

Insomnia Disorder

A VA Clinician's Guide to Managing
Insomnia Disorder (2019)



VA



U.S. Department of Veterans Affairs

Veterans Health Administration
PBM Academic Detailing Service
Employee Education System

Contents

Insomnia Disorder.....	3	Risks in elderly patients and patients with dementia	15
Background	3	Provider perceptions vs reality	16
Figure 1. Stepped Care for Management of Insomnia Disorder.....	3	Figure 5. Weighing the potential risks versus benefits of medication use	16
Table 1. Brief summary of the ISI.....	4	Doxepin.....	17
Figure 2. Acute Insomnia to Insomnia Disorder.....	5	Figure 6. Doxepin Use.....	18
Clinical Pearl	5	Ramelteon.....	18
Figure 3. Common causes of sleep disturbance	6	Trazodone	19
Make the diagnosis, if present.....	7	Mirtazapine	20
Table 2. Symptoms and patient behaviors in insomnia disorder.....	7	Amitriptyline	20
Clinical Pearl	8	Gabapentin	21
Table 3. Components and aims of CBT-I.....	9	Figure 7. Gabapentin Use	21
Offering CBT-I to Veterans	9	Melatonin	22
Managing insomnia disorder.....	9	Table 7. Sedating Treatment Options for Patients with Co-morbidities ⁺	22
CBT-i Coach	9	Figure 8. Recommendations for Managing Insomnia Disorder When Medications are Being Considered for Short-term Use	23
Table 4. Frequently asked questions and answers regarding CBT-I	10	Risk Reduction Strategy: Tapering and Discontinuing Pharmacotherapy.....	24
Provide or refer Veterans with insomnia disorder to CBT-I.....	11	Figure 9. CBT-I and Successful Benzodiazepine Discontinuation	24
Figure 4. Shared Decision-Making for CBT-I.....	11	Consider referral to a sleep disorder specialist.....	25
Other Clinical Considerations: Pharmacotherapy	12	Special thanks to our expert reviewers:	26
Clinical Pearl	12	References.....	27-32
Table 5. FDA-Approved Agents for Insomnia.....	13		
Table 6. Guideline recommendations for patients with insomnia disorder and no co-morbidities	13		
Risks of substance use disorders.....	14		
Specific Risks of Benzodiazepine	14		
Benzodiazepines are Associated with Significant Risk in the Elderly	15		

Insomnia Disorder

Identification and management of insomnia disorder is important to reduce risk for additional conditions and promote overall better health. Studies show that insomnia is a risk factor for hypertension, alcohol use, depression, psychiatric morbidity, suicidality, and increased mortality.^[1-10]

It has also been shown to reduce productivity at work, increase absenteeism, and reduce quality of life.^[2, 14]

Background

Insomnia disorder involves a persistent (occurring for at least three nights per week for at least three months) difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment.^[2, 11]

Insomnia is the second most common overall complaint reported in general primary care settings (after pain), with about 30–50% of adults reporting sleep trouble in a given year.^[2]

Complications of Insomnia

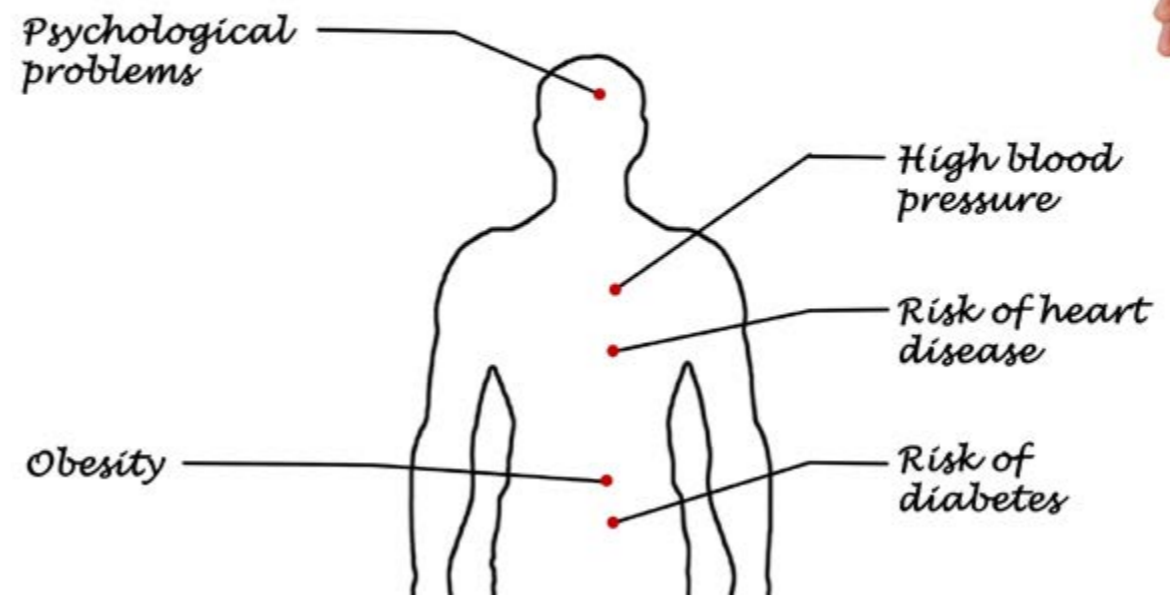
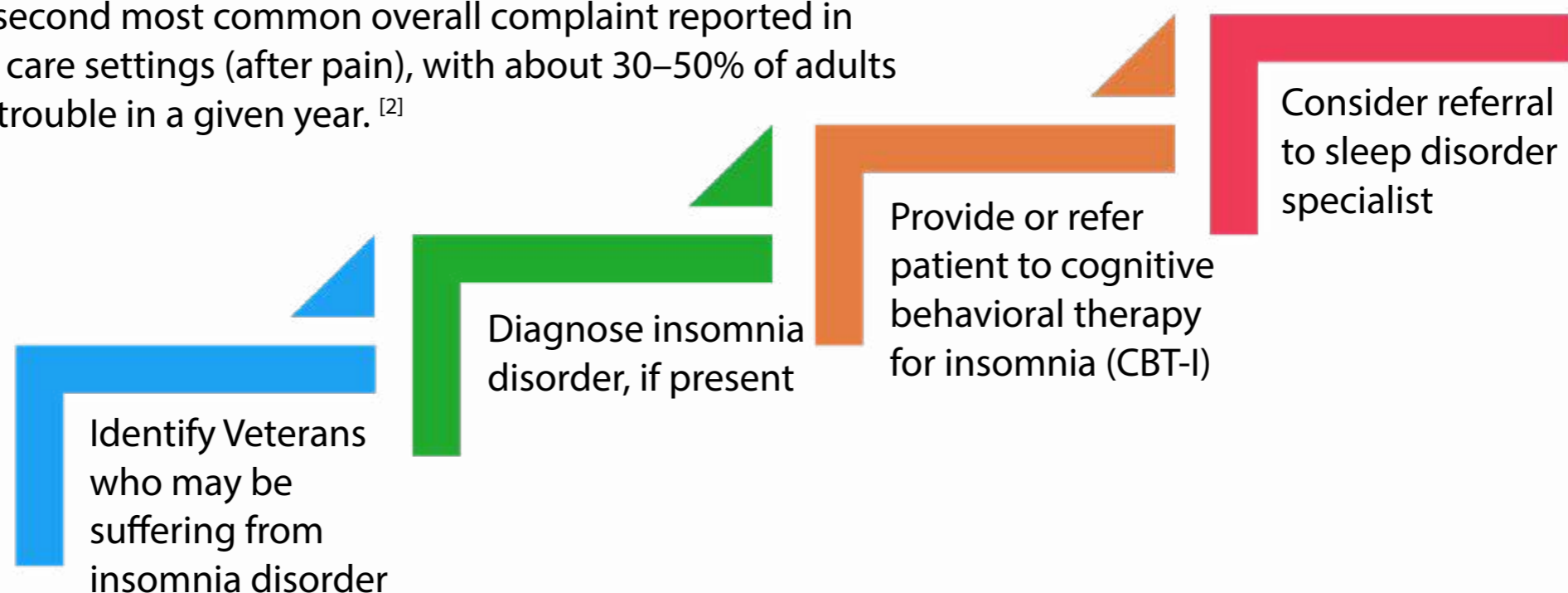


Figure 1. Stepped Care for Management of Insomnia Disorder



Identify Veterans who may be suffering from insomnia disorder

- Ask Veterans if they are having trouble sleeping, such as: difficulty getting to sleep or maintaining sleep, suffering from early-morning awakening, having poor quality sleep, or excessive daytime sleepiness.
- The Insomnia Severity Index (ISI) is a useful screening tool that can be found in MyHealtheVet and in CPRS under the Mental Health Assistant. ^[12, 13]

Table 1. Brief summary of the ISI^[13]

Rate the current severity of your insomnia problem(s)						
		0	1	2	3	4
1	Difficulty falling asleep?					
2	Staying asleep?					
3	Waking up too early?					
4	Satisfied with your sleep pattern?					
5	How noticeable is the impairment in your quality of life from your sleep problem?					
6	How worried are you about your sleep pattern?					
7	How much does your sleep problem interfere with your daily functioning (e.g., daytime fatigue, mood, ability to function at work/daily chores)?					

Scores from each question can be added to determine level of insomnia (e.g., 0–7 = No clinically significant insomnia; 22–28 = Severe clinical insomnia)

Identify Veterans who may be suffering from insomnia disorder

Figure 2. Acute Insomnia to Insomnia Disorder



Acute insomnia symptoms can occur with various medical and psychiatric comorbidities and will sometimes go away on their own with management of the comorbidity or good sleep hygiene (please see the Quick Reference Guide for sleep hygiene guidance).

- If acute insomnia persists for three or more months at a frequency of at least three times per week and meets the above criteria, it is considered insomnia disorder and requires treatment. ^[1, 2, 11]



Clinical Pearl

Alcohol is often used by Veterans to induce sedation; however, over time, its effect on sleep latency (time it takes to fall asleep) diminishes while sleep disruption persists. This use can lead to a vicious cycle of daytime dysfunction, early morning awakening, insomnia, and increased alcohol use. ^[14-16]

Identify Veterans who may be suffering from insomnia disorder

Figure 3. Common causes of sleep disturbance* [1, 6, 17]

Medical comorbidities	<ul style="list-style-type: none">• BPH• GERD• Pain• Allergies• Migraines• COPD• Heart disease• Diabetes• Hypertension
Sleep disorders	<ul style="list-style-type: none">• Sleep apnea• Restless legs syndrome
Psychiatric disorders	<ul style="list-style-type: none">• Depression• Anxiety• PTSD
Substance use	<ul style="list-style-type: none">• Drugs and alcohol• Caffeine• Nicotine
Medications	<ul style="list-style-type: none">• Certain antidepressants (e.g. bupropion, SSRIs/SNRIs)• CNS stimulants• Opioids• Diuretics
Activities/ Psychosocial	<ul style="list-style-type: none">• Work schedule• Travel• Sleep environment• Deployments and/or adjusting to civilian life

* This list is not all inclusive. BPH = Benign prostatic hyperplasia, CNS = central nervous system, COPD = chronic obstructive pulmonary disease, GERD = Gastroesophageal reflux disease, PTSD = Posttraumatic stress disorder, SNRIs = Selective serotonin and norepinephrine reuptake inhibitors, SSRIs = Selective serotonin reuptake inhibitors

Diagnose Veterans who may be suffering from insomnia disorder

Make the diagnosis, if present

If the sleep disturbance does not resolve, it is important to evaluate the patient for insomnia disorder and make the diagnosis if insomnia disorder is present.

Table 2. Symptoms and patient behaviors in insomnia disorder^{[11]*}

Symptoms of insomnia disorder	Example patient behaviors	Possible daytime complaints
Difficulty initiating sleep	<ul style="list-style-type: none"> Laying in bed for hours but unable to fall asleep Drinking alcohol or using drugs in an attempt to fall asleep 	<ul style="list-style-type: none"> Difficulty concentrating Difficulty maintaining attention Difficulty remembering things
Difficulty maintaining sleep	<ul style="list-style-type: none"> Waking up multiple times per night due to any number of identifiable factors and/or for unknown reasons Waking one or more times per night and remaining awake for an extended period of time 	<ul style="list-style-type: none"> Reduced productivity at work or school Daytime sleepiness Low energy or fatigued
Early morning awakening with inability to return to sleep	<ul style="list-style-type: none"> Waking up hours before the alarm is set to go off and being unable to fall back to sleep 	<ul style="list-style-type: none"> Mood disturbances (such as mood lability or irritability)

*Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria require a predominant complaint of dissatisfaction with the quality or quantity of sleep, associated with one (or more) of the above symptoms. These symptoms result in clinically significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning; problem occurs despite ample opportunity to sleep.

.....
If the patient suffers from insomnia disorder, make the diagnosis and offer treatment.^[17, 18]



Managing insomnia disorder

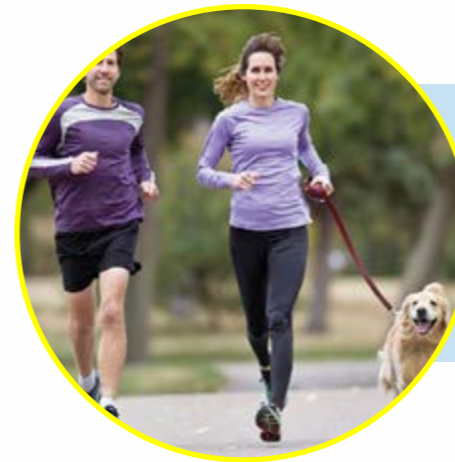
Cognitive behavioral therapy for insomnia (CBT-I) is recommended as the first line treatment for insomnia disorder. [1, 5, 14, 19, 20]

Patients often develop perpetuating behavioral and psychological factors that can lead to further wakefulness, negative expectations, and distorted beliefs about their insomnia.

CBT-I can be used to address these factors.

Factors that perpetuate sleep problems [19, 21-23]

- Irregular bedtime and/or waketime
- Spending excessive time in bed trying to sleep
- Avoidance behaviors during waking hours (e.g., cancelling activities out of fear they will interfere with sleep)



Clinical Pearl

All patients with insomnia disorder should adhere to good sleep hygiene.



Managing insomnia disorder

Table 3. Components and aims of CBT-I^[23]

Technique	Aims
Stimulus control	If not sleeping, stay out of bed to strengthen bed and bedroom as sleep cues.
Sleep restriction	Limit time in bed to increase sleep drive and consolidate sleep.
Relaxation, buffer, worry time	Reduce arousal.
Cognitive restructuring	Address thoughts and beliefs that interfere with sleep and adherence.
Circadian rhythm entrainment	Shift or strengthen the circadian sleep/wake rhythm.
Sleep hygiene	Address substances, exercise, eating, environment.

Offering CBT-I to Veterans

Veteran acceptance of CBT-I may be a challenge as not all Veterans may be willing or able to participate; however, many Veterans prefer to use approaches other than medications when they are made available to them.

- ✓ Understand what options are available for access to CBT-I
- ✓ Consider a shared decision-making approach to discuss this first-line treatment option with Veterans. ^[24]



CBT-i Coach is an app designed for people who are engaged in Cognitive Behavioral Therapy for Insomnia with a healthcare provider, or who have experienced symptoms of insomnia and would like to improve their sleep habits.

Managing insomnia disorder

Table 4. Frequently asked questions and answers regarding CBT-I^[23]

<p>What does CBT-I require from the Veteran?</p>	<ul style="list-style-type: none"> ✓ Attend six 50 to 60-minute weekly individual or 90-minute group therapy sessions (though some people may improve with fewer sessions or need more sessions). ✓ Complete a daily sleep diary and follow recommended treatment guidelines between sessions. ✓ Participate in evaluation of progress and determining whether initial goals for treatment were achieved.
<p>For which patients is CBT-I most helpful?</p>	<p>CBT-I can be tailored for Veterans with varied presentations, including those involving comorbidities.</p> <ul style="list-style-type: none"> • There is empirical support for CBT-I for the treatment of those with insomnia and: <ul style="list-style-type: none"> * A history of substance use disorder (not active abuse/use) * Psychiatric conditions such as PTSD, depression, bipolar disorder, anxiety disorders, and psychotic disorders * Chronic pain conditions * Other sleep disorders, such as sleep apnea
<p>Are there ever times when CBT-I is not indicated?</p>	<p>Yes. Some examples are if the Veteran:</p> <ul style="list-style-type: none"> • Does not meet criteria for insomnia disorder • Is working night or rotating shifts • Has poorly controlled seizure disorders or severe, unstable psychiatric symptoms.
<p>Can CBT-I be done in Primary Care?</p>	<p>CBT-I can be offered in Primary Care Mental Health Integration (PCMHI) settings and is typically offered as a “brief” course of treatment 4 sessions lasting 15-45 minutes per session)</p>

Managing insomnia disorder

Figure 4. Shared Decision-Making for CBT-I^[24]

Tips and example conversation starters

S	Seek your patient's participation	<p>"Now that we've identified the problem, let's think about what to do next. I'd like us to make this decision together."</p> <p>"There is good information about different treatment options I'd like to discuss with you before we decide on a treatment plan."</p>
H	Help your patient explore and compare treatment options	<p>"What treatment options are you familiar with for insomnia?"</p> <p>"Here are some options we can consider..."</p> <p><i>Discuss available treatment options and clearly communicate risks and benefits of each option. Use simple visual aids when possible.</i></p>
A	Assess your patient's values and preferences	<p>"As you think about your options, what's important to you?"</p> <p>"When you think about possible risks, what matters most to you?"</p> <p><i>Use open-ended questions, acknowledge the values and preferences that matter to your patient.</i></p>
R	Reach a decision with your patient	<p>"Would you like more time to think about your treatment options?"</p> <p>"What questions do you have for me about these options?"</p> <p>"Considering what we've discussed, which treatment option do you think is right for you?"</p>
E	Evaluate your patient's decision	<p>"Let's plan on reviewing this decision at your next appointment."</p> <p>"If you don't feel like your symptoms are improving, please schedule a follow-up visit so we can discuss the current approach."</p> <p><i>Patient buy-in is essential!</i></p>

Please remember to reach out to your local academic detailer to discuss the challenges you are encountering in your practice. They are available to partner with you to address your challenges, connect you with local resources, and help improve the care of Veterans.

Provide or refer Veterans with insomnia disorder to CBT-I

Managing insomnia disorder

Other Clinical Considerations: Pharmacotherapy

If the patient has completed CBT-I but still suffers from insomnia, or if CBT-I is not a good option for that patient, a short pharmacotherapy treatment period of 2 to 4 weeks of intermittent dosing may be considered.

^[1] CBT-I can be considered at any point in treatment.



Clinical Pearl

A 30-day prescription with refills is not needed as extended use is discouraged.

When pharmacotherapy is used, it is important to consider various factors such as: ^[14, 25]

- Symptom pattern (e.g., sleep onset or sleep maintenance difficulties)
- Treatment goals and patient preference
- Past treatment responses
- Availability of other treatments
- Comorbid conditions and contraindications
- Concurrent medication interactions
- Potential adverse effects

There are several FDA-approved medications for insomnia; however, most trials are industry sponsored, raising concerns about publication bias.

- Low confidence regarding the overall estimation of risks versus benefits of medications used for insomnia disorder.^[2, 26]
- Potential benefits of medications on sleep quality and daytime function should be balanced against the risk of side effects as well as physical and psychological addiction with long-term use.^[26]



Clinical Pearl

Short-term pharmacotherapy should be supplemented with behavioral and cognitive therapies when possible.^[2]

Managing insomnia disorder

Table 5. FDA-Approved Agents for Insomnia

Listed on the VA National Formulary (VANF)	Not currently listed on VANF
Doxepin Eszopiclone Temazepam Zaleplon* Zolpidem IR, CR*	Ramelteon Suvorexant

*Prior Authorization-Facility (PA-F) medications that are formulary, but require prior approval at the facility level before dispensing.

Table 6. Guideline recommendations for patients with insomnia disorder and no co-morbidities [2, 27]

Please note: This figure is based on guidelines that do not consider individual patient characteristics such as comorbidities or drug interactions.

Medication* (listed in alphabetical order)	VA/DoD 2019 CPG Strength of Recommendation	Type of Insomnia	AASM Guideline Strength of Recommendation
Diphenhydramine	Weak against	Sleep onset and/or sleep maintenance insomnia	Not Recommended
Doxepin	Weak for (3 or 6 mg)	Sleep maintenance insomnia	Weak Recommendation
Eszopiclone	Weak for	Sleep onset and/or sleep maintenance insomnia	Weak Recommendation
Ramelteon	Neither for nor against	Sleep onset insomnia	Weak Recommendation
Suvorexant	Neither for nor against	Sleep maintenance insomnia	Weak Recommendation
Temazepam	Weak against	Sleep onset and/or sleep maintenance insomnia	Weak Recommendation
Zaleplon	Weak for	Sleep onset insomnia	Weak Recommendation
Zolpidem	Weak for	Sleep onset insomnia and/or sleep maintenance insomnia	Weak Recommendation

* VA/DoD 2019 CPG considers kava “strong against” and chamomile, melatonin, and valerian “weak against”; AASM = American Academy of Sleep Medicine; CPG = Clinical Practice Guideline

Managing insomnia disorder

When selecting a medication to use for a patient with insomnia, we often find ourselves with only a few FDA-approved medications, most of which have significant risks for many Veterans and weak evidence to support their use. Consider the following examples:

1. Risks of substance use disorders

Benzodiazepines are widely acknowledged to cause physical dependence, with withdrawal effects possibly seen within as little as 4-6 weeks of continued therapy, and can cause addiction in some. ^[28]

2. Risks in patients with Posttraumatic Stress Disorder

Benzodiazepines are ineffective for the treatment and prevention of PTSD and any potential benefits are outweighed by the risks. ^[29-31]

58-100%

Patients prescribed benzodiazepines on a chronic basis became physically dependent. ²³

50%

Patients with substance use disorder history will develop benzodiazepine use disorder. ²³

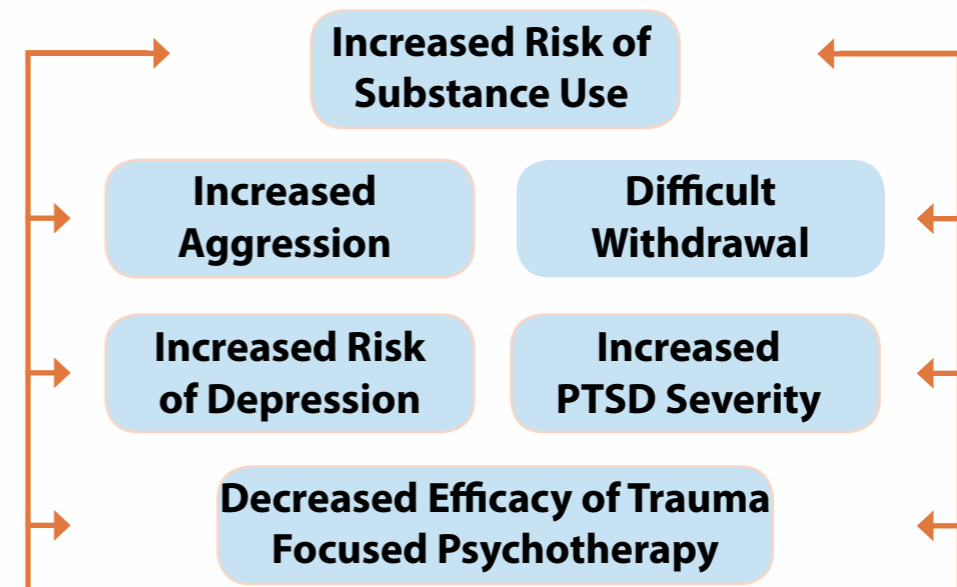
5-10%

Patients newly started on benzodiazepines develop a substance use disorder. ²⁴



Benzodiazepines are often not the primary substance abused, and when combined with other substances, can have fatal consequences. ²⁵

Specific Risks of Benzodiazepine Use in PTSD



Benzodiazepine ^[29]

Managing insomnia disorder

3. Risks in elderly patients and patients with dementia

Sedative hypnotics for the treatment of insomnia have a small magnitude of effect and substantial risk in patients ≥ 60 years old. [32]

Benzodiazepines are Associated with Significant Risk in the Elderly [32-36]

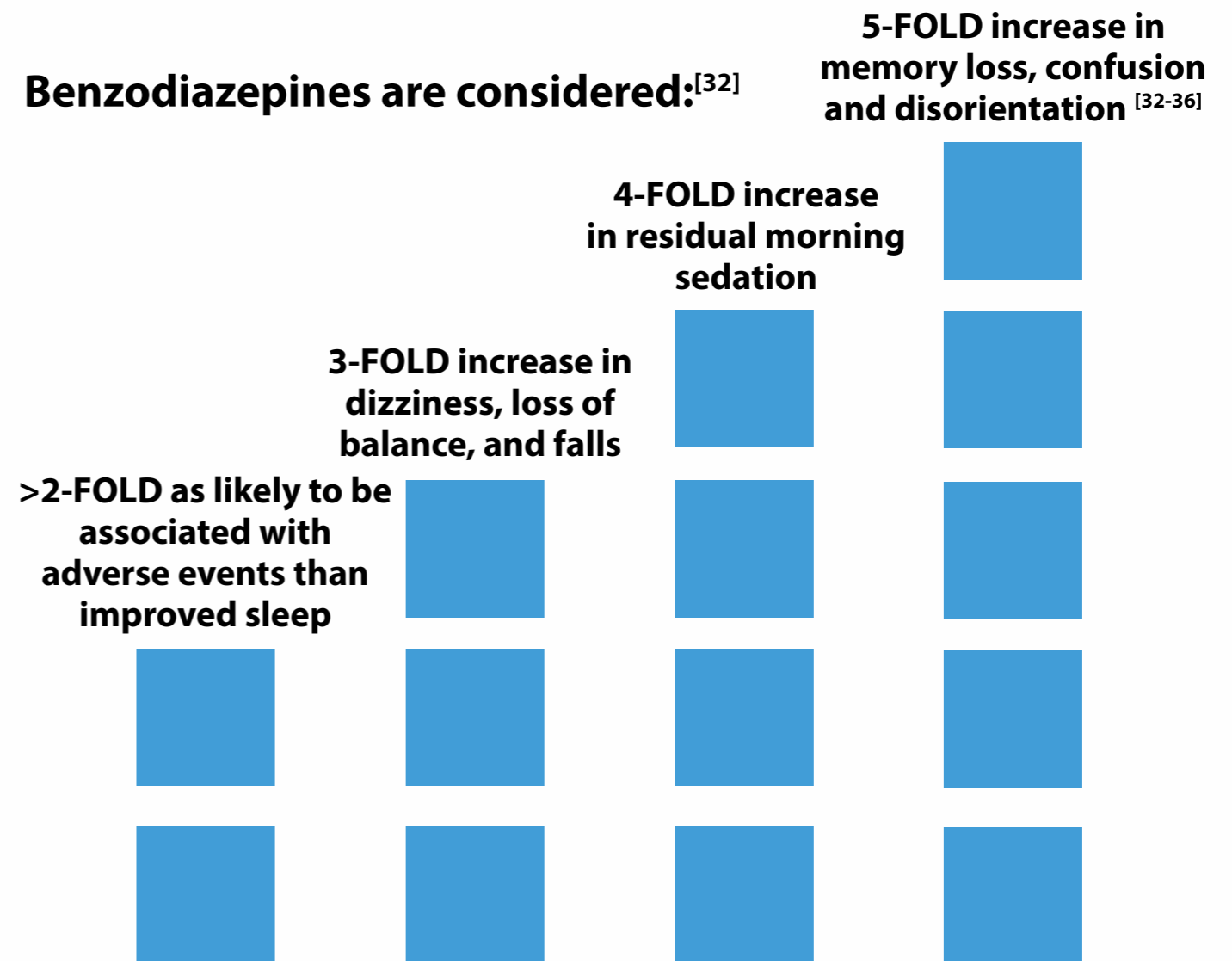
FALLS

HIP FRACTURES

SEDATION

COGNITIVE IMPAIRMENT

Benzodiazepines are considered: [32]



Don't underestimate the risks of some controlled substance medications.

Managing insomnia disorder

Provider perceptions vs reality

**This is
NOT
TRUE**

Some Provider Perceptions include:

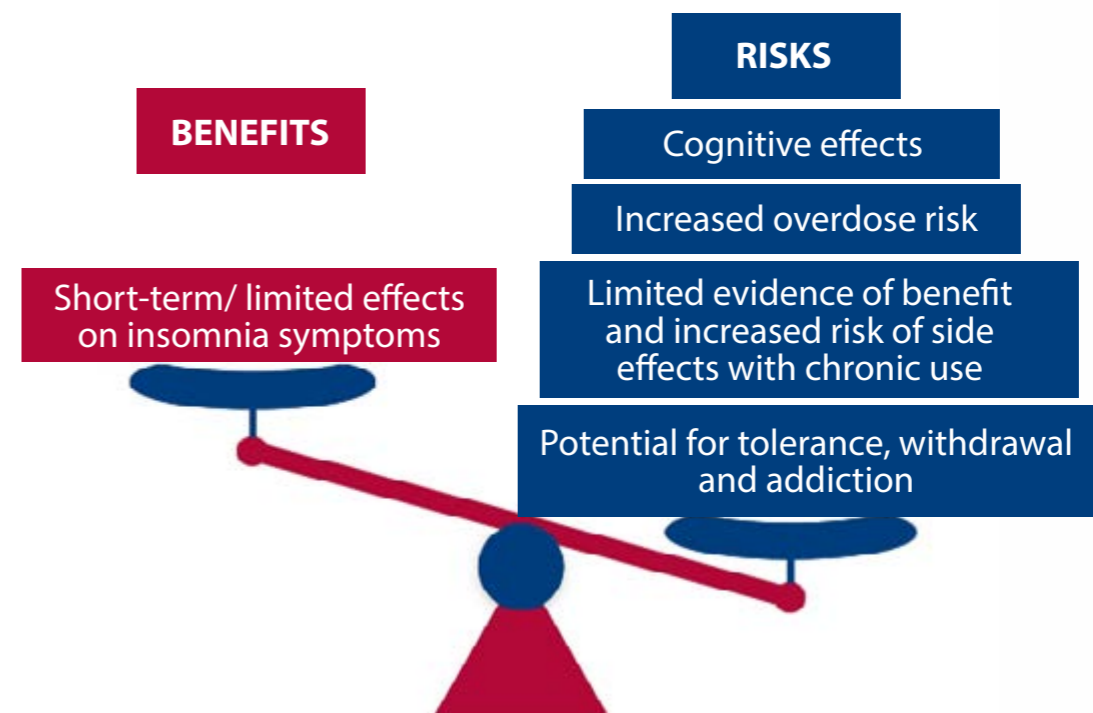
- A stable dose of benzodiazepine means that it is safe and effective.
- Attempts to discontinue will fail.

When surveyed about benzodiazepine use, prescribers underestimate the risks in their geriatric patients.^[37]

Figure 5. Weighing the potential risks versus benefits of medication use ^[38]

In general, avoid benzodiazepines if the patient:

- Has a substance use disorder
- Has PTSD
- Has a chronic respiratory disease (e.g., sleep apnea)
- Has a history of traumatic brain injury
- Has dementia or is elderly
- Is receiving other CNS depressants such as opioids



Managing insomnia disorder

Available evidence does not examine the long-term risks of tolerance, withdrawal, difficulty with discontinuation, and addiction in medications used in insomnia disorder. Therefore, we are including information in this brochure about medications without FDA-approved indication for insomnia, but which have some evidence of efficacy and no to low evidence of tolerance and addictive potential.

If you would like to consider a medication that is FDA-approved for insomnia and is not a controlled substance, consider the following options:

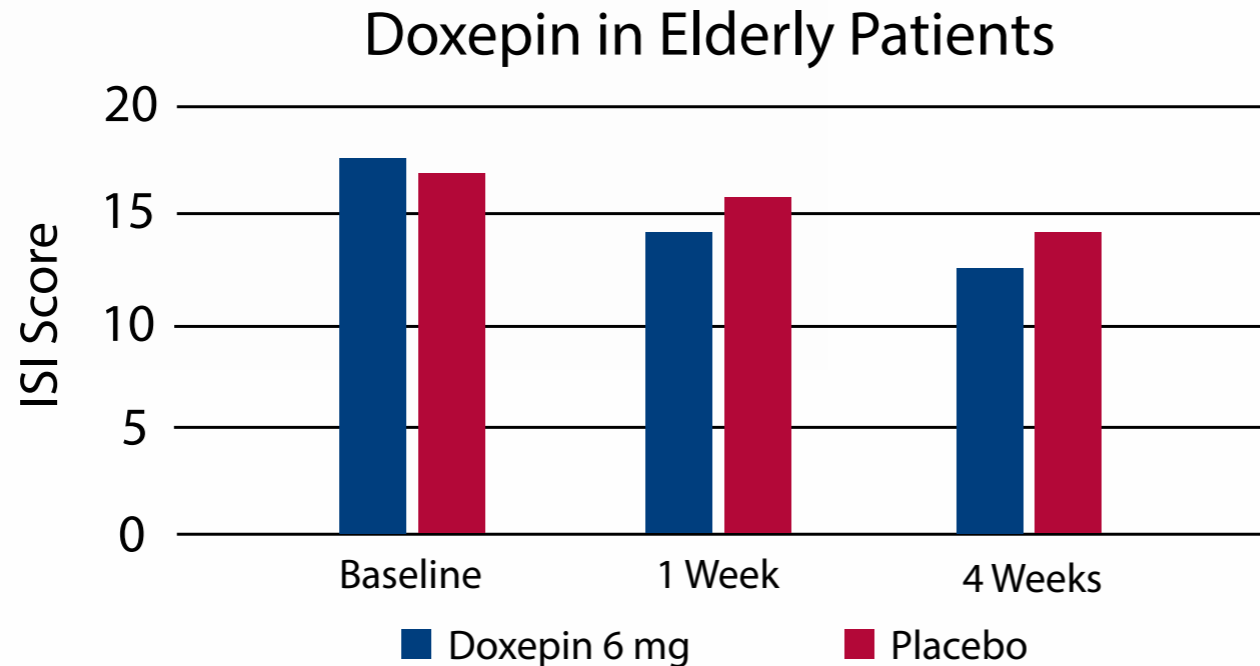
1. Doxepin

- FDA-approved for insomnia at low doses (3-6 mg)
- Better at sleep maintenance than sleep initiation ^[39]
- Does not appear to cause significant issues with tolerance or rebound insomnia ^[40-42]
- Has been shown in various studies to have a side effect profile comparable to placebo ^[40, 41, 43-45]
- Use with caution in patients at high risk for suicide due to risk of toxicity in overdose



Managing insomnia disorder

Figure 6. Doxepin Use^[40]



This randomized double-blind, placebo-controlled trial in 254 elderly outpatients found that low dose doxepin significantly improved total sleep time, wake time after sleep onset, sleep quality, and CGI and ISI scores (all p-values <0.05) compared to placebo.

Doxepin was also shown to be well-tolerated with a side effect profile comparable to placebo (27% incidence of adverse events with placebo vs 31% for doxepin).^[40]

2. Ramelteon

- FDA-approved for insomnia
- Helps decrease sleep latency but has not been shown to have significant effects on sleep maintenance^[1, 42]
- Does not appear to produce rebound insomnia or symptoms of withdrawal with prolonged use^[46]

Many medications are used “off-label” for sleep due to their sedating side effects. These medications may be most appropriate when Veterans have co-morbid psychiatric conditions for which alternative medications have been approved.

Many medications have side effects or other risks that may outweigh the benefits in some patients. It is important to weigh the risks and benefits before selecting an agent.

Managing insomnia disorder

Trazodone^[39]

- FDA-approved antidepressant
- When used at low doses, it primarily acts at alpha-1, histamine-1, and serotonin-2C and -2A receptors
- There are very few randomized controlled trials evaluating the safety and efficacy of trazodone for insomnia
 - * A small study suggests that low dose trazodone (50 mg at bedtime) improved sleep and did not impair cognition in patients with Alzheimer's disease^[47]
 - * A recent study indicates the risk of falls with low-dose trazodone is not statistically different from that of benzodiazepines in nursing home patients age 66 or older (5.7% trazodone, 6.0% benzodiazepines)^[48]
 - * May be an effective sleep aid when used in combination with an antidepressant in patients with depressive disorders^[1, 49]



Managing insomnia disorder

Mirtazapine

- FDA-approved antidepressant
- At low doses (7.5 – 15 mg), mirtazapine causes sedation primarily by acting as a histamine-1 receptor antagonist^[41]
- When titrated to therapeutic doses (15 – 45 mg) mirtazapine has been shown to block serotonin-2 receptors and produce favorable changes in sleep comparable to zolpidem and zaleplon^[50]

Amitriptyline

- FDA-approved antidepressant
- Commonly used at low doses for sleep due to histamine-1, muscarinic-1, and serotonin-2C antagonist activity
- Use caution in patients at risk for suicide due to risk of toxicity in overdose
- Associated with anticholinergic side effects, therefore avoid in elderly patients and others sensitive to these side effects



Managing insomnia disorder

Gabapentin ^[51]

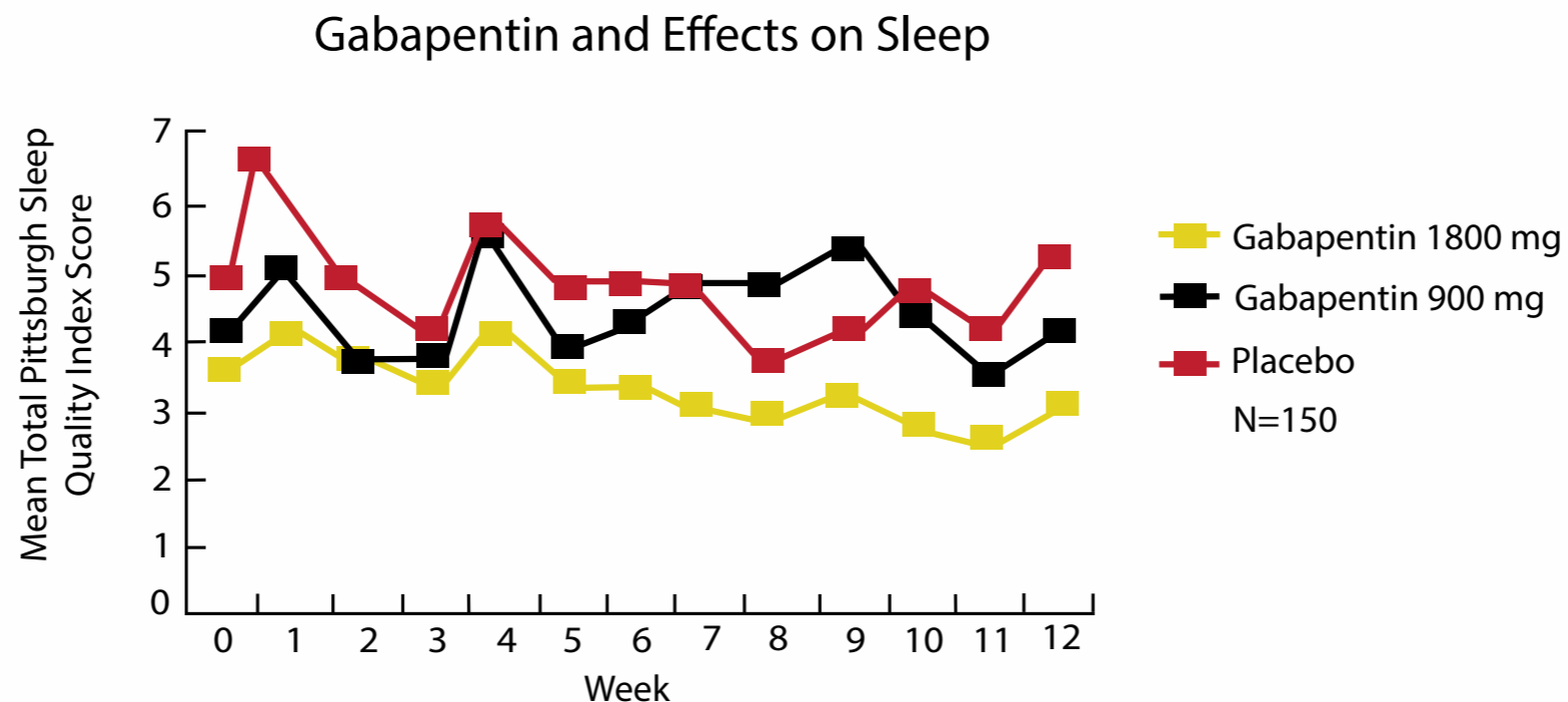
- Has been shown to increase slow-wave sleep (deep sleep), reduce sleep latency, and reduce arousals ^[52]
- May be used to reduce drinking and improve sleep in patients with alcohol use disorders ^[51, 53-55]
- Use with caution in patients with a history of substance abuse; potential for psychological and physical dependency exists ^[56]

Antihistamines

(Diphenhydramine, Doxylamine, Hydroxyzine)

- Diphenhydramine and Doxylamine available OTC
- Hydroxyzine may have more profound acute effects on sleep than over-the-counter (OTC) antihistamines ^[57]
- Associated with anticholinergic side effects, therefore avoid in elderly patients and others sensitive to these side effects

Figure 7. Gabapentin Use ^[51]



Managing insomnia disorder

Melatonin

- Available OTC; however, quality of evidence is considered very low and benefits were approximately equal to harms.^[2]
- May be more effective in patients aged 55 and older ^[58]



Table 7. Sedating Treatment Options for Patients with Co-morbidities⁺

	Pain	Depression	Anxiety Disorder	PTSD	Substance Use Disorder
Insomnia	Gabapentin	Mirtazapine	Hydroxyzine	Hydroxyzine	Hydroxyzine
	TCA	TCA	Mirtazapine	Mirtazapine	Mirtazapine
		Trazodone	TCA	Prazosin*	TCA
			Trazodone	TCA	Trazodone
				Trazodone	Gabapentin**

TCA= tricyclic antidepressant (e.g., amitriptyline, doxepin); +Medications are listed in alphabetical order;

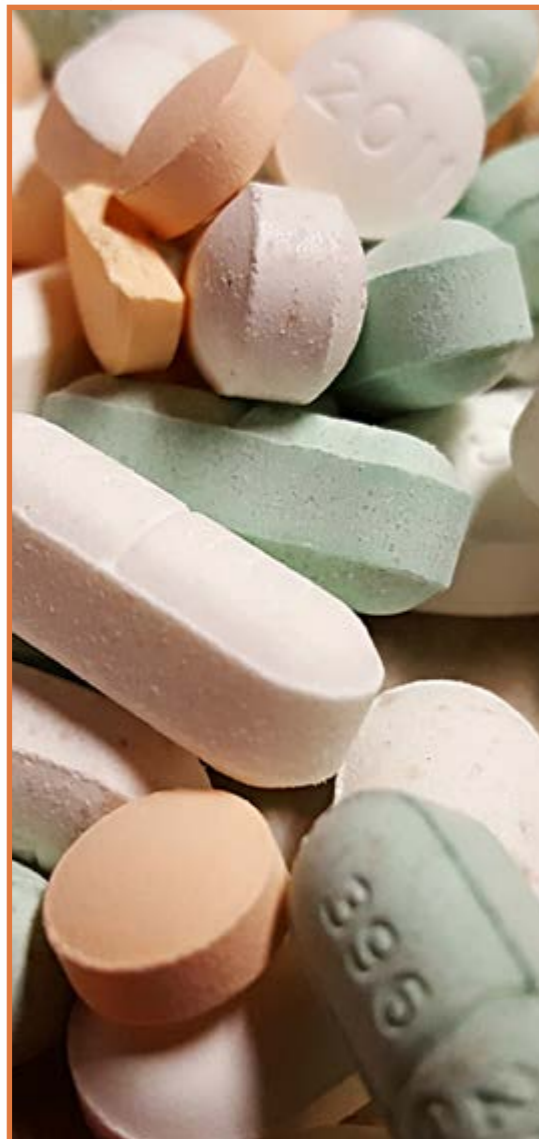
*May be considered for patients with trauma-associated nightmares;

**Gabapentin may be effective in reducing alcohol use as well as improving sleep in patients with Alcohol Use Disorder. Gabapentin should be used with caution due to risks of tolerance and dependence.

Managing insomnia disorder

When managing co-morbidities, ensure the Veteran is being offered or is receiving evidence-based treatment for that co-morbidity (e.g., psychotherapy for PTSD). The schematic below describes risk reduction strategies and recommendations when prescribing medications for insomnia disorder.

Figure 8. Recommendations for Managing Insomnia Disorder When Medications are Being Considered for Short-term Use ^[1, 2, 14, 59, 60]



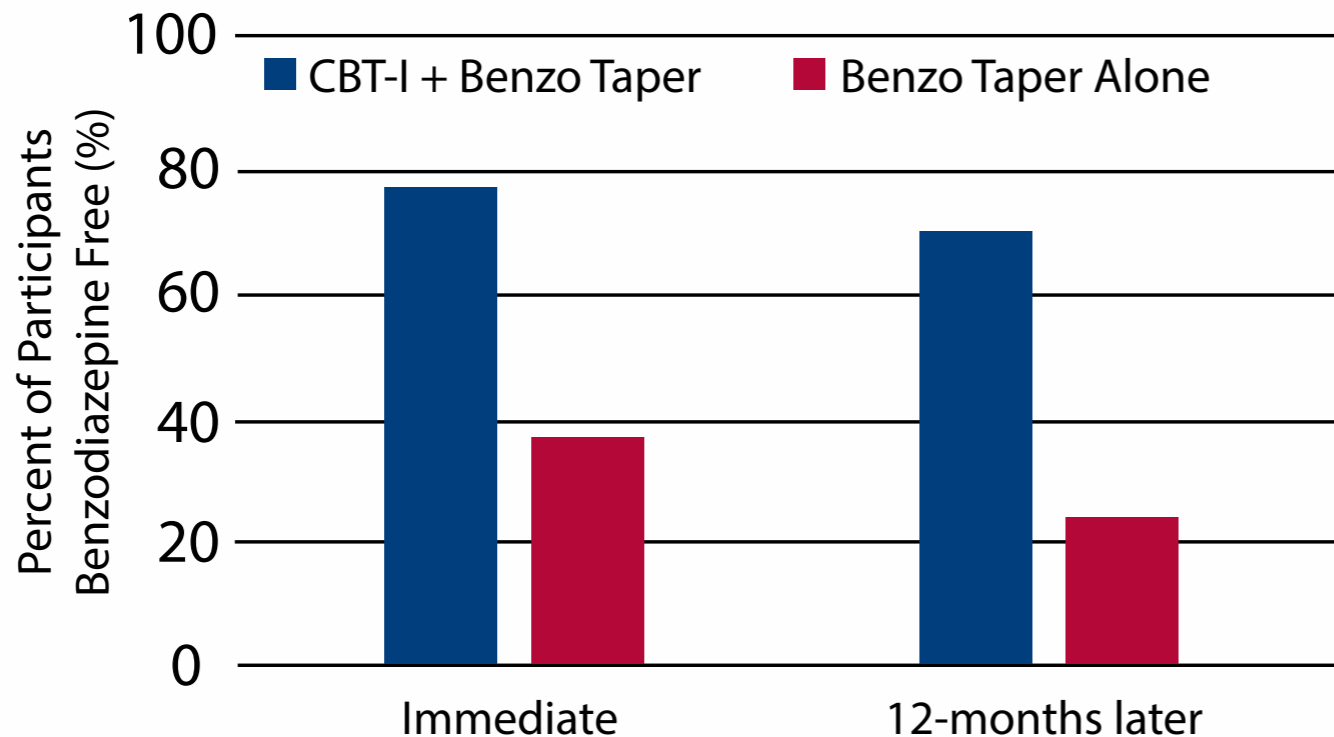
- Pharmacotherapy should be discussed with patients using a shared decision-making approach, considering:
 - * Treatment goals and expectations; safety concerns; potential side effects and drug interactions; other treatment modalities (cognitive and behavioral treatments); potential for dosage escalation; and rebound insomnia.
- Regular follow-up of patients during the initial period, to evaluate the effectiveness, possible side effects, and need for ongoing medication.
- Try to use the lowest effective dosage of medication and taper medication when conditions allow.
 - * CBT-I can help facilitate tapering/discontinuation of medicines.
- Patients with severe, refractory, and/or chronic insomnia should receive an adequate trial of CBT-I, consistent follow-up, ongoing assessment of effectiveness, monitoring for adverse effects, and evaluation for previously unidentified causes of insomnia, new onset, or exacerbation of existing comorbid disorders.

Managing insomnia disorder

Risk Reduction Strategy: Tapering and Discontinuing Pharmacotherapy^[1, 61, 62]

- Discontinuing treatment, even if only temporarily, is useful as a strategy to:
 - * Reduce long-term risk of tolerance and adverse effects
 - * Determine if treatment was helpful and whether medication is still needed.
- Tapers can take the form of a dose reduction or a decrease in the number of doses per week.

Figure 9. CBT-I and Successful Benzodiazepine Discontinuation^[63]



According to one randomized controlled trial in patients with chronic insomnia, use of CBT-I was strongly associated with being benzodiazepine-free both immediately after treatment as well as at a 12-month follow-up visit.

CBT-I was provided in eight weekly small group sessions. Benzodiazepine tapering was supervised by a physician who met weekly with each participant over the eight-week period.

Results immediately after treatment: 77% (n=34) vs. 38% (n=29), 95% CI 2.4 – 30.9; at 12-month follow-up: 70% (n=33) vs. 24% (n=29), 95% CI 2.5 – 26.6.

Long-term treatment with medication is not the optimal treatment strategy for patients with insomnia.

Consider medication risk reduction strategies and/or tapering whenever possible.

Managing insomnia disorder

Follow-Up

Consider referral to a sleep disorder specialist

If patients don't respond to initial treatment, consider referral to a sleep disorder specialist: ^[2]

- To investigate/evaluate:
 - * Clinical suspicion of breathing (sleep apnea) or movement disorders, when initial diagnosis is uncertain
 - * Failure of treatment (behavioral or pharmacologic), or
 - * Precipitous arousals occurring with violent or injurious behavior
- Consideration of other treatment options or combinations





Managing insomnia disorder

This summary was written by:

Daina L. Wells, Pharm.D., BCPS, BCPP

Sarah Popish, Pharm.D., BCPP

Julianne Himstreet, Pharm.D., BCPS

Special thanks to our expert reviewers:

Allen Blaivas, MD

Adam Bramoweth, Ph.D.

Janet Dailey, Pharm.D.

Karen Drexler, MD

Philip Gehrman, Ph.D., CBSM

Jennifer Martin, Ph.D.

Macgregor Montano, Pharm.D.

Wilfred Pigeon, MD

Ilene Robeck, MD

Richard Ross, MD, Ph.D.

Michael Saenger, MD, FACP, ADAAPM

Todd Semla, MS, Pharm.D., BCGP, FCCP, AGSF

Ilse Wiechers, MD, MPP, MHS



Managing insomnia disorder

References

1. Schutte-Rodin, S., et al., *Clinical guideline for the evaluation and management of chronic insomnia in adults*. J Clin Sleep Med, 2008. 4(5): p. 487-504.
2. Sateia, M.J., et al., *Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline*. J Clin Sleep Med, 2017. 13(2): p. 307-349.
3. Miller, M.B., et al., *Insomnia severity as a mediator of the association between mental health symptoms and alcohol use in young adult veterans*. Drug Alcohol Depend, 2017. 177: p. 221-227.
4. Baglioni, C., et al., *Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies*. J Affect Disord, 2011. 135(1-3): p. 10-9.
5. Baron, K.G., et al., *Sleep Variability Among Older Adults With Insomnia: Associations With Sleep Quality and Cardiometabolic Disease Risk*. Behav Sleep Med, 2017. 15(2): p. 144-157.
6. Budhiraja, R., et al., *Prevalence and polysomnographic correlates of insomnia comorbid with medical disorders*. Sleep, 2011. 34(7): p. 859-67.
7. Sofi, F., et al., *Insomnia and risk of cardiovascular disease: a meta-analysis*. Eur J Prev Cardiol, 2014. 21(1): p. 57-64.
8. Woznica, A.A., et al., *The insomnia and suicide link: toward an enhanced understanding of this relationship*. Sleep Med Rev, 2015. 22: p. 37-46.
9. Leggett, A.N., A.J. Sonnega, and M.C. Lohman, *The association of insomnia and depressive symptoms with all-cause mortality among middle-aged and old adults*. Int J Geriatr Psychiatry, 2018.
10. Chakravorty, S., et al., *Sleep Management Among Patients with Substance Use Disorders*. Med Clin North Am, 2018. 102(4): p. 733-743.
11. Association, A.P., *Diagnostic and Statistical Manual for Mental Disorders*. 5th Edition ed. 2013, Arlington, VA: American Psychiatric Association.
12. Morin, C.M., et al., *The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response*. Sleep, 2011. 34(5): p. 601-8.
13. Morin, C.M. *Insomnia Severity Index*. Available from: <http://mapi-trust.org/questionnaires/isi/#conditions>



Managing insomnia disorder

References

14. Qaseem, A., et al., *Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians*. *Ann Intern Med*, 2016. 165(2): p. 125-33.
15. Brown, C.A., R. Berry, and A. Schmidt, *Sleep and military members: emerging issues and nonpharmacological intervention*. *Sleep Disord*, 2013. 2013: p. 160374.
16. Mustafa, M., et al., *Sleep problems and the risk for sleep disorders in an outpatient veteran population*. *Sleep Breath*, 2005. 9(2): p. 57-63.
17. Maness, D.L. and M. Khan, *Nonpharmacologic Management of Chronic Insomnia*. *Am Fam Physician*, 2015. 92(12): p. 1058-64.
18. Ulmer, C.S., et al., *Veterans Affairs Primary Care Provider Perceptions of Insomnia Treatment*. *J Clin Sleep Med*, 2017. 13(8): p. 991-999.
19. Bramoweth, A.D. and A. Germain, *Deployment-related insomnia in military personnel and veterans*. *Curr Psychiatry Rep*, 2013. 15(10): p. 401.
20. Trauer, J.M., et al., *Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis*. *Ann Intern Med*, 2015. 163(3): p. 191-204.
21. Akerstedt, T. and K.P. Wright, Jr., *Sleep Loss and Fatigue in Shift Work and Shift Work Disorder*. *Sleep Med Clin*, 2009. 4(2): p. 257-271.
22. Siomos, K.E., et al., *Insomnia symptoms among Greek adolescent students with excessive computer use*. *Hippokratia*, 2010. 14(3): p. 203-7.
23. *About Cognitive Behavioral Therapy for Insomnia*. Available from:
https://vaww.portal.va.gov/sites/OMHS/cbt_insomnia/Lists/CBTAbout/AllItems.aspx.
24. *AHRQ. SHARE Approach Workshop - Module 1: Shared Decision Making*. AHRQ Pub. No.14-0056-1-EF 2014; Available from:
<https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/education/curriculum-tools/shareddecisionmaking/workshop/module1/shareworkshop-mod1guide.pdf>.
25. Hilty, D., et al., *Algorithms for the assessment and management of insomnia in primary care*. *Patient Prefer Adherence*, 2009. 3: p. 9-20.



Managing insomnia disorder

References

26. Bonnett MH, A.D., *Behavioral and pharmacologic therapies for chronic insomnia in adults*, B. R, Editor. 2018, UpToDate.com: <https://www.uptodate.com/contents/behavioral-and-pharmacologic-therapies-for-chronic-insomnia-in-adults#H3553718232>.
27. Bonnett MH, A.D., *Treatment of Insomnia in Adults*. 2017, UpToDate, Inc. : UpToDate.com.
28. Taylor D, P.C., Kapur S, *The Maudsley Prescribing Guidelines in Psychiatry* 12th Edition. 2015, West Suseex: Wiley Blackwell.
29. Guina J, e.a., *Benzodiazepines for PTSD: A Systematic Review and Meta-Analysis*. J Psychiatr Pract, 2015. 21(4): p. 281-303.
30. *Management of Post-Traumatic Stress.*, D.O.o.Q.a.P.a. Washington, V.H. the Veterans Affairs and Department of Defense Development Work Group, and D.o.V.A. Administration, Editors. 2010.
31. Defense, D.o.V.A.a.D.o., *VA/DOD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF POSTTRAUMATIC STRESS DISORDER AND ACUTE STRESS DISORDER*. 2017.
32. Glass, J.e.a., *Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits*. BMJ, 2005. 331(7526): p. 1169.
33. Billioti de Gage, S.e.a., *Benzodiazepine use and risk of dementia: prospective population based*. BMJ, 2012. 345: p. e6231.
34. Wang, P.e.a., *Hazardous benzodiazepine regimens in the elderly: effects of half-life, dosage, and duration on risk of hip fracture*. Am J Psychiatry, 2001. 158(6): p. 892-8.
35. Tamblyn, R., et al, *A 5-year prospective assessment of the risk associated with individual benzodiazepines and doses in new elderly users*. J Am Geriatr Soc,, 2005. 53(2): p. 233-41.
36. Paterniti S, D.C., and Alperovitch A, *Long-term benzodiazepine use and cognitive decline in the elderly: the Epidemiology of Vascular Aging Study*. J Clin Psychopharmacol, 2002. 22(3): p. 285-93.
37. Cook JM, e.a., *Physicians' perspectives on prescribing benzodiazepines for older adults: a qualitative study*. J Gen Intern Med,, 2007. 22(3): p. 303-307.



Managing insomnia disorder

References

38. Glass, J., et al., *Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits*. *Bmj*, 2005. 331(7526): p. 1169.
39. Everitt, H., et al., *Antidepressants for insomnia in adults*. *Cochrane Database Syst Rev*, 2018. 5: p. Cd010753.
40. Lankford A, e.a., *Efficacy and safety of doxepin 6 mg in a four-week outpatient trial of elderly adults with chronic primary insomnia*. *Sleep Med* 2012. 13: p. 133-138.
41. *Silenor [package insert]*, I. Somaxon Pharmaceuticals, Editor. 2010: San Deigo, CA:.
42. SM, S., *Stahl's Essential Psychopharmacology, Neuroscientific Basis and Practical Applications*. Vol. 3rd ed. . 2008, New York, NY: Cambridge University Press.
43. Singh H, B.P., *Novel therapeutic usage of low-dose doxepin hydrochloride*. *Expert Opin Investig Drugs*, 2007. 16(8): p. 1295-1305.
44. Roth T, e.a., *Efficacy and safety of doxepin 1 mg, 3 mg, and 6 mg in adults with primary insomnia*. *Sleep*, 2007. 30(11): p. 1555-61.
45. Krystal AD, e.a., *Efficacy and safety of doxepin 1 mg and 3 mg in a 12-week sleep laborator and outpatient trial of elderly subjects with chronic primary insomnia*. *Sleep*, 2010. 33(11): p. 1553-1561.
46. *DrugPoint Summary*. Thomson Micromedex.
47. Camargos, E.F., et al., *Trazodone improves sleep parameters in Alzheimer disease patients: a randomized, double-blind, and placebo-controlled study*. *Am J Geriatr Psychiatry*, 2014. 22(12): p. 1565-74.
48. Bronskill Susan E, e.a., *Low-Dose Trazodone, Benzodiazepines, and Fall-Related Injuries in Nursing Homes: A Matched-Cohort Study*. *Am Geriatr Soc*, 2018. 66: p. 1963-1971.
49. Tariq SH, P.S., *Pharmacotherapy for insomnia*. *Clin Geriatr Med*, 2008: p. 93-105.
50. Winokur A, e.a., *Comparative effects of mirtazapine and fluoxetine on sleep physiology measures in patients with major depression and insomnia*. *J Clin Psychiatry*, 2003. 64: p. 1224-9.



Managing insomnia disorder

References

51. Mason, B.J., et al., *Gabapentin treatment for alcohol dependence: a randomized clinical trial*. JAMA Intern Med, 2014. 174(1): p. 70-7.
52. Panel, T.A.G.S.B.C.U.E., *American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. JAGS, 2012.
53. Kolla BP, M.M., Schneekloth T, *Pharmacological treatment of insomnia in alcohol recovery: a systematic review*. Alcohol and Alcoholism, 2011. 46(5): p. 578-85.
54. Karam-Hage M, B.K., *Open pilot study of gabapentin versus trazodone to treat insomnia in alcoholic outpatients*. Psychiatry and Clinical Neurosciences, 2003. 57: p. 542-44.
55. Karam-Hage M, B., KJ, *Gabapentin treatment for insomnia associated with alcohol dependence*. Am J Psychiatry, 2000. 157: p. 151.
56. Lexicomp, *Gabapentin: Drug Information (Lexicomp)*. 2018: UpToDate.
57. Wilson SJ, e.a., *British association for psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders*. J Psychopharmacol, 2010. 24(11): p. 1577-1600.
58. Wade, A.G., et al., *Efficacy of prolonged release melatonin in insomnia patients aged 55-80 years: quality of sleep and next-day alertness outcomes*. Curr Med Res Opin, 2007. 23(10): p. 2597-605.
59. Reeves, R.L., *Comparison of triazolam, flurazepam, and placebo as hypnotics in geriatric patients with insomnia*. J Clin Pharmacol, 1977. 17(5-6): p. 319-23.
60. Beaulieu-Bonneau, S., et al., *Long-Term Maintenance of Therapeutic Gains Associated With Cognitive-Behavioral Therapy for Insomnia Delivered Alone or Combined With Zolpidem*. Sleep, 2017. 40(3).



Managing insomnia disorder

References

61. Dorsey, C.M., K.A. Lee, and M.B. Scharf, *Effect of zolpidem on sleep in women with perimenopausal and postmenopausal insomnia: a 4-week, randomized, multicenter, double-blind, placebo-controlled study*. Clin Ther, 2004. 26(10): p. 1578-86.
62. Morin, C.M., et al., *Randomized clinical trial of supervised tapering and cognitive behavior therapy to facilitate benzodiazepine discontinuation in older adults with chronic insomnia*. Am J Psychiatry, 2004. 161(2): p. 332-42.
63. Baillargeon, L., et al., *Discontinuation of benzodiazepines among older insomniac adults treated with cognitive-behavioural therapy combined with gradual tapering: a randomized trial*. Cmaj, 2003. 169(10): p. 1015-20.