

## PRACTICE PARAMETER

# Practice Parameters for the Psychological and Behavioral Treatment of Insomnia: An Update. An American Academy of Sleep Medicine Report

An American Academy of Sleep Medicine Report

Standards of Practice Committee of the American Academy of Sleep Medicine

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**Table 1—AASM Classification of Evidence**

### Evidence Study Design Levels

I	Randomized well-designed trials with low alpha and beta error*
II	Randomized trials with high alpha and beta error*
III	Nonrandomized concurrently controlled studies
IV	Nonrandomized historically controlled studies
V	Case series

Adapted from Sackett<sup>9</sup>

\*Alpha (type I error) refers to the probability that the null hypothesis is rejected when in fact it is true (generally acceptable at 5% or less, or  $p < 0.05$ ). Beta (Type II error) refers to the probability that the null hypothesis is mistakenly accepted when in fact it is false (generally trials accept a beta error of 0.20). The estimation of Type II error is generally the result of a power analysis. The power analysis takes into account the variability and the effect size to determine if sample size is adequate to find a difference in means when it is present (Power generally acceptable at 80-90%).

**Table 2—AASM Levels of Recommendations**

Term	Definition
Standard	This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.
Guideline	This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
Option	This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

Adapted from Eddy<sup>10</sup>

		SIZE OF TREATMENT EFFECT									
		CLASS I <i>Benefit &gt;&gt;&gt; Risk</i> Procedure/Treatment <b>SHOULD</b> be performed/ administered	CLASS IIa <i>Benefit &gt;&gt; Risk</i> <i>Additional studies with focused objectives needed</i> <b>IT IS REASONABLE</b> to per- form procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment <b>MAY BE CONSIDERED</b>	CLASS III No Benefit or CLASS III Harm <table><tr><th>Procedure/ Test</th><th>Treatment</th></tr><tr><td>COR II: Not Helpful</td><td>No Proven Benefit</td></tr><tr><td>COR II: Excess Cost w/o Benefit/ or Harmful</td><td>Harmful to Patients</td></tr></table>	Procedure/ Test	Treatment	COR II: Not Helpful	No Proven Benefit	COR II: Excess Cost w/o Benefit/ or Harmful	Harmful to Patients
Procedure/ Test	Treatment										
COR II: Not Helpful	No Proven Benefit										
COR II: Excess Cost w/o Benefit/ or Harmful	Harmful to Patients										
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is useful/effective</li><li>■ Sufficient evidence from multiple randomized trials or meta-analyses</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation in favor of treatment or procedure being useful/effective</li><li>■ Some conflicting evidence from multiple randomized trials or meta-analyses</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation's usefulness/efficacy less well established</li><li>■ Greater conflicting evidence from multiple randomized trials or meta-analyses</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li><li>■ Sufficient evidence from multiple randomized trials or meta-analyses</li></ul>						
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is useful/effective</li><li>■ Evidence from single randomized trial or nonrandomized studies</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation in favor of treatment or procedure being useful/effective</li><li>■ Some conflicting evidence from single randomized trial or nonrandomized studies</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation's usefulness/efficacy less well established</li><li>■ Greater conflicting evidence from single randomized trial or nonrandomized studies</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li><li>■ Evidence from single randomized trial or nonrandomized studies</li></ul>						
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is useful/effective</li><li>■ Only expert opinion, case studies, or standard of care</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation in favor of treatment or procedure being useful/effective</li><li>■ Only diverging expert opinion, case studies, or standard of care</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation's usefulness/efficacy less well established</li><li>■ Only diverging expert opinion, case studies, or standard of care</li></ul>	<ul style="list-style-type: none"><li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li><li>■ Only expert opinion, case studies, or standard of care</li></ul>						

Classification of level of evidence	
Level 1	High-quality evidence backed by consistent results from well-performed randomized controlled trials, or overwhelming evidence from well-executed observational studies with strong effects
Level 2	Moderate-quality evidence from randomized trials (that suffer from flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias, or other limitations)
Level 3	Low-quality evidence from observational evidence or from controlled trials with several serious limitations
Useful practice point	Not backed by sufficient evidence; however, a consensus reached by working group, based on clinical experience and expertise
Grading of recommendation based on the quality of evidence	
Grade A	Strong recommendation to do (or not to do) where the benefits clearly outweigh the risk (or vice versa) for most, if not all patients
Grade B	Weaker recommendation where benefits and risk are more closely balanced or are more certain

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*evidence-based*

## RECOMMENDATIONS ACCORDING TO TYPE OF INSOMNIA

3.1 Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary insomnia. [4.2]  
(Standard)

3.2 Psychological and behavioral interventions are effective and recommended in the treatment of secondary insomnia. [4.3, 4.4]  
(Standard)



## RECOMMENDATIONS FOR SPECIFIC THERAPIES

3.3 Stimulus control therapy is effective and recommended therapy in the treatment of chronic insomnia. [4.3, 4.4, 4.5] (Standard)

3.4 Relaxation training is effective and recommended therapy in the treatment of chronic insomnia. [4.6] (Standard)

3.5 Sleep restriction is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.4, 4.6] (Guideline)

3.6 Cognitive behavior therapy, with or without relaxation therapy, is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.6](Standard)

3.7 Multicomponent therapy (without cognitive therapy) is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.8, 5.0] (Guideline)

**3.8 Paradoxical intention is effective and recommended therapy in the treatment of chronic insomnia. [4.2, 4.6] (Guideline)**

**3.9 Biofeedback is effective and recommended therapy in the treatment of chronic insomnia. (Guideline)**

**3.10 Insufficient evidence was available for sleep hygiene education to be an option as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined from the available data. [4.6, 4.7] (No recommendation level)**

**3.11 Insufficient evidence was available for imagery training to be an option as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined from the available data. [4.7] (No recommendation level)**

**3.12 Insufficient evidence was available for cognitive therapy to be recommended as a single therapy. [4.6] (No recommendation level)**

## RECOMMENDATIONS RELEVANT TO SPECIFIC PATIENT GROUPS

3.14 Psychological and behavioral interventions are effective and recommended in the treatment of insomnia in older adults. [4.4] (Standard)

3.15 Psychological and behavioral interventions are effective and recommended in the treatment of insomnia among chronic hypnotic users. [4.5] (Standard)

# **INSOMNIA GUIDELINE -EVALUATION AND MANAGEMENT OF CHRONIC INSOMNIA IN ITALY**

- 1) Insomnia is a frequent pathology in Italy and worldwide and symptoms of insomnia must be always evaluated in the clinical practice**
- 2) Consider the presence of insomnia if subjects referring nocturnal symptoms, are dissatisfied with sleep quality and quantity, and report Daytime Symptoms interfering with daily life activities**
- 3) Consider the duration of insomnia: insomnia can be acute and/or episodic lasting for a period within 1month and/or 3 months, or chronic lasting longer than 3 months. An acute/episodic insomnia may be a risk for a chronic form**
- 4) Consider the type of insomnia in order to choose the specific treatment: subjects may report difficulty falling asleep, frequent awakenings, difficulty returning to sleep, awakening too early in the morning or a combination of them**
- 5) Consider the presence of coexisting mental and/or medical disorders: insomnia may be a risk, a comorbid condition or a symptom that may negatively impact on the trajectory of the mental or medical comorbid disorder. Consider also another coexisting sleep disorder**

## **Recommendation for insomnia evaluation and assessment in a sleep center**

**6) Consider as a first step a clinical evaluation through the sleep history and detailed medical, substance use, and psychiatric history**

**7) Insomnia evaluation should address specific insomnia complaints, sleep-wake patterns, other sleep-related symptoms, and daytime consequences. The history should help to establish the type and evolution of insomnia, predisposing, precipitating and perpetuating factors, and identification of comorbid medical, and/or psychiatric conditions**

**8) Evaluation of insomnia should include self-administered questionnaires. At least the patient should complete:**

1. A questionnaire assessing insomnia diagnosis and symptoms severity: The Italian version of the Insomnia Severity Index-ISI to evaluate insomnia symptoms and of the Sleep Condition Indicator-SCI to confirm insomnia diagnosis according to DSM-5 criteria
2. Sleepiness assessment: The Italian version of the Epworth Sleepiness Scale
3. Patterns of sleep-wake times and day-to-day variability: A one-week at home sleep diary (Italian version of the consensus conference sleep diary)
4. The sleep diary should be used prior to and during the course of active treatment and in the case of relapse



**9) Additional assessment instruments should include measures of:**

1. General patterns of sleep-wake times and day-to-day variability with one week of actigraphic registration together with the one week sleep diary at the moment of the first assessment
2. Cognitive perpetuating factors: dysfunctional beliefs and attitudes about sleep  
– Italian version of Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS)
3. Arousal perpetuating factors: pre sleep arousal-Italian version of Pre-Sleep Arousal Scale (PSAS)
4. Predisposing factors in relation to stress: stress-related sleep reactivity- Italian version of FIRST-Ford Insomnia Response Test Questionnaire

**10) If other sleep disorders are reasonably suspected to be related to insomnia instrumental examination are suggested. Polysomnography is not indicated in the routine evaluation of chronic insomnia**

**11) Other laboratory testing (e.g., blood, radiographic) is not indicated for the routine evaluation of chronic insomnia unless there is suspicion for comorbid disorders.**

## Diagnostic Pathways for insomnia in Italy

GPs play a key role in the early phases of insomnia detection and they should evaluate insomnia symptoms in their daily clinical practice. At least they should briefly evaluate insomnia symptoms (recommendation 1-5) with a few questions:

- 1) Is the quality of your sleep good during the night? What are your symptoms?
- 2) Do you have sleepiness or fatigue during the day due to your bad sleep?
- 3) How long have you been suffering from these symptoms?
- 4) Could these sleep symptoms be related to your medical or mental disorder?
- 5) Did your bed-partner report you snoring or having strange behaviors during the night?

GPs should send the subject to a sleep specialist if the answers to these questions are indicative of 1) chronic-persistent insomnia, treatment resistant insomnia 2) Sleepiness which adversely affects daytime activities, or 3) Sleep disorders that may require instrumental evaluation

## **Recommendation for Insomnia treatment in a primary care setting**

- 1. In a patient with acute insomnia an attitude “wait and see” should be taken and no treatment should be initiated until insomnia persists for more than 1 month**
- 2. In a patient with acute insomnia, 1) in person or self-help CBT-I 2) pharmacological treatment or 3) a combination of the two may be considered as therapeutic options**
- 3. In a patient with chronic insomnia without comorbidity the first line treatment should be: 1) in person or self-help CBT-I, 2) pharmacological treatment or 3) a combination of the two according to the clinical context and the patient’s preference 4) the GPs should try first a treatment and then if there is treatment resistance GPs should send the patient to a sleep center.**
- 4. In a patient with chronic comorbid insomnia the comorbidity should be treated first while specific insomnia treatment should be initiated only in case of insomnia persistence in spite of the appropriate treatment of the comorbidity**
- 5. In a patient with chronic comorbid insomnia specific insomnia treatment should be initiated regardless of the comorbidity treatment and outcome**

- 6. In a patient of adult age, with insomnia without comorbidity: Z-drugs are preferable to benzodiazepines as a pharmacological option**
- 7. In a patient of adult age, with insomnia without comorbidity: Z-drugs as well as benzodiazepines or off label drugs may be considered as a therapeutic option according to the clinical context and the patients' preference**
- 8. In a patient aged 55 years or more, with chronic insomnia without comorbidity. Melatonin 2 mg prolonged release is preferable to any hypnotics as therapeutic option**
- 9. In a patient aged 65 years or more, with chronic insomnia without comorbidity. The first line treatment should consist of melatonin, BDZ, Z drugs or off label drugs according to the clinical context and the patients' preference**
- 10. The duration of a hypnotic pharmacological treatment in a patient with insomnia should last no more than 4 weeks**
- 11. The duration of a pharmacological treatment in a patient with insomnia may last more than 4 weeks provided the patient is under clinical monitoring with intermittent treatments being encouraged**



**12. Zopiclone is indicated for the treatment of sleep onset and sleep maintenance insomnia in adults**

**13. Zaleplon is indicated for the treatment of sleep onset insomnia in adults**

**14. Zolpidem is indicated for the treatment of sleep onset and sleep maintenance insomnia in adults**

**15. Triazolam is indicated for the treatment of sleep onset insomnia in adults**

**16. Temazepam is indicated for the treatment of sleep onset and sleep maintenance insomnia**

**17. Lorazepam is indicated for the treatment of sleep onset and sleep maintenance insomnia**

**18. Trazodone is indicated for the treatment of sleep onset or sleep maintenance insomnia**

**19. Melatonin is indicated for the treatment of sleep onset insomnia in adults**