chinese herbal compound

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1. Introduction

Psychosomatic disorders constitute a heterogeneous spectrum of conditions jointly mediated by psychological stress, social adversity, and dysregulation of the neuro–endocrine–immune network. Their clinical characteristics reflect a multidimensional biopsychosocial model of medicine.[1] The pathogenesis of these disorders emphasizes the interaction among environmental stressors, emotional–cognitive dysfunction, and physiological dysregulation, while their clinical manifestations often present as compound symptom clusters, including anxiety, depressive symptoms, sleep disturbances, and autonomic nervous system dysfunction.[2] At present, no specific laboratory biomarkers have been established for the diagnosis of psychosomatic disorders. Symptom expression often exhibits marked temporal fluctuations and contextual variability, posing substantial challenges for accurate diagnosis and treatment. This underscores the critical importance of precise application of dynamic psychological assessment techniques, particularly systematic evaluations targeting patients' mental–psychological dimensions, including perception, thought processes, emotional responses, and cognitive patterns.[3,4]

In this consensus, "psychosomatic disorders" are defined operationally within contemporary psychosomatic and biopsychosocial frameworks as conditions in which psychological, behavioral, and social factors play a substantial role in the onset, exacerbation, or persistence of physical symptoms. This definition emphasizes functional impairment and symptom experience rather than strict categorical diagnoses and is intended to complement, rather than replace, existing diagnostic systems, such as the International Classification of Diseases, 11th Edition, and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

With accelerating urbanization and the widespread adoption of digital lifestyles, especially following the COVID-19 pandemic, the global incidence of psychosomatic disorders has been increasing annually. The World Health Organization is increasingly recognizing these conditions as a significant public health challenge. Clinical practice shows that over 60% of first-time patients initially present to non-psychiatric departments in general hospitals, such as neurology, gastroenterology, and cardiology.[5] Comorbid anxiety and depression are associated with reduced treatment efficacy for underlying medical conditions and prolonged hospitalization. However, limited integration of psychosomatic medicine within existing healthcare systems, together with persistent stigma toward mental disorders, contributes to high rates of underdiagnosis and misdiagnosis, resulting in inefficient use of medical resources and strained doctor–patient relationships.

Traditional Chinese medicine (TCM) proposed the "Seven Emotions" theory in the *Inner Canon of the Yellow Emperor* (*Huangdi Neijing*; 黄帝内經), linking emotional fluctuations, including joy, anger, worry, pensiveness, sadness, fear, and fright, to organ function and forming a unique "unity of body and spirit" diagnostic and therapeutic system. Modern research has confirmed that TCM constitution types such as "liver–qi stagnation" and "dual deficiency of heart and spleen" are significantly associated with specific psychosomatic symptom clusters. The TCM principle of "three-cause adaptation" (personalized adjustments of the treatment plan based on the patient's constitution, seasonal changes, and regional environment) aligns conceptually with the personalized treatment paradigm of modern psychosomatic medicine. Based on this, the integrative medicine model emphasizes a "body–mind holistic treatment" strategy, in which pharmacological treatments (e.g., Tianmeng oral liquid, Shugan Jieyu capsules, and other Chinese patent medicines) are combined with evidence-based psychological interventions, such as cognitive–behavioral therapy and mindfulness training.

Clinically, treatment of psychosomatic disorders mainly relies on selective serotonin (5-HT) reuptake inhibitors, selective 5-HT–norepinephrine reuptake inhibitors, and benzodiazepines, but these methods are associated with issues such as drug resistance, risk of metabolic syndrome, and withdrawal syndromes. Tianmeng oral liquid, a Chinese herbal compound listed in the national medical insurance catalog, exerts its effects through a "multi-component, multi-target, multi-pathway" integrative regulatory mode, demonstrating significantly higher overall efficacy than placebo in treating insomnia.[6] This consensus integrates real-world study data and, for the first time, proposes a precision-oriented application framework of "individualized dosage–flexible course–combined therapy."

2. Methodology

2.1. Development of the consensus

A systematic literature search was conducted in accordance with Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines. The workflow included identification, screening, eligibility assessment, and study inclusion. The structured process is summarized in Table 1.

2.1.1. Search strategy

Using Chinese and English terms, including "Tianmeng," "Tianmeng oral liquid," "sweet dream oral liquid," "psychosomatic disorders," "anxiety," "depression," "insomnia," "sleep disorders," "neurosis," "emotional disorders," "autonomic dysfunction," "clinical efficacy," "safety," and "herbal compound," as search keywords/subject headings, a systematic search was conducted from database inception to the most recent date in the following databases:

(i) English-language databases: PubMed, Web of Science, Cochrane Library, and EMBASE.
(ii) Chinese-language databases: China National Knowledge Infrastructure, Chinese Biomedical Database, Wanfang Data, and CQVIP.

2.1.2. Literature management

All retrieved citations were imported into EndNote X9.31 for reference management. The software was used to organize records and remove duplicates or low-quality studies. Preliminary screening was conducted based on titles and abstracts, excluding studies unrelated to the topic and those not published in Chinese or English.

2.1.3. Full-text screening and data extraction

Full texts of the preliminarily screened articles were obtained and reviewed in detail to confirm eligibility for inclusion (e.g., randomized controlled trials, cohort studies, case series, or expert consensus documents that explicitly involved the application of Tianmeng oral liquid in psychosomatic diseases or psychosomatic disorders). Key information was ultimately extracted from the included studies, including study design, sample size, interventions, efficacy outcomes, safety data, and main conclusions.

2.1.4. Evidence appraisal and strength of recommendations

Given the heterogeneity of study designs, populations, and outcome measures across the available literature, a formal Grading of Recommendations, Assessment, Development and Evaluation-based evidence grading system was not applied in this consensus. Instead, the expert panel conducted a qualitative appraisal of the evidence, taking into account study design, sample size, consistency of findings, and clinical relevance.

In cases where direct high-quality evidence was limited or unavailable, recommendations were formulated through structured expert discussion, integrating available empirical data with accumulated clinical experience. The strength of evidence supporting each recommendation is therefore described narratively rather than quantitatively.

2.2. Construction of clinically relevant questions on Tianmeng oral liquid in the diagnosis and treatment of psychosomatic disorders

Based on a systematic literature synthesis and analysis, a clinical practice-oriented questionnaire survey was conducted in collaboration with experts from psychosomatic medicine-related disciplines. Opinions and recommendations on clinical questions, medication strategies, and clinical indicators were collected from clinical specialists in psychosomatic medicine, psychiatry, sleep and circadian rhythm medicine centers, cardiology, neurology, geriatrics, TCM encephalopathy, and acupuncture. Both online and offline discussion rounds were organized. Ultimately, seven key questions closely related to the clinical diagnosis and treatment of psychosomatic disorders were identified, existing research evidence was evaluated, and expert consensus statements were formulated. The focus was placed on the multidimensional clinical application of Tianmeng oral liquid in psychosomatic disorders:

(i) Question 1: What are the dose-adjustment strategies and recommended treatment courses of Tianmeng oral liquid for different types of insomnia (primary, comorbid, and geriatric)?
(ii) Question 2: What are the interactions and monitoring priorities when Tianmeng oral liquid is co-administered with psychotropic medications?
(iii) Question 3: What are the targeted mechanisms by which Tianmeng oral liquid ameliorates anxiety and depressive symptoms in patients with cardiovascular and cerebrovascular diseases?
(iv) Question 4: How can TCM syndrome differentiation be used to optimize indication selection for Tianmeng oral liquid?
(v) Question 5: What are the patterns of efficacy maintenance and the safety data associated with long-term use (more than six months) of Tianmeng oral liquid?
(vi) Question 6: What risk assessment framework should be applied when using Tianmeng oral liquid in special populations (hepatic or renal insufficiency, adolescents, and lactating women)?
(vii) Question 7: What synergistic enhancement models can be achieved by combining digital interventions (cognitive behavioral therapy for insomnia [CBT-I], biofeedback) with Tianmeng oral liquid?

Table 1. Flow of literature retrieval and screening

PRISMA phase	Stage description	Details	Number (*n*)
Identification	Records identified through database searching	PubMed; Web of Science; Cochrane Library; EMBASE; China National Knowledge Infrastructure; Chinese Biomedical Database; Wanfang Data; CQVIP	85
	Additional records identified through other sources	Reference lists; expert recommendations (if applicable)	78
Screening	Records after duplicates removed	Duplicates removed using EndNote X9.31	56
	Records after applying exclusion criteria	Irrelevant topic; not related to Tianmeng oral liquid; non-psychosomatic focus; non-Chinese/English	50
Eligibility	Full-text articles assessed for eligibility	Full-text review performed	38
Inclusion	Studies included in the qualitative synthesis	Randomized controlled trials; cohort studies; case series; expert consensus documents	38

Abbreviations: PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses.

2.3. Assessment of psychosomatic disorders

In constructing an assessment system for psychosomatic disorders based on influencing factors in disease onset and progression, clinical characteristics, and the current status of domestic and international clinical practice, a multidimensional assessment framework is recommended.[7]

2.3.1. Core assessment dimensions

The dimensions assessed included: (i) symptom–environment sensitivity, with emphasis on the dynamic association between symptom severity and life events; (ii) course characteristics, with particular attention given to identifying chronicity (duration > 6 months) and relapse–remission patterns, (iii) lifestyle profile, with evaluations such as sleep–wake rhythms, dietary structure, and physical activity habits, and (iv) developmental history, with focus on early attachment patterns and school adaptation capacity.

2.3.2. Social function assessment matrix

Psychosocial domains that were evaluated include (i) relational networks, quantifying family support levels and workplace stress indices, (ii) stress load, grading assessment using the life events scale, and (iii) adaptive resources, evaluating the economic buffering capacity and social support systems.

2.3.3. Standardized assessment instruments

Standardized assessment instruments included (i) the Patient Health Questionnaire-9[8] for depression, (ii) the Generalized Anxiety Disorder-7 scale[9] for anxiety, (iii) the Patient Health Questionnaire-15[10] for somatic symptoms, (iv) the Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), and polysomnography (PSG) for sleep, and (v) the Psychosomatic Symptom Scale[11] for overall psychosomatic status.

During the development of this expert consensus, three rounds of expert consultation were conducted, including 33 experts covering disciplines such as psychosomatic medicine, psychiatry, sleep and circadian rhythm medicine, cardiology, neurology, geriatrics, TCM encephalopathy, and acupuncture. Eventually, a clinical practice consensus covering diagnostic procedures, treatment pathways, and efficacy monitoring was established.

Given that the current classification systems for psychosomatic medicine remain under refinement, with diagnostic discrepancies between the International Classification of Diseases, 11th Edition and the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, this consensus provides guidance-based recommendations for TCM interventions in psychosomatic disorders grounded in existing clinical evidence.

3. Pharmacological mechanisms of Tianmeng oral liquid

Tianmeng oral liquid originates from the classical prescription, Gouqi pill, recorded in *Wonderful and Effective Prescriptions* (*Qixiao Liangfang;* 奇效良方) of the Ming Dynasty. Through long-term clinical application, it has been refined and optimized into a formulation consisting of 17 Chinese medicinal materials, including *Acanthopanax senticosus*, *Polygonatum sibiricum*, *Bombyx mori*, *Morus alba*, *Codonopsis pilosula*, *Astragalus membranaceus*, *Wurfbainia villosa*, *Lycium chinense*, *Crataegus pinnatifida*, prepared *Rehmannia glutinosa*, honey-processed *Epimedium brevicornum*, *Citrus reticulata* peel, *Poria cocos*, processed *Strychnos nux-vomica*, processed *Pinellia ternata*, *Alisma rhizoma*, and

Dioscorea opposita.

Among them, *Acanthopanax senticosus* and *Polygonatum sibiricum* serve as the "sovereign" (*jun*; 君) herbs. *Acanthopanax senticosus* is pungent and mildly bitter in flavor, warm in nature, and enters the spleen, kidney, and heart meridians; *Polygonatum sibiricum* is sweet and neutral, entering the spleen, lung, and kidney meridians. Together, they exert neuroregulatory effects, including sedation, tranquilization, and relief of anxiety.

Prepared *Rehmannia glutinosa* (which nourishes "yin" and blood, replenishes essence and marrow, and is a key herb for tonifying kidney yin) acts by enriching "kidney water" (*shen shui*; 肾水) to nourish the "heart spirit" (*shen*; 神), thereby improving yin deficiency insomnia. *Morus alba* nourishes yin and blood and tonifies the liver and kidney, promoting sleep while alleviating deficiency-related restlessness. *Lycium chinense* nourishes the liver and kidney and benefits "essence" (*jing*; 精); honey-processed *Epimedium brevicornum* warms the kidney and strengthens "yang," bones, and tendons; *Bombyx mori* tonifies the liver and kidney, strengthens yang, and astringes essence, and has traditionally been used for fatigue and insomnia associated with kidney-yang deficiency. These herbs function as "minister" (*chen*; 臣) herbs, exerting hormone-like effects through the combined actions of nourishing yin and supplementing yang.

The "assistant" (*zuo*; 佐) herbs include *Codonopsis pilosula*, which tonifies the middle burner, augments "qi," and strengthens the spleen and lung to promote the generation of qi and blood for nourishing the "heart spirit"; *Poria cocos*, which promotes urination, leaches dampness, strengthens the spleen, and calms the heart; *Citrus reticulata* peel, which regulates qi, strengthens the spleen, dries dampness, and resolves phlegm; processed *Pinellia ternata*, which dries dampness, transforms phlegm, and redirects rebellious qi; and *Dioscorea opposita*, which tonifies the spleen and lung, secures the kidney, replenishes "essence," and provides balanced supplementation of the triple burner, ensuring tonification without stagnation. Together, these herbs strengthen the spleen and stomach, regulate qi, relieve constraint, and promote digestion and absorption.

The "courier" (*shi*; 使) herb, processed *Strychnos nux-vomica*, is used in trace amounts. It is bitter in flavor and warm in nature, entering the liver and spleen meridians. Although raw *Strychnos nux-vomica* is highly toxic, standardized processing markedly reduces its toxicity, and it is administered at doses well below established safety thresholds (typically ≤ 0.3 g in crude-drug equivalents). At low doses, its active constituent strychnine exerts mild central excitatory effects, potentially through partial antagonism of inhibitory glycinergic neurotransmission. In the context of the compound formulation, it serves as a "medicinal guide," directing the actions of other herbs into the meridians. It exhibits bidirectional regulatory properties, facilitating both channel activation and central nervous system balance.[12]

Tianmeng oral liquid adheres to the principle of "coordinated regulation of the spleen and kidney." Through synergistic multi-target actions, it achieves integrative modulation of the neuro–endocrine–immune network. Its key features include an emphasis on coordinated regulation of the spleen and kidney, balancing both the innate foundation and acquired nourishment. Based on brain nourishment and tranquilization, it exerts coordinated effects of cognitive enhancement and calming of the spirit, consolidation of vital base, and harmonization of the spleen and stomach, thereby forming a distinctive advantage as a compound herbal formulation.

Its core mechanism lies in the bidirectional regulation of the central nervous system. Active constituents such as *Acanthopanax senticosus* and *Poria cocos* enhance the activity of the inhibitory neurotransmitter γ-aminobutyric acid (GABA), thereby producing sedative and tranquilizing effects. At the same time, the formulation modulates monoamine neurotransmitters, including 5-HT and norepinephrine, effectively alleviating anxiety and depressive symptoms and creating a favorable foundation for sleep. In addition, the antioxidant effects of components such as *Lycium chinense* and *Polygonatum sibiricum* protect neuronal cells and improve cognitive function.

With respect to endocrine regulation, the preparation modulates the hypothalamic–pituitary–adrenal axis, suppressing excessive cortisol secretion under stress and facilitating recovery from stress states, thereby achieving the effect of "consolidating the vital base." At the same time, "minister herbs" such as honey-processed *Epimedium brevicornum* and *Bombyx mori* exhibit hormone-like activities that may further regulate sex hormone balance, offering potential benefits for insomnia associated with endocrine dysregulation.

Furthermore, the compound formulation simultaneously emphasizes "harmonization of the spleen and stomach." "Assistant herbs," including *Codonopsis pilosula*, *Astragalus membranaceus*, *Crataegus pinnatifida*, and *Citrus reticulata* peel, act synergistically to enhance digestive enzyme activity and promote gastrointestinal motility, thereby improving digestion and absorption and eliminating the pathological basis described as "when the stomach is not in harmony, one cannot sleep in peace." The polysaccharide-rich components contained in the formula also modulate immune function and suppress

inflammation, providing a stable internal milieu for the nervous system.

Although used in trace amounts, the "courier" herb, processed *Strychnos nux-vomica*, unblocks the channels and exerts a subtle bidirectional balancing effect on the central nervous system. Low doses of strychnine (a constituent of processed *Strychnos nux-vomica*) have a mild excitatory effect on the central nervous system, potentially by antagonizing the inhibitory neurotransmitter glycine, thereby transiently enhancing neuronal excitability. This subtle excitatory action may contribute to "bidirectional regulation" alongside the sedative effects of other herbs, preventing excessive inhibition and the resultant somnolence. It is particularly suitable for patients with insomnia accompanied by daytime lethargy and fatigue (corresponding to the TCM state of "only desiring sleep"), reflecting the characteristic of "central nervous system balance." In addition, it facilitates channel circulation and improves microcirculation.[XX] Based on the official package insert, the common adverse reactions for Tianmeng oral liquid include nausea, vomiting, abdominal pain, diarrhea, dry mouth, and other gastrointestinal discomfort; dizziness and headache; palpitations; and allergic reactions such as rash or itching. These reactions are generally mild and infrequent.

In summary, through coordinated multisystem actions, this formulation facilitates a shift from single-target symptomatic sedation toward comprehensive systems-level regulation. This profile reflects the scientific connotation of multi-component, multi-target integrative modulatory characteristics inherent to Chinese herbal compound formulations.

4. Clinical application of Tianmeng oral liquid in psychosomatic disorders

4.1. Dose-adjustment strategies and recommended treatment courses of Tianmeng oral liquid for different types of insomnia

The dosage and treatment course of Tianmeng oral liquid should be individualized according to the type of insomnia. For adults with primary insomnia, the conventional dosage is 10–20 mL per dose, administered orally twice daily (morning and evening). For patients with insomnia comorbid with prominent anxiety or depressive symptoms, the addition of Tianmeng oral liquid (20–40 mL/day) based on antidepressant or anxiolytic therapy may further improve sleep quality. For geriatric insomnia, the recommended starting dose is 10 mL once daily, taken at bedtime.

4.1.1. Primary insomnia

Adult patients with insomnia may generally initiate treatment with a moderate dose of 10 mL per dose, twice daily. After 1–2 weeks of treatment, the dosage may be adjusted based on clinical efficacy and tolerability.[13]

If the therapeutic response remains insufficient after two weeks (e.g., an ISI score reduction of < 30%), the dose may be increased to 20 mL twice daily, with careful monitoring for gastrointestinal reactions (particular attention should be paid to tolerability when combined with sedative medications). The combination of Tianmeng oral liquid with sedative–hypnotic agents can significantly shorten sleep latency and prolong total sleep time. At comparable efficacy, the dose of sedative–hypnotics may be reduced to one-third to one-half of the original dose, with a marked reduction in adverse effects related to tolerance and dependence.[14]

A conventional course of 4–8 weeks is recommended, with four weeks constituting one treatment cycle. After symptom remission, the dosage should be gradually tapered to 10 mL per dose for maintenance, with a total treatment duration not exceeding eight weeks. Adjustments should be made according to disease duration and individual response. Efficacy assessment (e.g., PSQI and ISI scores) is generally conducted at week 4, by which time most patients show significant improvement. Indices of sympathetic nervous system hyperexcitability often improve significantly only after eight weeks, indicating that premature dose reduction or discontinuation should be avoided. Sustaining treatment through eight weeks yields more pronounced and durable benefits.[15,16] From a health economics perspective, Tianmeng oral liquid (or capsules) combined with sedative–hypnotics is superior in cost-effectiveness for the treatment of primary insomnia.[17]

An "alternate-day tapering" approach is recommended to avoid rebound insomnia, in conjunction with sleep diary-based evaluation. Dynamic monitoring using the ISI scale is recommended by expert consensus.

4.1.2. Comorbid insomnia

For patients with insomnia accompanied by cardiovascular, respiratory, or metabolic diseases, Tianmeng oral liquid may be administered at the above-mentioned dosages, based on standard treatment. For example, in patients who had undergone coronary artery bypass grafting, oral administration of 20 mL per dose twice daily for eight consecutive weeks significantly improved postoperative anxiety, depression, and sleep quality.[18] In patients with diabetes complicated by depression, administration of 10 mL per dose twice daily resulted in improvements in sleep and anxiety comparable to those achieved with 50 mg sertraline after eight weeks.[19] In patients with

chronic obstructive pulmonary disease and insomnia, the addition of 20 mL twice daily to conventional therapy shortened sleep latency, reduced nocturnal awakenings, and significantly decreased PSQI scores after four weeks of treatment.[20] Tianmeng oral liquid (or capsules) has been shown to effectively improve sleep efficiency while reducing the incidence of adverse reactions.[13]

For different subtypes of insomnia or comorbid insomnia, dosage adjustment should be individualized based on both clinical response and safety considerations, with close follow-up and dynamic assessment. For patients with suboptimal therapeutic response, available clinical studies suggest that the dosage may be cautiously increased up to 20 mL per dose or administered three times daily, under appropriate medical supervision.[13] For instance, in patients with post-stroke depression accompanied by insomnia, a regimen of 20 mL per dose administered three times daily for six consecutive weeks has been reported to be associated with favorable clinical outcomes.[21] In cancer patients with chemotherapy-related insomnia, dose escalation to 15 mL per dose has been explored; however, hepatic and renal function should be carefully evaluated.[22] Renal function should be assessed using estimated creatinine clearance, such as that calculated by the Cockcroft–Gault formula, prior to and during treatment.

For the treatment course, a minimum treatment duration of six weeks is recommended. If Patient Health Questionnaire-9 and/or Generalized Anxiety Disorder-7 scores decrease by ≥50%, treatment may be extended to 12 weeks, with a gradual transition to non-pharmacological interventions such as CBT-I.

4.1.3. Geriatric insomnia

In older adults, reduced cytochrome P450 enzyme activity necessitates a 30–50% reduction in dosage.[23] Frail or elderly patients are advised to initiate treatment at a low dose (10 mL per dose) to minimize adverse reactions.[24]

If the estimated glomerular filtration rate (eGFR) is <60 mL/min, the dosage should be further reduced to 5 mL per dose, with close monitoring of fall risk. Particular attention should be paid to safety concerns related to benzodiazepine use in older adults.

For the treatment course, the recommended duration is limited to 2–4 weeks, in combination with sleep restriction therapy, to avoid long-term dependence. If continued use is required, cognitive function (assessed using the Montreal Cognitive Assessment) and balance ability should be evaluated every three months.

Dosing recommendations in this consensus are based on the available clinical evidence, where reported, supplemented by expert clinical experience. Where possible, dosing ranges are aligned with published studies; however, the evidence base remains limited and heterogeneous.

Statements regarding potential reduction of concomitant psychotropic medications are presented cautiously and should not be interpreted as standardized or routine practice. Any adjustment of existing pharmacotherapy should be individualized, implemented gradually, and conducted under close clinical supervision with appropriate monitoring.

4.2. Interactions and monitoring priorities when Tianmeng oral liquid is co-administered with psychotropic medications

The co-administration of Tianmeng oral liquid with psychotropic medications may produce synergistic therapeutic effects and help reduce the required dosage and adverse reactions of Western medications. During combination therapy, close monitoring is required for additive sedative effects (e.g., somnolence) as well as antipsychotic-related adverse effects, including corrected QT interval prolongation and serum prolactin levels.

4.2.1. Co-administration with sedative–hypnotic agents

In the treatment of post-stroke sleep disorders, non-benzodiazepine sedative–hypnotics such as eszopiclone are commonly used. When combined with Tianmeng oral liquid, a synergistic improvement in sleep quality has been observed. Patients receiving combination therapy demonstrated greater improvements in PSQI scores compared with those treated with eszopiclone alone.[25,26] Following combination treatment, sleep latency was shortened and total sleep time was prolonged, with no serious adverse events reported.

4.2.2. Co-administration with antidepressant and antipsychotic medications

Adjunctive treatment with Tianmeng oral liquid in combination with antidepressants has been shown to significantly enhance antidepressant efficacy.[27] In patients with post-stroke depression, combined therapy with Tianmeng oral liquid resulted in a significantly greater reduction in Hamilton Depression Rating Scale scores than antidepressant monotherapy, with a lower incidence of complications.[28] In peri-menopausal women with depression accompanied by anxiety, combined treatment with Tianmeng oral liquid and paroxetine significantly reduced depressive symptoms.[29] In addition, Tianmeng oral liquid combined with risperidone has been shown to ameliorate risperidone-induced hyperprolactinemia

in female patients with schizophrenia, increase bone mineral density, and improve menstrual irregularities and galactorrhea.[18]

4.2.3. Drug interactions and monitoring

To date, no clinically significant pharmacokinetic interactions involving Tianmeng oral liquid have been clearly documented. Nevertheless, routine clinical monitoring is advisable when it is co-administered with psychotropic medications. In particular, given that certain antipsychotic agents are associated with corrected QT interval prolongation and hyperprolactinemia, the following monitoring measures are recommended during combination therapy:

(i) When using medications associated with corrected QT prolongation, such as ziprasidone or citalopram, electrocardiographic evaluation should be performed at baseline and during the early phase of treatment (e.g., at 4–8 weeks).[30]

(ii) When using medications with a high risk of elevating prolactin levels, such as risperidone or chlorpromazine, serum prolactin concentrations should be monitored at baseline and again after three months of treatment.[31,32]

4.3. Targeted mechanisms by which Tianmeng oral liquid ameliorates anxiety and depressive symptoms in patients with cardiovascular and cerebrovascular diseases

Tianmeng oral liquid directly improves anxiety, depressive mood, and sleep architecture by bidirectionally modulating neurotransmitters such as 5-HT and GABA, and by upregulating brain-derived neurotrophic factor (BDNF) expression. Its capacity to regulate the hypothalamic–pituitary–target gland axis function effectively counteracts the endocrine disturbances and autonomic dysfunction commonly observed in patients with cardiovascular and cerebrovascular diseases.

4.3.1. Autonomic nerve function and sleep architecture

Tianmeng oral liquid has been shown to ameliorate autonomic nerve dysfunction and restore sympathetic–parasympathetic balance.[33] Clinically, patients with diabetes mellitus and coronary heart disease frequently exhibit manifestations of sympathetic overactivity, such as palpitations and irritability; these symptoms can be alleviated following administration of Tianmeng oral liquid. After treatment with Tianmeng capsules (or oral liquid), middle-aged and older patients with neurosis demonstrated a marked increase in nocturnal slow-wave sleep (stages III/IV), prolonged total sleep time, and a reduced number of nocturnal awakenings.[13] Tianmeng oral liquid significantly improved deep sleep architecture and is beneficial for regulating sleep disorders driven by anxiety and tension.

4.3.2. Neurotransmitters and neurotrophic regulation

Animal experiments have shown that acute sleep deprivation disrupts 5-HT and GABA balance in the brain. Following administration of Tianmeng oral liquid, sleep-deprived rats exhibited restoration in brain 5-HT and GABA levels, accompanied by improvements in cognitive function.[34] In a 5-HT antagonist model, Tianmeng oral liquid conversely increased 5-HT and GABA concentrations in the raphe nuclei and hippocampus, while promoting hippocampal BDNF expression, thereby effectively alleviating insomnia symptoms. In addition, Tianmeng oral liquid enhanced immune function and improved learning and memory performance; these effects may be mediated by reductions in peripheral inflammatory factors and raphe nucleus 5-HT levels, together with increased hippocampal BDNF expression.[35] Collectively, these findings indicate that Tianmeng oral liquid counteracts stress-related injury and promotes sleep and emotional stability by bidirectionally regulating neurotransmitters and neurotrophic factors.

4.3.3. Neuroendocrine modulation

Tianmeng oral liquid can modulate stress-related endocrine axes. Combined use of Tianmeng oral liquid has been shown to partially ameliorate endocrine disturbances induced by risperidone.[36] In the treatment group, levels of thyroid-stimulating hormone, triiodothyronine, and thyroxine differed significantly from those in the control group, and prolactin levels were significantly reduced.[36] Findings from rat experiments were consistent with clinical observations, suggesting that Tianmeng oral liquid may suppress pituitary signaling pathways and thereby reduce antipsychotic-induced hyperprolactinemia. These results indicate that the alleviation of anxiety and depressive symptoms in patients with cardiovascular and cerebrovascular diseases by Tianmeng oral liquid is partly attributable to its regulatory effects on the hypothalamic–pituitary–target gland axes (such as the hypothalamic–pituitary–thyroid axis and the hypothalamic–pituitary–gonadal axis).[37] Accordingly, in clinical practice, Tianmeng oral liquid has also been used as an adjunctive therapy for male pattern hair loss[38], erectile dysfunction[39], and eczema.[40]

4.3.4. Neuroprotection and cognitive enhancement

Experimental animal studies have demonstrated that Tianmeng oral liquid activates the hippocampal extracellular signal-regulated kinase/cAMP response

element-binding protein signaling pathway and improves learning and memory performance in sleep-deprived rats.[34] This neuroprotective effect may facilitate cognitive recovery in patients with cardiovascular and cerebrovascular diseases and mitigate brain functional decline caused by the diseases and by sleep disorders.[41] Furthermore, components of Tianmeng oral liquid that tonify the heart and spleen (such as *Codonopsis pilosula* and *Astragalus membranaceus*), together with calming herbs (such as *Acanthopanax senticosus* and *Poria cocos*), exert qi- and blood-tonifying as well as "heat-clearing" and "spirit-calming effects," thereby synergistically improving cardiac neurosis and anxiety–depression associated with cardiovascular and cerebrovascular diseases. In summary, Tianmeng oral liquid acts through an integrated neuro–endocrine–immune network to exert targeted improvements in negative emotional states among patients with cardiovascular and cerebrovascular diseases.

4.4. Application of traditional Chinese medicine syndrome differentiation to optimize indication selection for Tianmeng oral liquid

Based on the theory of TCM syndrome differentiation, Tianmeng oral liquid is particularly indicated for patients with insomnia and palpitations presenting with syndromes of dual deficiency of qi and blood of the heart and spleen, or "disharmony" between the heart and kidney (typically manifested as shortened sleep duration and reduced deep sleep). Its therapeutic actions of "supplementing qi and tonifying the kidney, nourishing the heart, and calming the spirit" are well aligned with the pathophysiological features of deficiency-type sleep disorders. Clinically, it is recommended that potential responders be identified through an integrated approach combining the four TCM diagnostic methods (including tongue and pulse examination) with modern indicators (such as PSG, PSQI, and relevant blood biomarkers), with particular emphasis on patients exhibiting insufficient slow-wave sleep and a syndrome pattern of dual deficiency of the heart and spleen, thereby enabling precision medication.

The definitions, clinical manifestations, and key points of differentiation for the major relevant syndromes are summarized as follows.

4.4.1. Syndrome of dual deficiency of the spleen and kidney

This syndrome is most commonly caused by excessive rumination or prolonged illness, leading to depletion of the spleen and kidneys and resulting in insufficient blood supply to the heart and inadequate nourishment of the "heart spirit," thereby causing insomnia. Patients typically experience difficulty initiating sleep or frequent awakenings; they often feel drowsy, but sleep is light and unrefreshing. Additional features include mental fatigue and lassitude, palpitations, forgetfulness, scant sleep with excessive dreaming, poor appetite, and a sallow complexion. Tongue presentation is pale and enlarged with a thin white coating, and the pulse is thready and weak. The key diagnostic feature is that deficiency predominates over "excess" (shí; 实), and treatment should focus on tonifying the heart and spleen, nourishing the blood, and calming the "heart spirit."

This pattern is commonly characterized by light sleep, easy awakening, and difficulty entering deep sleep. Objective PSG findings typically include prolonged sleep latency, reduced total sleep time, and a marked reduction in slow-wave (deep) sleep. This presentation is similar to the "heart failing to store the spirit" type of insomnia, in which insufficiency of "heart blood" and instability of the "heart spirit" result in inadequate deep sleep. Somatic symptoms include insomnia with excessive dreaming, mental fatigue, forgetfulness, palpitations, shortness of breath, poor appetite, and general weakness. Most patients with this syndrome exhibit reduced baseline slow-wave sleep.[41] For such patients, the standard formulation of Tianmeng oral liquid is recommended to supplement qi and tonify the kidney, strengthen the spleen and nourish the heart, and provide calming and sedative effects, thereby significantly improving sleep quality. A dosage of 10–20 mL per dose, twice daily, combined with spleen- and qi-tonifying herbs (such as *Dioscorea opposita* and *Poria cocos*), is recommended to markedly improve sleep quality and daytime fatigue.

4.4.2. Syndrome of yin deficiency with hyperactive "fire"

This syndrome is commonly observed in late-stage insomnia associated with liver–kidney yin deficiency and disharmony between the heart and kidney. Patients typically present with vexation and restlessness with insomnia, difficulty falling asleep, restless sleep at night, or even sleeplessness throughout the night. Concomitant manifestations include tidal fever of the palms, soles, and chest, night sweating, dry mouth with scant fluids, tinnitus, and forgetfulness, all indicative of yin deficiency with internal heat.The tongue is red with scant coating, and the pulse is thready and rapid. The key point of differentiation lies in the presence of yin deficiency accompanied by residual heat, necessitating nourishment of yin and clearance of heat, with particular attention to spontaneous sweating, heat signs, and changes in tongue body.

This pattern is characterized by "internal heat disturbing the spirit," leading to difficulty initiating sleep and frequent

nocturnal awakenings. Clinically, PSG often reveals a reduced proportion of deep sleep and increased awakenings during rapid eye movement sleep. Hyperactive internal heat may cause night sweating and palpitations, resulting in markedly unstable sleep. Somatic manifestations include insomnia with excessive dreaming, irritability, heat sensations in the palms and soles, and a red tongue with scant fluids. For such patients, the principal prescription may consist of Tianmeng oral liquid at 10–20 mL per dose, twice daily, combined with heat-clearing and "fire-purging" herbs, such as *Anemarrhena asphodeloides*, *Coptis chinensis*, or *Gardenia jasminoides*, to pacify the liver, subdue yang, nourish yin, and clear heat. Studies suggest that Tianmeng oral liquid can inhibit proinflammatory factors and other stress-related substances[34], which may also help alleviate yin deficiency-related internal heat.[43] However, in cases of pronounced excess heat, e "heat-clearing" and "spirit-calming" therapies should be considered.

4.4.3. Syndrome of liver constraint transforming into "fire"

This is an excess-heat syndrome most often caused by prolonged emotional depression or anger transforming into "fire" and disturbing the heart. Patients typically present with a sudden onset of insomnia accompanied by irritability, emotional volatility, or frequent sighing; sleep is characterized by difficulty falling asleep, excessive dreaming, and easy awakening. The tongue is red with a yellow coating, and the pulse is wiry and rapid. The key therapeutic principle is to soothe the liver, relieve constraint, and drain "liver fire" (*gan huo*; 肝火), as this pattern commonly involves hyperactivity of "liver fire" disturbing both the liver and the heart.

This syndrome primarily results from emotional constraint transforming into "fire." Clinically, patients experience difficulty initiating sleep, excessive dreaming, and frequent awakenings, with vivid, disturbing dreams. PSG findings often include an increased proportion of light sleep, disordered rapid eye movement cycles (a stage typically associated with vivid dreaming), and shortened total sleep time. Persistent "liver fire" disturbing the heart may also reduce slow-wave sleep. Somatic manifestations include depressive or irritable mood, bitter taste in the mouth, distension in the hypochondriac region, chest oppression, irritability, and menstrual irregularities in women. Management should focus on soothing the liver and relieving constraint; Tianmeng oral liquid may be combined, as appropriate, with "liver-soothing" herbs such as *Bupleurum chinense* and *Cyperus rotundus*, alongside enhanced psychological counseling and lifestyle modification.

4.4.4. Syndrome of disharmony between the heart and kidney

In this pattern, the "heart spirit" fails to be anchored due to inadequate coordination between the heart and kidney, with insufficient kidney "essence" failing to restrain "heart fire." Clinical manifestations include difficulty initiating sleep or complete sleeplessness, accompanied by vexation, forgetfulness, tidal fever with night sweating, tinnitus, and palpitations. The tongue tip is red with scant coating, and the pulse is thready and rapid. Treatment should emphasize harmonizing the heart and kidney, nourishing yin, and subduing hyperactive yang.

This syndrome is primarily caused by kidney yin deficiency with deficiency heat ascending to disturb the "heart spirit." Clinically, it is characterized by difficulty falling asleep and frequent awakenings. PSG commonly reveals prolonged sleep latency, shortened sleep duration, and reduced deep sleep. The principal prescription is Tianmeng oral liquid at 20 mL per dose, administered twice daily (morning and evening), combined with therapies aimed at harmonizing the heart and kidney and nourishing yin while subduing yang. In cases with severe difficulty initiating sleep or pronounced early awakening, adjunctive use of zolpidem or zopiclone may be considered to facilitate sleep onset, with cautious addition of estazolam, lorazepam, or trazodone to enhance sleep depth and alleviate early awakening symptoms.

4.5. Patterns of efficacy maintenance and safety data associated with long-term use of Tianmeng oral liquid

Tianmeng oral liquid is suitable for long-term maintenance treatment (more than six months) of sleep disorders and insomnia associated with anxiety and depression.[44] During the initial phase (4–8 weeks), standard dosing (10–20 mL per dose, twice daily) can be used to achieve symptom control, followed by gradual tapering to the minimum effective dose for maintenance. For patients with comorbid underlying diseases or those receiving concomitant medications, liver and renal function tests, as well as electrocardiographic examinations, are recommended every three months. Long-term treatment should adhere to the principle of "gradual dose reduction" and be integrated with non-pharmacological interventions, such as sleep hygiene education and cognitive behavioral therapy, to enhance safety and treatment adherence.

4.5.1. Long-term efficacy maintenance patterns

An individualized "initial treatment–consolidation–maintenance" model is recommended for long-term use. After symptom relief is achieved during the initial course

(4–8 weeks), the dose may be gradually reduced under physician supervision to the minimum effective dose for long-term maintenance. During the maintenance phase, sleep and emotional indices (e.g., PSQI and Hamilton Anxiety Rating Scale scores) should be regularly assessed every 4–8 weeks. If clinical efficacy remains stable, maintenance therapy may be continued; if the response is suboptimal, timely adjustment of the treatment regimen or the addition of psychological or physical non-pharmacological interventions should be considered.

During this phase, most patients achieve meaningful symptom improvement and may, under medical supervision, initiate gradual dose tapering followed by transition to a consolidation phase or a period of drug-free observation. However, a subset of patients with a prolonged disease course or recurrent symptoms may require entry into a long-term maintenance phase lasting more than six months. During maintenance treatment, clinical efficacy, particularly regarding sleep quality and emotional status, should be reassessed at 4–8-week intervals to guide ongoing therapeutic decisions.

4.5.2. Safety monitoring and management during long-term use

Overall, the available evidence suggests that Tianmeng oral liquid is generally safe and well-tolerated when used long-term. Reported adverse reactions are typically mild, including dizziness, nausea, somnolence, weight gain, and dry mouth, most of which are well tolerated, and serious adverse events appear to be uncommon. Meta-analyses indicate that, when used as an adjunct to conventional Western medications, Tianmeng oral liquid not only significantly improves clinical efficacy but also reduces the overall incidence of adverse reactions.[13] In contrast to benzodiazepines, Tianmeng oral liquid has not been associated with clinically significant dependence or rebound symptoms following discontinuation, providing a better treatment adherence advantage in the long-term management of chronic insomnia and anxiety. It is particularly suitable for patients who are intolerant to the adverse effects of Western medications or who require sustained regulation of mood and sleep. Therefore, given clear indications and dynamic risk monitoring, Tianmeng oral liquid represents a viable long-term therapeutic option owing to its favorable safety profile.

4.5.3. Precautions for long-term use

Despite its generally favorable safety and tolerability profile, several considerations warrant particular attention during long-term use of Tianmeng oral liquid:

(i) Individualized medication: The principle of "gradual dose reduction" should be followed, with progressive dose reduction after symptom improvement. In special populations, particular attention should be paid to drug metabolism capacity, potential adverse reactions, and drug–drug interactions during long-term therapy. For patients with a history of polypharmacy, chronic underlying diseases, or special physiological conditions, dosage and treatment duration should be flexibly adjusted based on clinical presentation and monitoring results.

(ii) Dynamic monitoring: For patients with underlying conditions (such as chronic liver disease or renal impairment) or those receiving concomitant Chinese or Western medications, baseline examinations, including liver and renal function tests and electrocardiography, are recommended every three months to facilitate early detection of potential risks.

Although no definitive safety signals have been identified to date, the existing evidence base remains insufficient to draw firm conclusions regarding rare or long-term adverse effects. Therefore, the safety-related recommendations in this consensus should be interpreted as precautionary guidance rather than definitive risk assessments.

4.6. Risk assessment framework for the use of Tianmeng oral liquid in special populations

For patients with hepatic or renal impairment, a systematic assessment of liver enzymes, serum creatinine, and eGFR should be performed prior to initiation of therapy. Patients with mild to moderate dysfunction are recommended to start at a reduced dose with close and ongoing monitoring, whereas those with severe dysfunction are generally contraindicated. Adolescent patients should be treated with caution after careful clinical evaluation. In lactating women, a comprehensive risk–benefit assessment is required, and Tianmeng oral liquid should be considered only when the anticipated benefits clearly outweigh potential risks; if used, short-term administration in combination with non-pharmacological interventions is preferable. For all special populations, a structured monitoring strategy should be established, including regular assessment of hepatic and renal function and evaluation of treatment response, with timely adjustment or discontinuation of therapy in the event of abnormal findings. Particular attention is warranted given the presence of processed *Strychnos nux-vomica* in the formulation, which should be carefully considered in clinical decision-making to ensure patient safety.

4.6.1. Use in patients with hepatic or renal insufficiency

Patients with hepatic or renal insufficiency are more sensitive to drug components due to reduced metabolism and excretion capacity, necessitating extra caution when using Tianmeng oral liquid. Before clinical application, a comprehensive assessment of liver and kidney function, including key indices such as liver enzymes and serum creatinine, should be conducted and considered as a core determinant for safe use.

For patients with mild to moderate impairment, low-dose initiation under physician guidance is recommended, with gradual dose adjustment as tolerated. For patients with severe impairment, careful evaluation of the risk–benefit ratio is required, generally avoiding use to prevent potential adverse reactions. In the management of insomnia and chronic emotional disorders, Tianmeng oral liquid may serve as a low-adverse-effect alternative or adjunct, optimizing overall treatment safety.

Prior to initiating therapy, all patients should undergo thorough liver and renal function evaluations (e.g., liver enzymes, serum creatinine, eGFR), which form the basis for treatment decisions. For mild to moderate dysfunction, low-dose initiation with close monitoring is recommended, avoiding prolonged use. For severe dysfunction, risk–benefit assessment should guide decisions, and use is generally discouraged. A dynamic monitoring plan should be established during treatment, with periodic reassessment of liver and renal function. Therapy should be immediately discontinued and appropriate interventions taken if function shows worsening trends to ensure safety.

4.6.2. Cautious use in adolescents and lactating women, with multi-modal interventions

Tianmeng oral liquid, as a Chinese herbal compound, is widely used in the treatment of insomnia, anxiety, and related emotional disorders.[44] Its formulation is derived from natural herbs, generally mild and low-toxicity, and demonstrates good adherence and tolerability.[45] However, due to the inclusion of processed *Strychnos nux-vomica*, special populations, including adolescents, lactating women, and patients with hepatic or renal impairment, require careful individualized safety assessment and cautious use.

In adolescent**s**, the nervous system is still developing, making them more sensitive to pharmacological agents. Tianmeng oral liquid should only be used in adolescents with a clear indication, under the assessment and supervision of a qualified physician. The principles of "lowest effective dose and short-term use" should be strictly followed, combined with psychological interventions and family support to enhance efficacy and minimize potential risks.

For lactating women requiring long-term management of sleep or emotional disorders, Tianmeng oral liquid may be considered within an integrative treatment framework when the anticipated benefits clearly outweigh the potential risks. Dynamic safety monitoring is recommended throughout the treatment course, and non-pharmacological interventions with established safety profiles should be prioritized whenever feasible.

In summary, given adolescents' and lactating women's specific vulnerabilities, careful risk–benefit assessment is essential. The use of Tianmeng oral liquid in these populations should adhere to the principles of "clear indication, lowest effective dose, and short-term intervention," and treatment decisions should be made under the guidance of experienced clinicians with continuous monitoring.

4.7. Synergistic enhancement models combining digital interventions with Tianmeng oral liquid

Compared with conventional pharmacotherapy, digital interventions such as CBT-I and biofeedback are non-invasive, highly safe, and highly individualized. The combination of these digital interventions with Tianmeng oral liquid can effectively improve symptoms of insomnia, anxiety, and depression, while significantly enhancing patient adherence and engagement in treatment.

4.7.1. Synergy between digital interventions and Tianmeng oral liquid

Common forms of digital interventions include CBT-I and neuroregulatory therapies, such as repetitive transcranial magnetic stimulation (rTMS), vagus nerve stimulation, transcranial direct current stimulation, and biofeedback.

The combined use of Tianmeng oral liquid with digital interventions establishes an integrated "pharmacological–non-pharmacological" treatment model. This model enables complementary advantages: Tianmeng oral liquid, with its mild pharmacological properties, can rapidly alleviate core symptoms during the early stage, providing a stable foundation for patients to engage in psychological or neuroregulatory treatments. Conversely, digital interventions enhance long-term behavioral correction and neurofunctional regulation, thereby reducing the risk of drug dependence and improving sustained efficacy. In clinical practice, individualized combination plans should be developed according to patient characteristics.

4.7.2. Cognitive behavioral therapy for insomnia combined with Tianmeng oral liquid

This combination is particularly suitable for chronic insomnia patients exhibiting significant cognitive distortions or excessive sleep-related worries. CBT-I is a first-line therapy for insomnia, and its core mechanism involves correcting maladaptive cognitions and behaviors to achieve emotional regulation and behavioral adjustment.[46]

The combined application of CBT-I with Tianmeng oral liquid can provide early relief of core symptoms, strengthen patient confidence and engagement, and thereby enhance the overall efficacy of CBT-I. Compared with CBT-I alone, the combination with Tianmeng oral liquid yielded more pronounced clinical benefits.[47,48] In practice, integrating Tianmeng oral liquid with CBT offers dual-target modulation of "pharmacological + psychological" mechanisms, providing an optimized intervention and treatment pathway.

4.7.3. Repetitive transcranial magnetic stimulation combined with Tianmeng oral liquid

The combination of rTMS and Tianmeng oral liquid is more suitable for treatment-resistant insomnia accompanied by anxiety or depressive symptoms. Neuroregulatory interventions such as rTMS have advantages, including operational simplicity and minimal adverse effects.[49]

The combined treatment of rTMS with Tianmeng oral liquid demonstrated superior efficacy in sleep improvement compared with rTMS alone and maintained favorable outcomes at one- and two-month follow-ups.[50] Thus, integrating Tianmeng oral liquid with neuroregulatory therapy offers a clinically advantageous approach.

4.7.4. Biofeedback combined with Tianmeng oral liquid

Biofeedback therapy, based on operant conditioning and instrumental learning of autonomic function, uses device-assisted training to achieve deep relaxation. It has demonstrated good efficacy in the treatment of anxiety, depression, and insomnia.[51,52] When combined with Tianmeng oral liquid, biofeedback therapy can achieve complementary and synergistic effects, enhancing overall treatment outcomes.

5. Limitations

Evidence regarding the safety and efficacy of Tianmeng oral liquid in special populations is limited. Most available data do not originate from dedicated trials in adolescents or patients with hepatic or renal impairment. As a result, the recommendations for these populations are necessarily conservative and should not be interpreted as definitive clinical guidance. The recommendations should be applied with clinical discretion and individualized patient assessment. For indications categorized as exploratory or low-evidence, recommendations should be interpreted as hypothesis-generating or experience-informed guidance rather than definitive therapeutic indications.

6. Conclusion

This expert consensus, grounded in the TCM holistic perspective and evidence-based medicine principles, systematically reviews the mechanisms, indications, dosing strategies, and combined intervention pathways of Tianmeng oral liquid in the treatment of psychosomatic disorders. It proposes a treatment framework of "syndrome differentiation–targeted intervention–multidimensional assessment–long-term follow-up," aiming to promote standardized application of Chinese patent medicines.

As a Chinese herbal compound included in the national medical insurance system, Tianmeng oral liquid exhibits a multi-component, multi-target, and multi-pathway regulatory profile. It has been applied in the management of insomnia, anxiety–depressive symptoms, neurosis, and emotion-related disturbances associated with cardiovascular and cerebrovascular conditions. Available clinical evidence suggests that Tianmeng oral liquid is generally well-tolerated and may improve sleep quality, regulate the autonomic nervous system, and modulate neurotransmitter activity and endocrine function. Its therapeutic potential appears particularly relevant in geriatric insomnia and in patients with comorbid conditions, such as post-stroke depression.

The consensus also acknowledges that several recommendations are currently supported by limited evidence, with a lack of large-scale randomized controlled trials. Certain syndrome classifications and mechanistic interpretations remain primarily based on expert consensus, and the effectiveness of Tianmeng oral liquid in specific populations requires further clarification. Accordingly, future research should prioritize the following directions: (i) conducting multicenter, large-sample clinical studies with long-term follow-up, including randomized controlled trials, long-term safety studies, and investigations in treatment-resistant populations; (ii) further elucidating regulatory mechanisms involving the hypothalamic–pituitary–adrenal axis, the gut–brain axis, and neural plasticity; (iii) exploring integrative treatment strategies combining Tianmeng oral liquid with evidence-based interventions, such as CBT-I, biofeedback, and rTMS; (iv) developing predictive models linking syndrome characteristics with therapeutic response by incorporating

objective measures, including tongue and pulse imaging, polysomnography, and biochemical biomarkers; and (v) strengthening patient health education to reduce stigma related to psychosomatic disorders and establishing integrated psychosomatic health management pathways.

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