

# Clinical Practice Guideline

## Adult Primary Insomnia: Diagnosis to Management

*This guideline was developed by a Clinical Practice Guidelines Working Group to assist physicians in the management of primary insomnia in adults. A companion guideline for the assessment of patients with insomnia accompanies this document. This guideline does not address the assessment and management of excessive daytime sleepiness (EDS) or the management of other primary sleep disorders (ie; obstructive sleep apnea, movement disorders in sleep or parasomnias).*

### EXCLUSIONS

- Children under the age of 18.
- Pregnant and/or lactating women.
- Geriatric patients: While the general principles of the management of primary insomnia apply to all adult patients it is important to note that “late life insomnia” requires specific interventions not addressed in this guideline.<sup>1</sup>

### RECOMMENDATIONS

- The management of primary insomnia is based on the foundation of behavioural and cognitive non-pharmacologic strategies. Pharmacologic interventions are adjunctive to the non-pharmacologic strategies. Adjunctive pharmacotherapy is used on a short-term (less than 7 days on a nightly basis) or intermittent (2-3 nights per week) for the sole purpose of **preventing** an exacerbation of the primary insomnia.
- The patient must be an active participant in treatment process. Primary insomnia is a chronic illness that requires regular follow-up and monitoring to evaluate the patient’s response to treatment and motivation to resolve the problem.
- The goal of management is to provide the patient with the tools necessary to manage the chronic nature of the illness and minimize dependence on sedative medications.

### Non-pharmacologic

Non-pharmacologic therapies are effective in the management of primary insomnia especially when behavioural and cognitive techniques are used in combination.<sup>2</sup> Behavioural techniques include sleep hygiene, sleep consolidation, stimulus control, and relaxation therapies. Cognitive techniques include cognitive behavioural therapy (CBT).<sup>3,4</sup>

### Behavioural Therapies

#### Sleep hygiene<sup>3</sup>

The following recommendations should be individualized to address patient needs/situation.

#### PRACTICE POINT

Initially, review of sleep behaviours and sleep hygiene advice with recommendations to adhere strictly to the principles of sleep hygiene will provide the clinician with an indication of the patient’s **motivation to change the behaviours** that are perpetuating the insomnia.

#### Sleep Hygiene Advice:

- Avoid vigorous exercise within 2 hours of bedtime.
- Avoid sleeping-in after a poor night of sleep.
- Avoid watching/checking the clock.
- Avoid excessive liquids or heavy evening meals.
- Avoid caffeine, nicotine, and alcohol before bed.
- Maintain a quiet, dark, safe, and comfortable sleep environment.
- Schedule a wind-down period before bed.

#### PRACTICE POINT

Educate the patient about the following issues:

- Alcohol helps with sleep initiation, it impairs sleep maintenance and can exacerbate other sleep disorders.
- Nicotine is a potent stimulant with a short half-life that induces awakenings as a result of withdrawal during the sleep period.
- Smoking cessation aids (nicotine replacement products and bupropion) can cause insomnia.

#### Sleep consolidation<sup>4</sup>

Some insomnia patients spend excessive time in bed trying to attain more sleep. Sleep consolidation is accomplished by compressing the total time in bed to match the total sleep need of the patient. This improves the sleep efficiency.

- Devise a “sleep prescription” with the patient: a fixed bedtime and wake time.
- Determine the average total sleep time.
- Prescribe the time in bed to current total sleep time plus 1 hour.
- The minimum sleep time should be no less than 5 hours.

The above recommendations are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making

- Set a consistent wake time (firmly fixed 7 days/week).
- The bed time is determined by counting backwards from the fixed wake time (For example: a patient estimates the total sleep time to be 5-6 hours/night, the total time in bed is 8 hours/night for a sleep efficiency of  $5.5/8 = 68\%$ . The prescribed total sleep time would be 6.5-7 hours/night, if the wake time is 6AM then the prescribed bedtime is 11-1130 PM).
- For the first 2-4 weeks these times should remain consistent and the clinician should monitor the patients adherence to the program with sleep logs (see sleep log attachment).
- Advise the patient that napping will reduce the depth and restorative quality of sleep the following night.
- Once the patient is sleeping for about 90 percent of the time spent in bed for five consecutive days, then the amount of time spent in bed is slowly increased by 15- 30 minute every 5 days. If sleep efficiency of 90 percent is maintained, then therapy is successful. The average total sleep time for most people is between 6 and 8 hours a night.

### PRACTICE POINT

1. Advise patients that the goal of treatment is to improve the continuity and restorative quality of sleep, not to make them “8-hour sleepers”. More often than not the total sleep time will be less than 8 hours per night.
2. Advise patients that they may suffer from daytime sleepiness in the initiation phase of compressing their sleep schedule.

### Stimulus control<sup>3</sup>

Stimulus control is designed to re-associate the bed/bedroom with sleep and to re-establish a consistent sleep-wake schedule. This is achieved by limiting activities that serve as cues for staying awake. The treatment consists of the following behavioural instructions:

- Avoid arousing activities before bed (late night phone calls, work, watching TV).
- Go to bed only when sleepy, even if later than prescribed sleep schedule.
- Set alarm for agreed upon wake time.
- Hide the clock.
- Get out of bed if not able to sleep - go to another room and relax.
  - Avoid eating, ingesting caffeine or smoking
  - Return to bed only when sleepy.

### Relaxation therapies

Relaxation therapy is designed to reduce physiological

and psychological arousal to promote sleep. Recommended relaxation therapies must be individualized and include:

- Progressive muscle relaxation.
- Biofeedback.
- Meditation.
- Imagery training.
- Light exercise/light stretching.
- Deep breathing.

### Cognitive Therapies<sup>3,4</sup>

#### Cognitive behavioral therapy (CBT)

CBT addresses the inappropriate beliefs and attitudes that perpetuate the insomnia. The goal of this technique/process is to identify dysfunctional sleep cognitions, challenge the validity of those cognitions, and replace those beliefs and attitudes with more appropriate and adaptive cognitions. Common faulty beliefs and expectations that can be modified include:

- Unrealistic sleep expectations (e.g., “I need to have 9 hours of sleep each night”).
- Misconceptions about the causes of insomnia (e.g., “I have a chemical imbalance causing my insomnia”).
- Amplifying the consequences (e.g., “I cannot do anything after a bad night’s sleep”).
- Performance anxiety and loss of control over ability to sleep (e.g., “I am afraid of losing control over my ability to sleep”).

### Pharmacologic

Pharmacotherapy should be considered an adjunctive therapy to cognitive and behavioural therapies in the comprehensive management of primary insomnia.

### Principles of Treatment

Pharmacotherapy is generally recommended at the lowest effective dose as short-term treatment lasting less than 7 days. Although long-term use of hypnotic agents is discouraged due to the potential for tolerance and dependence, there are specific situations and circumstances under which long term use of hypnotics may be appropriate.

- Short term (<7 consecutive nights)<sup>5</sup>:
  - Initially used to break the cycle of chronic insomnia and allow the patient to adapt to cognitive and behavioural interventions.
  - Used to manage an exacerbation of previously controlled primary insomnia.
- Long term intermittent<sup>6</sup> (self administered therapy to decrease arousal and prevent relapse):
  - Used on a limited PRN basis (<3 times/week) for occasional bouts of insomnia.
  - Used on a scheduled basis (i.e., <3 times/week) to ensure consistent adequate sleep in a patient with chronic primary insomnia where the goal of therapy is to prevent relapse.

## Therapeutic Options

<b>First-line Pharmacotherapy: Highest level of evidence supporting efficacy and safety</b>		
Agents	Recommended Dose	Comments
<b>Zopiclone</b>	3.75 - 7.5 mg	<ul style="list-style-type: none"> <li>Short half-life provides lower risk of morning hang-over effect</li> <li>Metallic after-taste most common adverse reaction.</li> </ul>
<b>Zaleplon</b>	NOLONGER AVAILABLE IN CANADA	<ul style="list-style-type: none"> <li>Ultra-short half-life. Used for sleep initiation and also PRN for night-time awakenings when there is still a minimum of 3 to 4 hours before rising.</li> </ul>
<b>Temazepam</b>	15-30 mg	<ul style="list-style-type: none"> <li>Intermediate half-life carries a low-moderate risk of morning hang-over effect.</li> </ul>

<b>Second-line Pharmacotherapy</b>		
Moderate level of formal evidence. Extent of current use and favorable tolerability support use as second-line agents		
Agents	Recommended Dose	Comments
<b>Amitriptyline</b>	10 - 50 mg	<ul style="list-style-type: none"> <li>Longer half-life carries risk of morning hang-over effect and cognitive impairment.</li> </ul>
<b>Trazodone</b>	25 - 50 mg	<ul style="list-style-type: none"> <li>Shorter half-life carries lower risk of morning hang-over effect.</li> </ul>

<b>Variable Evidence</b>		
Agents	Recommended Dose	Comments
<b>L'Tryptophan</b>	500 mg - 2 gm	<ul style="list-style-type: none"> <li>Evidence supporting efficacy is variable and insufficient. May be requested by individual patients looking for a "natural source" agent.</li> </ul>
<b>Melatonin</b>	1 - 5 mg	
<b>Valerian</b>	400-900 mg	

<b>Not Recommended</b>		
The following agents are not recommended for the management of conditioned insomnia except in cases where the agent is being used specifically to manage a co-morbidity such as depression.		
Agents	Comments	
<b>Antidepressants</b> - mirtazapine, fluvoxamine, tricyclics	<ul style="list-style-type: none"> <li>Relative lack of evidence</li> </ul>	
<b>Antihistamines</b> - chlorpheniramine, diphenhydramine, dimenhydrinate, doxylamine	<ul style="list-style-type: none"> <li>Relative lack of evidence or excessive risk of daytime sedation, psychomotor impairment and anticholinergic toxicity.</li> </ul>	
<b>Antipsychotics</b> (Conventional or 1st-Generation) - chlorpromazine, methotrimeprazine, loxapine	<ul style="list-style-type: none"> <li>Relative lack of evidence and unacceptable risk of anti-cholinergic and neurological toxicity.</li> </ul>	
<b>Antipsychotics</b> (Atypical or 2 <sup>nd</sup> -Generation) - risperidone, olanzapine, quetiapine	<ul style="list-style-type: none"> <li>Relative lack of evidence and unacceptable cost and risk of metabolic toxicity</li> </ul>	
<b>Benzodiazepines</b> (Intermediate and Long-Acting) - diazepam, clonazepam, flurazepam, lorazepam, nitrazepam, alprazolam, oxazepam <b>Benzodiazepines</b> (Short-Acting) - triazolam	<ul style="list-style-type: none"> <li>Excessive risk of daytime sedation and psychomotor impairment.</li> <li>No longer recommended due to unacceptable risk of memory disturbances, abnormal thinking and psychotic behaviors.</li> </ul>	
<b>Chloral's</b> - chloral hydrate, ethchlorvinyl	<ul style="list-style-type: none"> <li>Excessive risk of tolerance, dependence and abuse as well as adverse gastrointestinal and CNS effects.</li> </ul>	
<b>Muscle relaxants</b> - cyclobenzaprine, meprobamate	<ul style="list-style-type: none"> <li>Relative lack of evidence and excessive risk of adverse CNS effects.</li> </ul>	

## Management Plan

### PRACTICE POINT

The foundation of the management of primary insomnia is behavioural and cognitive therapy. Ongoing evaluation of the patient's motivation to adhere to the behavioral and cognitive strategies is an important part of monitoring the patient's progress. Adherence to, and compliance with these strategies is usually effective and minimizes the potential for dependence on medication.

#### First visit

- Prescribe behavioural and cognitive interventions.
- Use sleep logs and diaries to monitor the patient's progress (see sleep log attachment).
- Consider pharmacotherapy based on the patient's sense of urgency, need for relief and willingness (motivation) to follow the behavioural and cognitive recommendations.

#### Follow-up at 2 – 4 weeks

- Evaluate sleep efficiency and daytime symptoms.
- Reinforce behavioural interventions.
- Review or reconsider pharmacotherapy.

#### 3 month follow-up

- If there is no progress or limited improvement referral to sleep medicine program or psychologist may be warranted.

## Credibility

The insomnia guideline working group was comprised of family physicians, sleep medicine specialists, general internists, a psychiatrist, and a clinical pharmacist. The Alberta Medical Association Toward Optimized Practice (TOP) program guided the development process using the Appraisal of Guidelines For Research and Evaluation (AGREE) Instrument to evaluate the quality of the guideline.<sup>8</sup> An extensive review of the literature was performed and provided the following key documents as the foundation for the current state of the evidence:

- 1 “Current State Of The Science Of Chronic Insomnia”, National Institutes of Health.<sup>2</sup>
- 2 “Manifestations and Management of Chronic Insomnia in Adults”, The Agency for Healthcare Research and Quality, University of Alberta, Evidence based Practice Center.<sup>7</sup>

- 3 “Guidance on the use of Zaleplon, Zolpidem and Zopiclone For The Short-Term Management of Insomnia”, the British National Health Service, National Institute for Clinical Excellence.<sup>5</sup>
- 4 “Insomnia”, *Sleep Medicine Clinics*, Volume 1, Number 3, September 2006.<sup>4</sup>

The results and recommendations of these documents have been reviewed by the guideline committee and form the basis of the evidence for the background material and recommendations. The clinical tools have been developed by the guideline committee based on Canadian expert and primary care physician consensus. Funding for this project has been provided by the TOP program and no members of the guideline committee have received pharmaceutical or industry funding or support in their role as a committee member.

## References

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## Selected Readings

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## TOWARD OPTIMIZED PRACTICE (TOP) PROGRAM

The TOP Program is an initiative directed jointly by the Alberta Medical Association, Alberta Health and Wellness, the College of Physicians and Surgeons, and Alberta's Health Regions. The TOP Program promotes appropriate, effective and quality medical care in Alberta by supporting the use of evidence-based medicine.

### TOP Leadership Committee

Alberta Health and Wellness  
Alberta Medical Association  
Regional Health Authorities  
College of Physicians and Surgeons of Alberta

### TO Provide Feedback

The Guideline Working Group for Insomnia is a multi-disciplinary team composed of family physicians, sleep medicine specialists, a pharmacist, psychiatrist and a psychologist.

The team encourages your feedback. If you have difficulty applying this guideline, if you find the recommendations problematic, or if you need more information on this guideline, please contact:

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