Chinese Expert Consensus on Clinical Management of Menopause-Related Insomnia (Postprint)

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Abstract

Menopause-related insomnia is a common symptom in (peri)menopausal women that is frequently encountered in clinical practice yet often overlooked. It affects the health status of women during the (peri)menopausal period and even into old age. In China, there remains a lack of consensus and guidelines regarding the clinical management of menopause-related insomnia. To standardize the management of menopause-related insomnia and improve sleep health management levels during the (peri)menopausal period, a panel of experts was organized to formulate this consensus. The management of menopause-related insomnia primarily includes establishing a multidisciplinary expert team, pharmacological management, and non-pharmacological management, with the aim of providing guidance for clinical practice.

Full Text

Preamble

Chinese Expert Consensus on Clinical Management of Menopause-related Insomnia

Developed by: Climacteric Health Care Branch of Chinese Preventive Medicine Association, Gynecologic Endocrinology and Fertility Professional Committees of China Association for Promotion of Health Science and Technology, Professional Committees of Beijing Association of the Integration of Traditional and Western Medicine

Abstract: Menopause-related insomnia is a common symptom among perimenopausal women that is frequently encountered clinically yet often overlooked. If left unaddressed, it can affect women' s health during the perimenopausal period and even into old age. Currently, China lacks consensus statements and clinical guidelines specifically addressing the management of menopause-related insomnia. To standardize management protocols and improve sleep health among perimenopausal women, a panel of experts developed this consensus. The management of menopause-related insomnia primarily involves establishing multidisciplinary expert teams, pharmacological management, and non-pharmacological interventions, with the aim of providing practical guidance for clinical practice.

Keywords: Perimenopause; Menopause; Insomnia; Pharmacotherapy; Non-pharmacotherapy; Consensus

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Chinese Expert Consensus on Clinical Management of Menopause-related Insomnia

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Insomnia is one of the symptoms of poor sleep quality. When this symptom persists and cannot be relieved, it develops into a disease—insomnia disorder. Insomnia disorder refers to persistent sleep difficulty despite adequate sleep opportunity and circumstances, accompanied by daytime functional impairment attributable to the sleep disturbance, with symptoms occurring more than 3 times per week for at least 3 months [1].

Menopause-related insomnia refers to insomnia that is associated with menopause and cannot be attributed to other causes [2]. It is one of the most common perimenopausal symptoms, and if not promptly intervened, can evolve into chronic insomnia, leading to additional health problems and more severe functional impairment, causing significant distress during the perimenopausal period and into old age. Therefore, the management of menopause-related insomnia constitutes an important component of perimenopausal health

management. To address this, relevant experts were convened to review the latest clinical guidelines and expert consensus on menopause-related insomnia published by the American Academy of Sleep Medicine, American Psychiatric Association, Chinese Society of Neurology, Chinese Sleep Research Society, and Italian Sleep Medicine Association. After screening literature on menopause-related insomnia from PubMed, Web of Science, Wanfang Data, and CNKI, and incorporating clinical experience through repeated discussion and revision, the *Chinese Expert Consensus on Clinical Management of Menopause-related Insomnia* was developed to provide guidance for clinical practice.

1 Epidemiology of Menopause-related Insomnia

Insomnia is the most common sleep disorder, with an incidence of 10%–15% in adults [3]. The incidence of sleep disorders in women over 40 years old is approximately four times that of younger women [4]. Among perimenopausal women, the incidence of insomnia increases significantly, ranging from 13.2% to 65.1% [5-7]. Polysomnography results demonstrate reduced total sleep time, abnormal rapid eye movement sleep, prolonged sleep latency, and decreased sleep efficiency, manifesting as prolonged sleep onset, frequent nocturnal awakenings, long wake times, and difficulty maintaining sleep [8-9].

2 Pathogenesis of Menopause-related Insomnia

Sleep is a complex physiological process. The development of insomnia involves multiple factors operating at the levels of individual behavior, social environment, organs, cells, and molecules. Menopause-related insomnia occurs based on predisposing factors, is triggered by precipitating factors, and persists under perpetuating factors [10], as illustrated in Figure 1 [Figure 1: see original paper]. Common predisposing factors include prior insomnia or depression, perfectionistic personality, anxiety-prone temperament, hormonal changes, and family history of insomnia. Precipitating factors include aging, increased work and life stress, stressful events (such as bereavement), poor health status, pain, shift work, and vasomotor symptoms. Perpetuating factors include erroneous sleep cognitions and poor sleep hygiene, negative emotions, and vasomotor symptoms.

3 Impact of Menopause-related Insomnia on Women

Menopause-related insomnia is closely associated with the female endocrine system, and menopause and insomnia demonstrate independent correlations [10-11]. Estrogen and progesterone regulate and stabilize the circadian rhythm system. During the menopausal transition, declining estrogen levels reduce hypothalamic sensitivity to estrogen, causing circadian rhythm disruption [12-13] and triggering insomnia. Estradiol (E2) level decline is significantly associated with difficulty falling asleep and frequent nocturnal awakenings, while increased follicle-stimulating hormone (FSH) levels are significantly associated with frequent nocturnal awakenings [14]. Additionally, vasomotor symptoms

(hot flashes, night sweats) and neuropsychiatric symptoms (anxiety, depression) resulting from reproductive hormone changes can also trigger insomnia, with more severe symptoms increasing the likelihood of insomnia [15].

Menopause-related insomnia alters normal sleep-wake rhythms, causing severe physiological and psychological impacts. Short-term insomnia leads to decreased attention and memory impairment. Long-term insomnia not only increases the risk of obesity, hypertension, type 2 diabetes, malignant tumors, coronary heart disease, stroke, and cognitive dysfunction [16-17], but also causes autonomic nervous system dysfunction, endocrine disorders, reduced bone mineral density, and increased risk of osteoporosis and fractures [18]. It can also trigger or exacerbate existing psychiatric conditions such as depression, anxiety, and schizophrenia [13,19-21].

4 Clinical Screening and Diagnosis of Menopause-related Insomnia

Clinical screening for menopause-related insomnia includes history taking, subjective assessment, and objective examination, as shown in Figure 2 [Figure 2: see original paper]. History taking is the critical component, as only comprehensive case information can assist physicians in making accurate diagnoses.

4.1 History Taking

History taking requires attention to communication attitude and skills, with full consideration of patients' educational level and comprehension ability to guide them in stating facts. In addition to routine medical history inquiries, clinicians should focus on understanding perimenopausal and sleep-related symptoms. Perimenopausal history should include: (1) menstrual status in the past year and presence of other perimenopausal symptoms; (2) whether hormone therapy has been administered; and (3) other chronic medical conditions. Insomnia history should include: (1) sleep schedule, sleep status, insomnia manifestations, and impact on daytime functioning in the past month; (2) onset time of insomnia and its relationship with perimenopausal symptoms and menstrual bleeding pattern changes; (3) comorbid sleep disorders such as obstructive sleep apnea or restless legs syndrome; (4) comorbid conditions such as anxiety or depression; and (5) use of neuroactive medications and substance dependence.

4.2 Subjective Assessment

Clinical screening employs patient self-report scales. Commonly used perimenopausal symptom assessment scales include the modified Kupperman Index and Greene Climacteric Scale. Commonly used sleep assessment scales include the Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), Athens Insomnia Scale (AIS), and Epworth Sleepiness Scale (ESS). Clinicians should select either a "1+1" format (one perimenopausal symptom scale

+ one sleep scale) or "1+2" format (one perimenopausal symptom scale + two sleep scales) based on clinical circumstances.

4.3 Objective Examination

Sleep assessment includes: (1) Polysomnography (PSG), which monitors electrocardiography, electroencephalography, muscle activity, eye movements, and ventilatory function in real-time during patient wear. PSG can accurately characterize sleep architecture and represents the "gold standard" for evaluating sleep disorders, particularly obstructive sleep apnea. It can serve as an adjunctive diagnostic and differential diagnostic tool for insomnia and assess the effectiveness of cognitive behavioral therapy for insomnia. (2) Wrist actigraphy, which is more compact and portable than PSG, can evaluate sleep status and duration in home environments and effectively estimate total sleep time and sleep-wake transitions, though it lacks specificity and is not recommended as a PSG substitute. It may be used when PSG is unavailable or in large-scale population studies [22-23].

Perimenopausal comprehensive evaluation includes reproductive hormone panel, pelvic ultrasound, breast ultrasound, thin-prep cytologic test (TCT) + human papillomavirus (HPV) testing, comprehensive metabolic panel, thyroid function panel, bone mineral density, and electrocardiography.

Based on results from assessments and laboratory examinations, combined with the third edition of the International Classification of Sleep Disorders (ICSD-3) published by the American Academy of Sleep Medicine in 2014 [1] (see Table 1), menopause-related insomnia can be diagnosed [24].

5 Management of Menopause-related Insomnia

5.1 Establishment of Multidisciplinary Expert Teams

Women with menopause-related insomnia often fail to recognize the association between menopause and insomnia, resulting in visits to multiple hospital departments and increased consumption of time, human resources, material resources, and financial costs. A multidisciplinary expert team should be established, including gynecology, sleep medicine, psychiatry, endocrinology, cardiology, nursing, pharmacy, psychotherapy, exercise rehabilitation, and nutrition specialists. For patients with suspected menopause-related insomnia, systematic evaluation should be conducted at the initial visit. After excluding insomnia caused by psychological or thyroid issues, patients should be referred through the multidisciplinary team' s referral system to a gynecological endocrinology clinic for further evaluation and treatment, with individualized treatment plans developed to maximize feasibility, treatment efficacy, and patient compliance. The management flowchart for menopause-related insomnia is shown in Figure 3 [Figure 3: see original paper].

5.2 Management Strategies

5.2.1 Pharmacological Management Pharmacological therapy demonstrates excellent short-term efficacy for insomnia, but behavioral and psychological adjustments represent the primary corrective approaches, with long-term medication dependence being inadvisable. The overall goal of pharmacological management is for patients to understand medication effects, usage methods, and routes; adhere to prescribed timing and dosage without missed or incorrect doses; regularly monitor relevant laboratory indicators; learn to observe common adverse drug reactions; and assume responsibility for self-health management. Patients should attend follow-up appointments to dynamically adjust medication dosage based on treatment response, achieving maximal therapeutic effect with minimal effective dose to reduce medication-related adverse effects.

Pharmacological management for women with menopause-related insomnia primarily involves medications related to menopause, insomnia, and other comorbid conditions. An individualized medication list should be established to create a personal medication use profile, documenting medication initiation and discontinuation times, adverse reactions, dosage changes, and individual responses.

For patients using hormone replacement therapy, clinicians should evaluate indications, contraindications, and cautionary conditions before initiation; inform patients of the benefits and risks of hormone therapy; and emphasize the necessity of adherence and regular follow-up. After thorough communication and evaluation, eligible patients should receive individualized regimens based on age, years since menopause, hysterectomy status, and expectations regarding medication-induced bleeding, including estrogen alone, progesterone alone, sequential estrogen-progesterone, combined estrogen-progesterone, or tibolone, following the *Chinese Guidelines for Menopause Management and Menopausal Hormone Therapy 2023 Edition* [25]. All hormone types can improve chronic insomnia in perimenopausal women [25], though different hormone types and administration methods may affect efficacy. For example, among estrogens, 17β-estradiol and conjugated equine estrogens (CEE) can improve sleep quality, while estradiol valerate shows less pronounced effects, with transdermal estrogen demonstrating superior efficacy over oral administration [26]. Micronized progesterone can improve various aspects of self-reported sleep quality and sleep architecture in postmenopausal women, as progesterone metabolites are positive allosteric modulators of GABA-A receptors, producing sleep structural changes similar to benzodiazepines [27]. Six months of transdermal 17β-estradiol combined with micronized progesterone can improve sleep quality in patients with menopause-related insomnia. Tibolone, a synthetic steroid with estrogenic, progestogenic, and androgenic effects, improves sleep quality by stimulating β-endorphin production and release, and demonstrates stronger sleep-improving effects than estrogen due to its progestogenic properties [28]. If insomnia improvement remains inadequate with hormone therapy, insomnia-specific medications may be appropriately added short-term.

Currently, commonly used insomnia medications include benzodiazepines, non-benzodiazepine receptor agonists, melatonin receptor agonists, and antidepressants with hypnotic effects. (1) Benzodiazepines are categorized by half-life into short-acting, intermediate-acting, and long-acting forms. Short-acting benzodiazepines are generally not used for insomnia. Intermediate-acting benzodiazepines are primarily used for light sleep, easy awakening, and patients requiring clear-headedness upon morning awakening, including estazolam (1–2 mg/night), alprazolam (0.4–0.8 mg/night), and lorazepam (0.5–1.0 mg/night). Long-acting benzodiazepines, characterized by slow onset and long half-life, are mainly used for early morning awakening, with diazepam (5–10 mg/night) being commonly used. Benzodiazepines can increase total sleep time and reduce nocturnal awakenings, with common adverse effects including somnolence, dizziness, fatigue, amnesia, and falls. Long-term continuous use may lead to dependence and addiction, with possible withdrawal symptoms upon abrupt discontinuation, requiring careful monitoring. (2) Non-benzodiazepine receptor agonists such as zopiclone and zolpidem feature rapid onset and short half-life, primarily used for difficulty falling asleep or patients intolerant to next-day residual effects. These agents demonstrate better safety profiles with reduced next-day residual effects and generally do not produce daytime sleepiness, with lower dependence potential than traditional benzodiazepines. Common adverse effects include dysgeusia, dry mouth, and dizziness. Commonly used medications include zopiclone (3.75–7.5 mg/night), eszopiclone (1–3 mg/night), zolpidem (5–10 mg/night), and zaleplon (5–10 mg/night). These medications should be taken at bedtime, with adequate sleep time ensured after administration. Patients should avoid driving, operating machinery, and hazardous activities during medication periods, and alcohol and alcoholic beverages are contraindicated. (3) Melatonin and melatonin receptor agonists such as ramelteon and agomelatine lack consensus for insomnia treatment [29] and are rarely used in menopause-related insomnia, with mechanisms and efficacy requiring further validation. (4) Antidepressants such as trazodone and mirtazapine can also improve menopause-related insomnia symptoms to some extent.

When patients present with severe or recurrent conditions, they may be referred to psychiatry or sleep medicine departments through the multidisciplinary team referral system, with recent treatment information communicated to facilitate rapid familiarity with the patient' s condition. For patients with comorbid chronic diseases, original treatments should be continued without self-discontinuation, with regular visits to relevant specialty clinics.

5.2.2 Non-pharmacological Management

5.2.2.1 Sleep Hygiene Education and Health Education Leveraging the advantages of multidisciplinary teams, comprehensive assessment of physical and mental status should be conducted for patients with menopause-related insomnia, providing disease knowledge guidance to enable comprehensive understanding of perimenopause and insomnia, eliminating worry and fear, adjusting

psychological status, and improving sleep quality and duration. Sleep hygiene education forms the foundation of non-pharmacological management and should be integrated throughout the treatment process. Patients should be assisted in creating a favorable sleep environment, maintaining room temperature at 22–26°C and humidity around 40%, turning off lights before sleep, avoiding mobile phone use, and selecting appropriate bedding. Smoking and alcohol should be avoided, emotional fluctuations should be minimized 1–2 hours before bedtime, and consumption of coffee, strong tea, and other caffeinated substances should be avoided. Patients should not go to bed overly full or hungry.

5.2.2.2 Psychological Therapy Psychological therapy should be conducted by specially trained healthcare professionals or psychotherapists. Commonly used psychological therapies include cognitive behavioral therapy for insomnia (CBT-I), mindfulness therapy, hypnosis, and traditional Chinese medicine psychotherapy, with CBT-I recommended as first-line therapy for menopause-related insomnia by multiple guidelines [30-32]. CBT-I is a multimodal combined therapy including sleep hygiene education, behavioral therapy (sleep restriction and stimulus control), relaxation training (progressive muscle relaxation), and cognitive therapy (cognitive restructuring and paradoxical intention), with specific implementation detailed in the *Chinese Guidelines for Diagnosis and Treatment of Insomnia in Adults (2017 Edition)*. CBT-I typically involves 6–8 sessions of 30–50 minutes each, delivered through one-on-one consultation, group consultation, or web-based self-help formats, with effects visible in the short term and durable in the long term [33-34].

Mindfulness therapy is a convenient mind-body intervention that trains attention to return to the present moment, letting go of resistance to unpleasant experiences, coexisting with feelings non-judgmentally, and acting consciously, thereby increasing coping strategies for stress events. Primary mindfulness techniques include mindful breathing, mindful walking, mindful observation of thoughts and emotions, body scanning, and mindful yoga, with treatment cycles typically lasting 8–10 weeks, once weekly, 120 minutes per session.

Hypnosis is a special state of consciousness characterized by focused attention and reduced peripheral awareness, featuring enhanced responsiveness to suggestions. Hypnosis primarily targets menopause-related insomnia and hot flashes, aiming to educate and train subjects in self-hypnosis to alleviate underlying symptoms. A complete hypnosis program includes explanation and therapeutic relationship establishment, hypnotic susceptibility testing, hypnotic induction, implementation of hypnotic therapy, and hypnotic awakening. Hypnosis therapy includes therapist-guided hypnosis and self-hypnosis, which can alter erroneous sleep cognitions, relieve hot flashes and night sweats, improve sleep quality and duration, and demonstrates high patient satisfaction and acceptance, representing a promising insomnia treatment approach [35].

Traditional Chinese medicine psychotherapy TIP (Thought Imprint Psychotherapy in a Lowered Resistance State) integrates modern hypnosis therapy, psy-

choanalysis, cognitive behavioral therapy, and traditional Chinese psychological treatment [36]. TIP demonstrates sustained efficacy and low recurrence rates in treating chronic insomnia [37].

5.2.2.3 Physical Exercise Exercise improves insomnia while alleviating other perimenopausal symptoms, reducing osteoporosis and obesity incidence, and increasing life satisfaction. Due to advancing age and declining physical capacity, perimenopausal women may have reduced exercise tolerance. Women should be encouraged to select appropriate exercise modalities based on personal interests, abilities, and physical condition, with aerobic and resistance exercises recommended as primary forms. Exercise should begin at low intensity and progress gradually, incorporating warm-up, exercise, and cool-down phases. Exercise should induce warmth and mild sweating as appropriate, though vigorous exercise should be avoided within 2 hours of bedtime. When available, patients may follow exercise prescriptions provided by exercise rehabilitation specialists.

5.2.2.4 Dietary and Nutritional Management Patients should receive dietary guidance to ensure balanced nutrition without excess, maintaining BMI at 18.5–23.9 kg/m^2 and waist circumference <80 cm. Protein and calcium intake should be increased through meat, eggs, and dairy products, with increased consumption of probiotic yogurt [38]. Vitamin-rich fruits and vegetables should be increased, with daily tomato intake potentially increased to enhance melatonin cycling and improve sleep quality [39]. Caffeine-containing substances such as tea, coffee, chocolate, and ice cream should be reduced, as should fried and sugary foods. Water intake should be small-volume and frequent, totaling 1,500 ml daily.

5.2.2.5 Traditional Chinese Medicine Management Traditional Chinese medicine does not contain a specific disease term for insomnia, classifying it under "Bumei" (sleeplessness). Bumei was termed "inability to lie down" or "eyes not closing" in the *Neijing*, attributed to pathogenic factors lodging in viscera and defensive qi traveling in yang without entering yin. Menopause-related insomnia is considered to result primarily from liver depression, spleen deficiency, and kidney essence depletion causing visceral, qi-blood, and yin-yang imbalance. As women approach menopause, kidney qi gradually declines, tiangui gradually exhausts, and thoroughfare and conception vessels become deficient, causing yin-yang imbalance and visceral dysfunction, with heart-kidney disharmony and heart spirit losing nourishment resulting in inability to sleep at night.

Traditional Chinese medicine treatment includes pattern differentiation and treatment, external treatment methods, and other therapies. Pattern differentiation provides targeted treatment based on identified patterns, following the principle of supplementing deficiency and draining excess and adjusting visceral yin-yang balance. Excess patterns drain the excess, such as soothing liver and draining fire or clearing heat and transforming phlegm. Deficiency

patterns supplement the deficiency, such as fortifying spleen and boosting qi or supplementing liver and kidney. External treatment methods primarily include acupuncture, moxibustion, and auricular acupressure. Acupuncture involves point selection by clinical physicians after assessment, commonly using Sanyinjiao (SP6), Shenmen (HT7), Baihui (GV20), Shenshu (BL23), Taichong (LR3), and Xinshu (BL15). Moxibustion includes traditional moxibustion, ginger moxibustion, and thunder-fire moxibustion, which can be combined with acupuncture for enhanced effects in deficiency-cold pattern patients. Auricular acupressure involves applying uniformly sized, high-quality vaccaria seeds or magnetic beads to corresponding auricular points with slight pressure to induce sourness, numbness, distension, or warmth, retained for 72 hours per ear with alternating ears. Auricular acupressure continuously stimulates points through pressing, massage, and therapeutic manipulation, unblocking channel qi and blood, harmonizing yin-yang, and connecting with whole-body viscera to achieve tranquilizing and sleep-promoting effects [40-41]. Other therapies including herbal foot baths, five-element music therapy, aromatherapy, essential oil inhalation, gua sha, medicinal diets, and herbal pillows also demonstrate efficacy for menopause-related insomnia, with appropriate modalities selected based on patient circumstances and acceptance.

5.2.2.6 Physical Therapy Physical therapy involves treatment using physical agents (including but not limited to magnetism, light, electricity, and heat). Primary modalities include transcranial magnetic stimulation, light therapy, electroencephalographic biofeedback, fastigial nucleus stimulation, and hyperbaric oxygen therapy. Currently, domestic and international research on physical therapy for insomnia remains limited, with even fewer studies on physical therapy for menopause-related insomnia, requiring further investigation into mechanisms and efficacy.

5.3 Regular Follow-up

Based on personal medical records and medication histories, follow-up plans should be established with dedicated personnel conducting follow-up registrations. Patients receiving hormone therapy should be followed up at 1, 3, and 6 months after initiation, focusing on sleep improvement and adverse reactions. Patients not using hormone medications should be queried about sleep improvement; if no change is observed, further evaluation for treatment modification is warranted.

Menopause-related insomnia has high incidence and numerous influencing factors, requiring detailed history taking, comprehensive assessment of physical and mental status, establishment of multidisciplinary teams, and full utilization of multidisciplinary diagnostic and treatment advantages for early identification. Individualized pharmacological and non-pharmacological management strategies should be developed based on patient preferences to improve perimenopausal sleep health management.

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