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Insomnia Protocol

Clinical support for promoting sleep quality and restorative rest through evidence-based lifestyle, dietary, and nutrient interventions.*

Pathophysiology

Insomnia is a common sleep disorder characterized by difficulty falling asleep, staying asleep, or achieving restorative sleep despite adequate opportunity and environment. **Short-term insomnia** often arises from stress, schedule changes, or environmental disruptions and typically resolves within a few days or weeks. **Long-term insomnia** occurs three or more nights per week for at least three months and cannot be fully explained by another medical condition.[1] Insomnia is believed to result from **dysregulation of the sleep-wake cycle**, often involving hyperarousal of the central nervous system and altered stress-response pathways.[2]

Poor-quality sleep significantly impacts quality of life. It contributes to impaired memory, concentration, mood regulation, and daytime functioning while increasing risks of accidents, metabolic dysfunction, immune compromise, and chronic disease.[1] The prevalence of insomnia ranges from **10% to 40% in adults**, yet it remains underdiagnosed and undertreated. **Risk factors** include advanced age, female gender, depressed mood, high stress levels, hypnotic use, substance abuse, lower socioeconomic status, and family history of insomnia. **Medical and psychiatric comorbidities are common**, with associations to cardiovascular disease, diabetes, neurological and gastrointestinal disorders, depression, anxiety, and post-traumatic stress disorder.[2]

Diagnostic Biomarkers and Clinical Indicators

- **Clinical history and physical exam** to assess sleep quality and rule out contributing medical conditions (e.g., sleep apnea).[1]
- **Sleep diary** maintained for one to two weeks, documenting sleep/wake times, naps, caffeine/alcohol use, exercise, and daytime sleepiness.[1]
- **Polysomnography (sleep study)** to evaluate for circadian rhythm disorders, sleep apnea, or narcolepsy.[1]
- **Actigraphy** to monitor rest–activity cycles and sleep efficiency.[1]
- Comprehensive **thyroid** panel.
- **Adrenal** Stress Index: 4-point salivary cortisol.
- **Designs for Health Metabolomics Spotlight™** – CNS-Neurotransmitters/Hormones
- **Designs for Health Genomic Spotlight™** – Cognition and Endocrine Reports

Diet and Nutritional Considerations

- Encourage adoption of a **Mediterranean-style diet** and **low-glycemic load meals** to support sleep quality.[3]
  - **Emphasize** high-fiber foods (linked to more slow-wave sleep).[4]
  - **Limiting** saturated fat, added sugars, energy drinks, and sweetened beverages (associated with lighter, fragmented sleep).[4]
- Recommend **regular mealtimes** (including breakfast) and discourage eating within one hour of bedtime – particularly heavy, high-fat meals.[1,2,4]
- **Encourage intake of foods shown to promote sleep**, such as:[4]
  - Tart cherry juice (melatonin, antioxidants).
  - Kiwifruit (serotonin, folate, vitamins C and E).
  - Fatty cold-water fish, such as salmon and sardines (omega-3 fatty acids, vitamin D).
  - Dairy, if tolerated (tryptophan).
- Support use of **calming herbal teas** before bedtime (e.g., chamomile, valerian root, decaffeinated green tea).[5]

Lifestyle Interventions

- Recommend **Cognitive Behavioral Therapy for Insomnia (CBT-I)**, the evidence-based first-line approach for patients with insomnia.[2]
- Promote **stress-reduction strategies before bed**, such as breathwork, meditation, reading, listening to soothing music, or taking an Epsom salt bath.[1]
- Consider **acupuncture** as an adjunct tool, particularly in older adults.[6,7]
- Encourage **optimal sleep hygiene practices**.[1,8]
  - Consistent sleep–wake schedule, including weekends.
  - Avoid naps, particularly in the afternoon.
  - Limiting or avoiding caffeine, nicotine, and alcohol in the evening.
  - Bedroom temperature between 66-72°F (19-22°C).
  - Use blackout curtains to block external light.
  - Avoidance of screens before bed; use of blue-light-blocking glasses in the evening.
- Promote regular **daytime physical activity**, ideally completed at least five to six hours before bedtime.[1]
- **Review current medications** for agents that may disrupt sleep.[1]

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Supplement Protocol

Supplementation amounts are based on a 150-pound healthy adult and may be adjusted according to body weight. Practitioners should individualize protocol use by selecting some or all listed products, determining timing of introduction (i.e., all at once or staggered), and guiding duration based on clinical judgment, patient presentation, complaints, and biomarkers.

Options if Seeking Sleep Support Featuring Melatonin*

Product	Amount and Duration	Formula Highlights
Insomnitol™ Capsules or Chewables	Chew 2 tablets or take 2 capsules per day 30 to 60 minutes before bedtime 3 months; reevaluate biomarkers, signs, and symptoms	• Blend of botanicals, nutrients, and neurotransmitter precursors designed to support quality, restful sleep* • Promotes calm brain activity, promoting the body's natural ability to fall asleep and stay asleep* • Key ingredients include botanicals that support nervous system function, PharmaGABA® (a proprietary form of gamma-aminobutyric acid [GABA]), L-theanine, melatonin, 5-hydroxytryptophan (5-HTP), and the activated form of vitamin B6* **Warning:** Not recommended for use by pregnant or lactating women, or by those taking selective serotonin reuptake inhibitor (SSRI) or monoamine oxidase inhibitor (MAOI) medications.
Melatonin SRT™	1 tablet per day 20 minutes before bedtime 3 months; reevaluate biomarkers, signs, and symptoms	• Features 6 mg of melatonin per serving in a clinically trialed sustained-release technology to support sleep quality throughout the night; tablets are scored in half for those who prefer 3 mg in one sitting* • As a supplement, melatonin is helpful for regulating sleep and the body's daily rhythmic cycle* • Due to melatonin's relatively short half-life in the body, a sustained-release formula may be more suitable for those who experience difficulty staying asleep throughout the night*

Options for Occasional Stress-Related Sleep Disruptions and Support for Healthy Nighttime Cortisol Balance*

Product	Amount and Duration	Formula Highlights
BioSleep Peptides	Chew 1 tablet per day 30 to 60 minutes before bedtime 3 months; reevaluate biomarkers, signs, and symptoms	• Drug-free, non-melatonin supplement designed to support restorative, quality sleep and promote a more balanced mood upon waking* • May be especially beneficial for individuals experiencing stress-related sleep disruptions, such as difficulty falling asleep or waking up feeling unrefreshed* • Features PeptiSleep™, novel plant-based bioactive peptides from brown rice (*Oryza sativa*) for enhanced sleep support* **Warning:** Consult your doctor before use if you are being prescribed an orexin receptor antagonist.
StressArrest™	1 capsule per day 3 months; reevaluate biomarkers, signs, and symptoms	• Features GABA (gamma-aminobutyric acid), glycine, and targeted amounts of B vitamins to support healthy stress responses and neurotransmitter function* • GABA is a key neurotransmitter in the body involved in a normal, calm stress response • May support mental health, balanced mood, and adrenal gland health* **Warning:** Not recommended for use with alcohol. Not recommended for pregnant women. Consult with a health-care practitioner before use if you are taking prescription medication for anxiety or depression.
PS 150	1 capsule per day 3 months; reevaluate biomarkers, signs, and symptoms	• Phosphatidylserine (PS) promotes healthy hormone balance by helping to normalize cortisol release when the body is under stress* • Features 150 mg of non-soy, sunflower-sourced PS per capsule • PS is required for supporting brain and cognitive health*

To Help Promote Feelings of Relaxation, and if Not Supplementing with Magnesium During the Day*

Product	Amount and Duration	
TriMag Supreme™ Night	Mix 6 grams (approx. one scoop) of powder in 8 ounces of water per day 30 to 60 minutes before bedtime 3 months; reevaluate biomarkers, signs, and symptoms	• Combines three highly absorbable forms of magnesium and relaxation-supportive botanicals to help provide restful sleep, and a healthy mood and stress response* • One serving provides 300 mg of elemental magnesium in an easy-to-mix powder • Lavender and lemon flavored, and sweetened with stevia

This information is provided as a medical and scientific educational resource for the use of physicians and other licensed health-care practitioners ("Practitioners"). This information is intended for Practitioners to use as a basis for determining whether to recommend these products to their patients. All recommendations regarding protocols, dosing, prescribing and/or usage instructions should be tailored to the individual needs of the patient considering their medical history and concomitant therapies. This information is not intended for use by consumers.

For a list of references cited in this document, please visit:
https://www.designsforhealth.com/api/library-assets/literature-reference---insomnia-protocol

Dosing recommendations are given for typical use based on an average 150-pound healthy adult. Health-care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities; appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations regarding herb-drug and nutrient-drug interactions, please refer to reliable, evidence-based resources such as the Natural Medicine Database or Stargrove MB, Treasure J, McKee DL. *Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategies*. Mosby-Elsevier; 2008.

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**