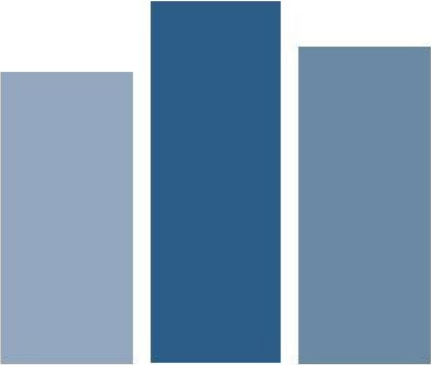


MICIS



Maine Independent Clinical Information Service



Beyond Counting Sheep: Evidence-Based Treatment of Insomnia



Disclosures

- MICIS does not accept any money from pharmaceutical companies nor other ineligible companies.
- None of the individuals in control of content for this activity have relevant financial relationships to disclose.
- Speaker has no conflicts of interest.

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This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the Hanley Center for Health Leadership and Education and the Maine Independent Clinical Information Service (MICIS). The Hanley Center for Health Leadership and Education is accredited by the Maine Medical Association Committee on Continuing Medical Education and Accreditation to provide continuing medical education for physicians.

Learning Objectives

After completing this activity, learners will be able to:

- Develop a framework for diagnosing and differentiating chronic insomnia
- Describe and recommend CBT-I as first line insomnia treatment
- Select insomnia medications when indicated based on pharmacological properties and safety profiles

Outline

Diagnosing and
differentiating
insomnia

First line
management:
CBT-I

Medication
management

Diagnosing and Differentiating Insomnia

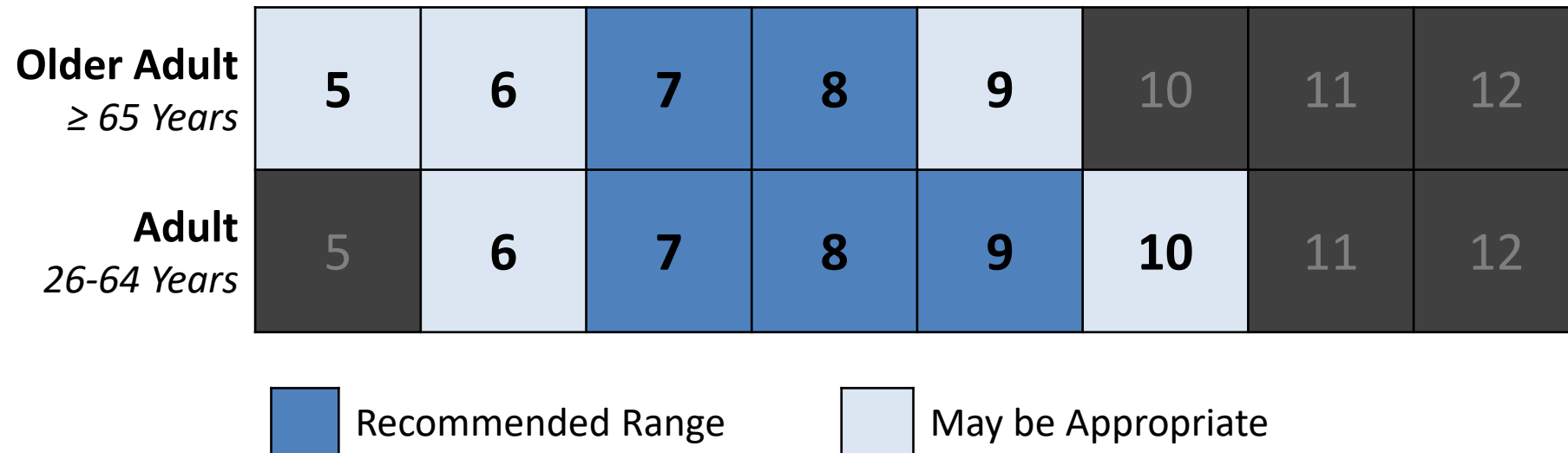
Insomnia - Definition

- Persistent difficulty with sleep
 - *initiation, or*
 - *duration, or*
 - *consolidation, or*
 - *quality*
- despite adequate sleep opportunity and circumstances
- resulting in related *daytime consequence or concern*

Insomnia is common

- Most prevalent sleep disorder in adults
 - Prevalence increases with age
- 5 million office visits per year in the US
- 10-20% of all adults meet the criteria for chronic insomnia
- Up to 50% of adults over 65 years of age report insomnia

Recommended Sleep Duration by Age



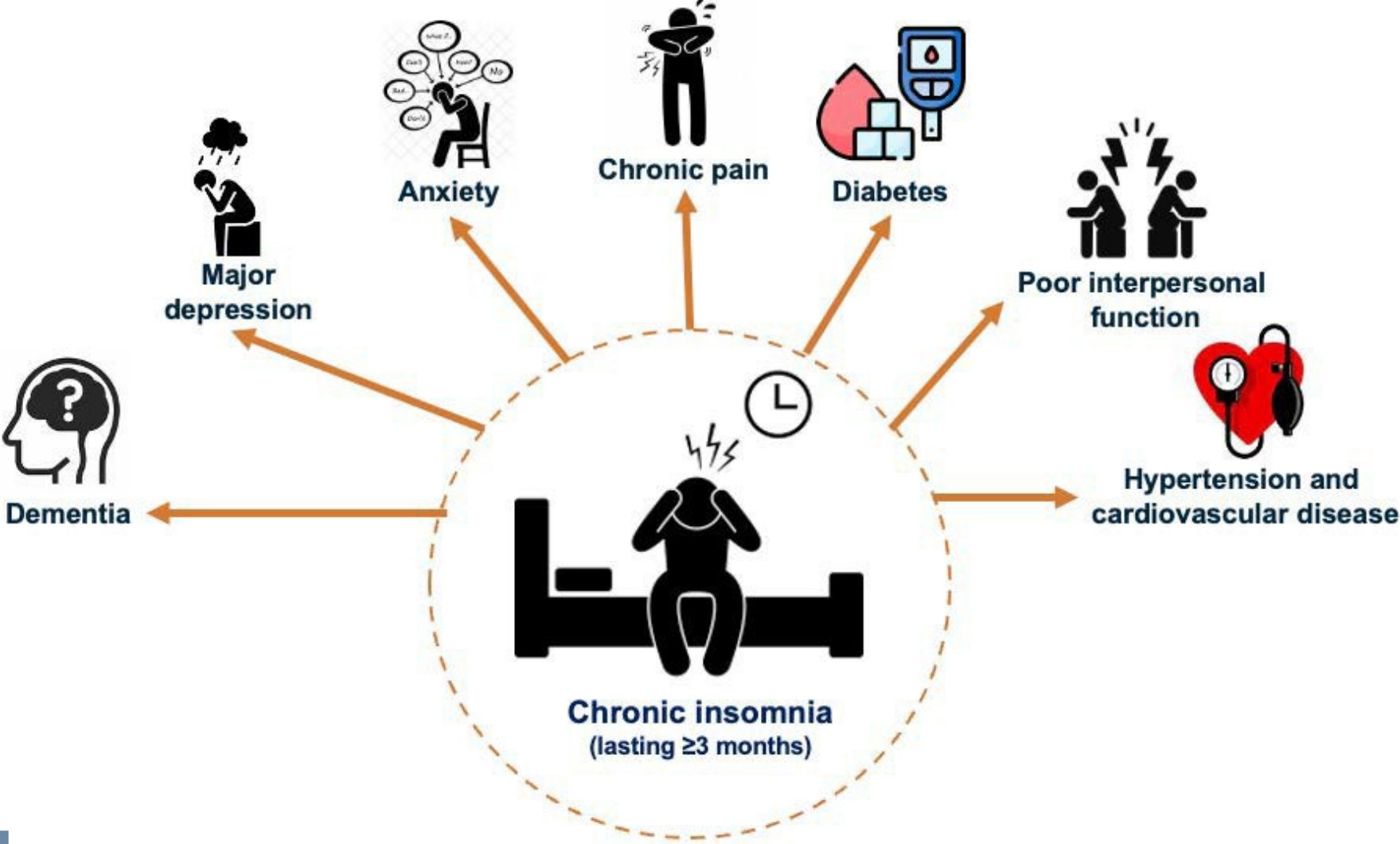
*Older adults require **fewer hours of sleep** on average than younger adults*

Key Takeaway:

Older adults fall asleep faster, but sleep less & have frequent awakenings

Measurement	Normal range	Change with increasing age
Sleep latency	<20 minutes	Unchanged or reduced
Total sleep time	7-9 hours	Reduced
Sleep efficiency	>85%	Reduced
Wake after sleep onset	<15% of time in bed	Increased

Chronic Insomnia Has Many Health Consequences



CASE STUDY: Nancy

Chief complaint: not sleeping

- 69 yo female
- PMHx: HTN, lipids, DJD-knee
- OTC product no longer helping
- “What do you think about marijuana gummies for sleep, doc?”



Freepik.com

Social History:

- Married, lives with husband
- Retired 5 yr ago
- Never smoker
- ETOH about 3x/month

Meds:

- Bisoprolol/HCT
- Atorvastatin
- Naproxen BID prn
- OTC doxylamine ½ tab (12.5mg) nightly

Initial Sleep Assessment Queries

Domain	Example
Nature of sleep problem	trouble with sleep onset, sleep maintenance, or both
Frequency of sleep problem	nightly vs. sporadic
Chronicity of sleep problem	days, weeks, months, years
Patient's sleep schedule and habits	sleep opportunity, sleep hygiene

Making the Diagnosis

Presence of *all* the following:

- Patient/caregiver reports difficulty related to initiating or maintain sleep as desired
- Reported sleep/wake complaints cannot be explained by a plausible alternative
- Patient/caregiver reports a daytime consequence or concern related to nighttime sleep difficulty

Use Duration of Symptoms to Guide Treatment

ACUTE INSOMNIA	CHRONIC INSOMNIA
<p>Sleep problems occur for <3 months with an identifiable trigger (e.g., death of spouse, life transition)</p>	<p>Sleep problems occur for ≥3 days per week for ≥3 months (the focus of this talk)</p>


Insomnia Assessment Tools


- Sleep diary
- Questionnaires
- Actigraphy and/or wearable technology
- Polysomnography (PSG) or home sleep testing (HST)


Sleep Diary

The evaluation of insomnia should be supported with a sleep diary for 7-14 days

 Time to bed

 Time tried to sleep

 Number and duration of awakenings

 Time of final awakening

 Time got out of bed

Sleep diary should be completed to the best of the patient's recollection and at the same time every day – **BUT** not in the middle of the night!

Insomnia severity index (ISI)

- Validated screening tool for use in primary care
- Detects and quantifies patient's perception of insomnia severity and assesses impact on daytime functioning
- Can also help monitor treatment response
- Correlates with sleep diaries, PSG, and patient self-report
 - Sensitivity = 86%
 - Specificity = 88%

Insomnia Severity Index

<p>Rate severity:</p> <ul style="list-style-type: none"> • difficulty falling asleep • difficulty staying asleep • problem waking up to too early 	<table> <tr> <td><input type="checkbox"/> No problem</td> <td><input type="checkbox"/> Severe</td> </tr> <tr> <td><input type="checkbox"/> Mild</td> <td><input type="checkbox"/> Very severe</td> </tr> <tr> <td><input type="checkbox"/> Moderate</td> <td></td> </tr> </table>	<input type="checkbox"/> No problem	<input type="checkbox"/> Severe	<input type="checkbox"/> Mild	<input type="checkbox"/> Very severe	<input type="checkbox"/> Moderate	
<input type="checkbox"/> No problem	<input type="checkbox"/> Severe						
<input type="checkbox"/> Mild	<input type="checkbox"/> Very severe						
<input type="checkbox"/> Moderate							
<p>Satisfaction with current sleep</p>	<table> <tr> <td><input type="checkbox"/> Very satisfied</td> <td><input type="checkbox"/> Dissatisfied</td> </tr> <tr> <td><input type="checkbox"/> Satisfied</td> <td><input type="checkbox"/> Very dissatisfied</td> </tr> <tr> <td><input type="checkbox"/> Neutral</td> <td></td> </tr> </table>	<input type="checkbox"/> Very satisfied	<input type="checkbox"/> Dissatisfied	<input type="checkbox"/> Satisfied	<input type="checkbox"/> Very dissatisfied	<input type="checkbox"/> Neutral	
<input type="checkbox"/> Very satisfied	<input type="checkbox"/> Dissatisfied						
<input type="checkbox"/> Satisfied	<input type="checkbox"/> Very dissatisfied						
<input type="checkbox"/> Neutral							
<p>Regarding your sleep problem:</p> <ul style="list-style-type: none"> • interferes with daily functioning • noticeable to others • your level of worry/distress 	<table> <tr> <td><input type="checkbox"/> Not at all</td> <td><input type="checkbox"/> Much</td> </tr> <tr> <td><input type="checkbox"/> A little</td> <td><input type="checkbox"/> Very much</td> </tr> <tr> <td><input type="checkbox"/> Somewhat</td> <td></td> </tr> </table>	<input type="checkbox"/> Not at all	<input type="checkbox"/> Much	<input type="checkbox"/> A little	<input type="checkbox"/> Very much	<input type="checkbox"/> Somewhat	
<input type="checkbox"/> Not at all	<input type="checkbox"/> Much						
<input type="checkbox"/> A little	<input type="checkbox"/> Very much						
<input type="checkbox"/> Somewhat							

Wearable Technology

- “Wearable sleep trackers” are devices available over-the-counter.
- Most measure motion and bio-signals (e.g., heart rate variability, oxygen saturation, temperature) which allows for extrapolation of sleep data
- Provide abundant data in the home environment, including multiple nights (obviating the “first night” effect seen on many sleep studies)

Actigraphy measures much of the same information but requires a clinician, usually a sleep medicine specialist, to order and interpret.

Comparison of Polysomnography & Wearable Technology

Variable	Apple Watch	Garmin	Polar	Oura (Gen.2)	WHOOP (3.0)	Somfit
<i>Two-state Analysis</i>						
Sensitivity for sleep (%)	97	98	92	94	90	92
Sensitivity for wake (%)	26	27	51	57	56	57

Most common wearable devices have high sensitivity (>90%) for detecting sleep but low sensitivity for detecting wakefulness.

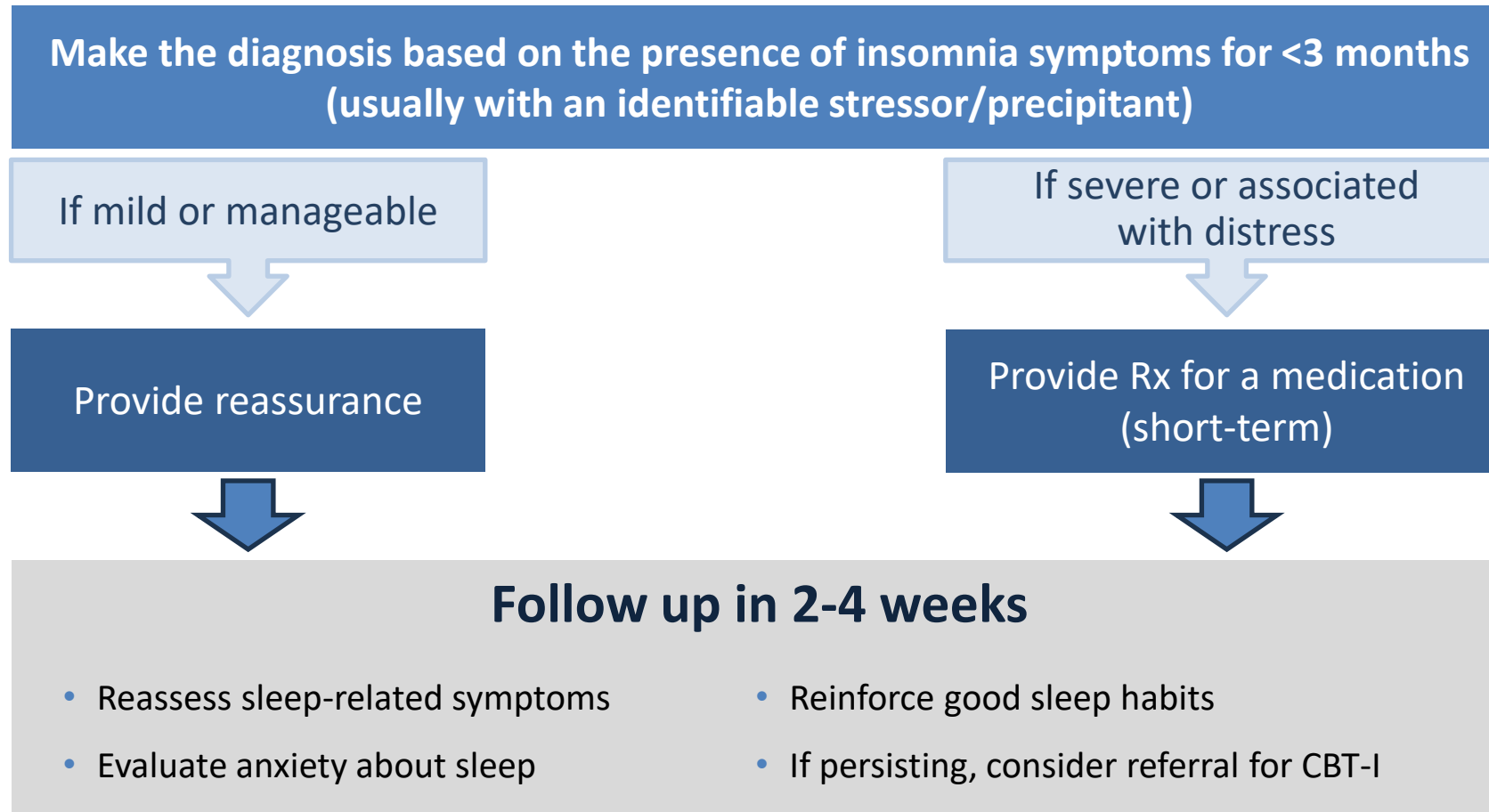
Objective Sleep Studies

- Indicated when an alternative sleep diagnosis is suspected
 - ? sleep-disordered breathing
 - ? movement disorder of sleep
- Polysomnography (PSG) or home sleep testing (HST)
 - Neither necessary nor sufficient to diagnose insomnia

Addressing Sleep Complaints

- Treat relevant co-occurring conditions that impact sleep
 - e.g. depression, substance use disorder, restless leg syndrome, obstructive sleep apnea
- Adjust medication schedules to facilitate restful sleep
 - e.g. move evening diuretic or stimulant doses to earlier in the day
- Provide education about sleep hygiene and counseling about sleep behaviors and the sleep environment

Primary Care Approach to Short-term (Acute) Insomnia



Primary Care Approach to CHRONIC Insomnia

Obtain relevant medical history, medication list, and sleep history.
Treat comorbid conditions and optimize medications.



Treat with cognitive behavior therapy for insomnia (CBT-I)



Maintain close follow-up

- ? improvements in sleep quality/duration
- ? insomnia related daytime impairment
- ? Consider pharmacotherapy with a deprescribing plan

Treatment

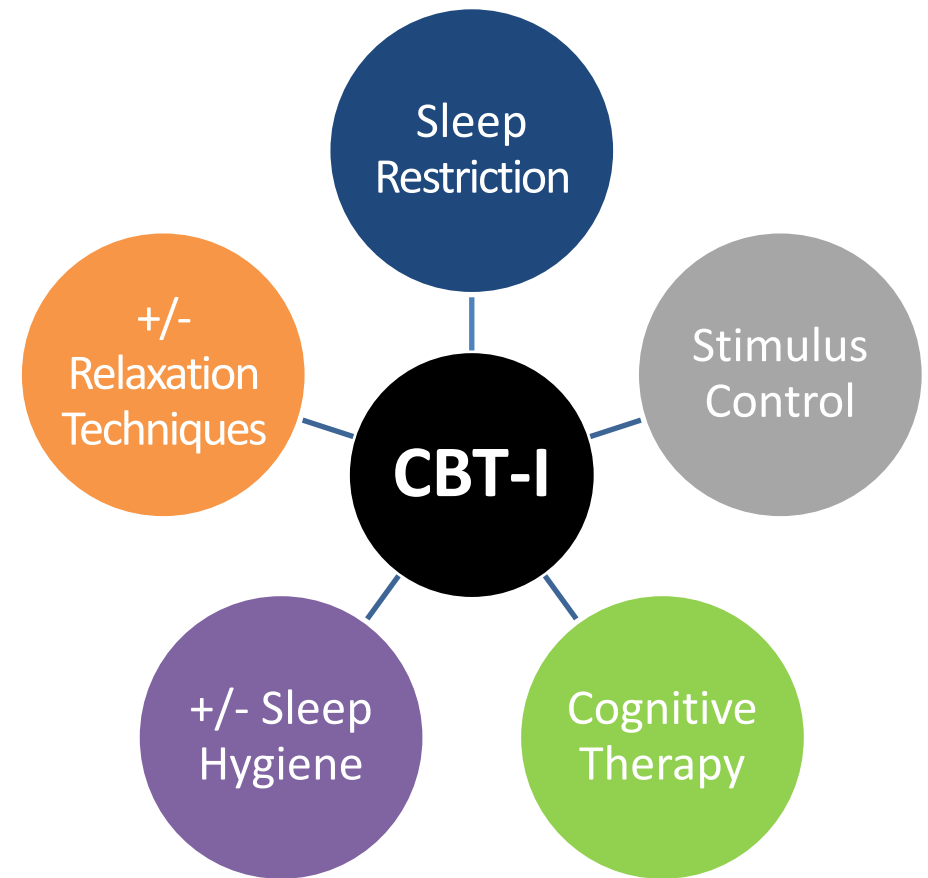
Goal: improve sleep quality/duration and insomnia-related daytime impairment

- Cognitive behavioral therapy for insomnia (CBT-I) - first-line in adults of any age
 - Group settings reduce cost & increase availability
 - Alternatively, recommend digital CBT-I alternative
- Pharmacotherapy: adjunctive, not recommended as first-line

First Line Management: CBT-I

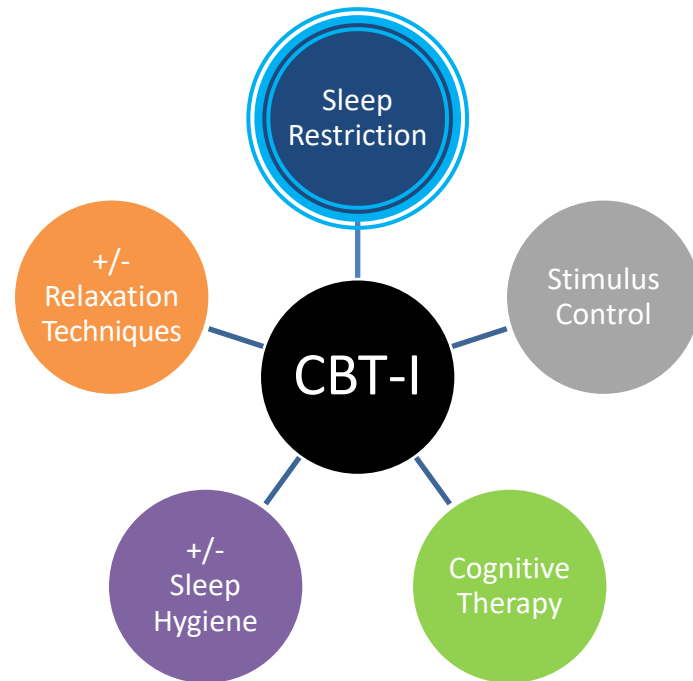
Cognitive Behavioral Therapy for Insomnia (CBT-I)

- Structured, time-limited treatment
- Uses cognitive & behavioral tools coupled with education
- Improves sleep efficiency, duration & quality
- Treats root causes
- Comparable effect to medication in the short-term
- More sustainable effect in the long-term



Sleep Consolidation (aka “Sleep Restriction”)

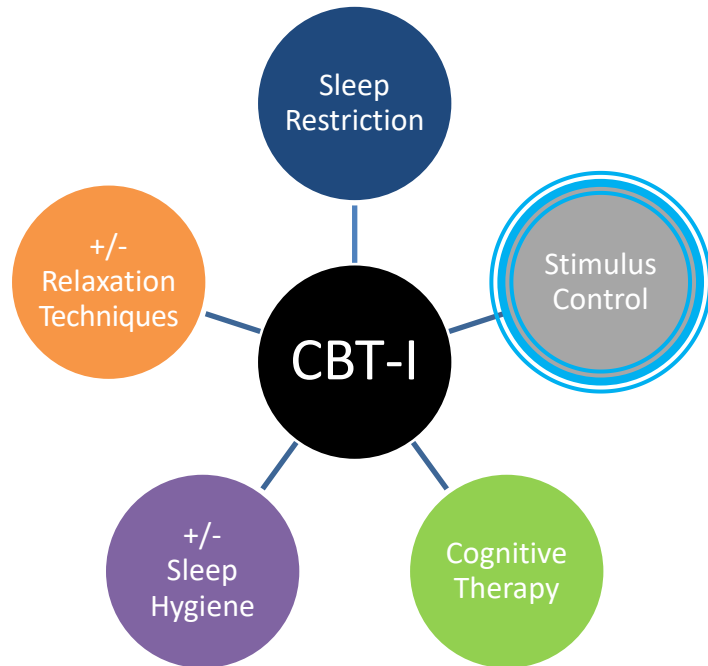
Goal: Improve sleep efficiency by reducing time spent awake in bed (i.e., increase sleep drive)



- Sleep diary for 1-2 weeks
- Limit time in bed to average total sleep time plus 30 minutes (as long as >6 hours of sleep)
- Wake up at the same time every day regardless of bedtime or if sleepy
- Adjust in 15-minute increments until optimized

Stimulus Control

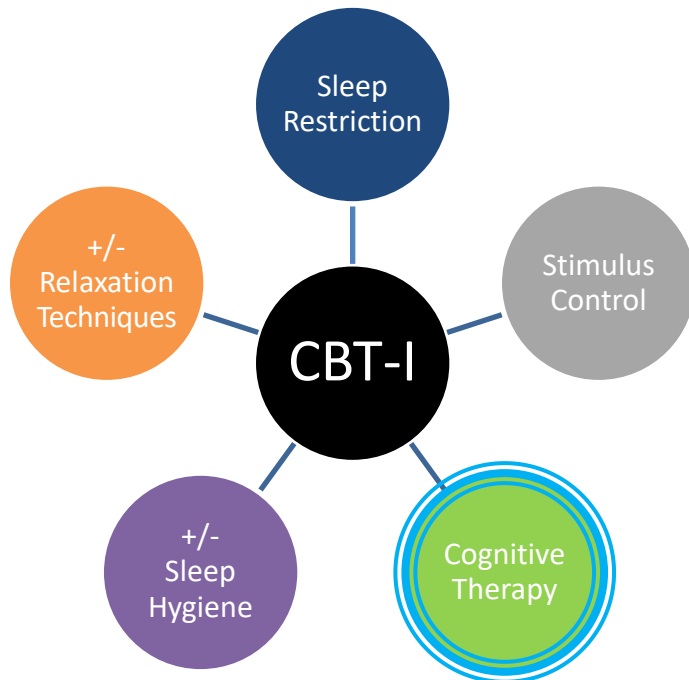
Goal: Promote a consistent sleep-wake schedule & reduce the conditioned response around sleep



- Use the bedroom only for sleep & sex
- Avoid screens before bed
- Don't go to bed until sleepy
- Avoid clock-watching
- Leave the bedroom if awake for more than 20 minutes
 - Return only when sleepy

Cognitive Therapy

Goal: Reframe dysfunctional beliefs & attitudes about sleep to become neutral or positive



- Identify, expose & address dysfunctional beliefs & attitudes about sleep
- Reframe negative beliefs, attitudes & associations

Instead of *“I dread going to bed because I won’t be able to sleep”*



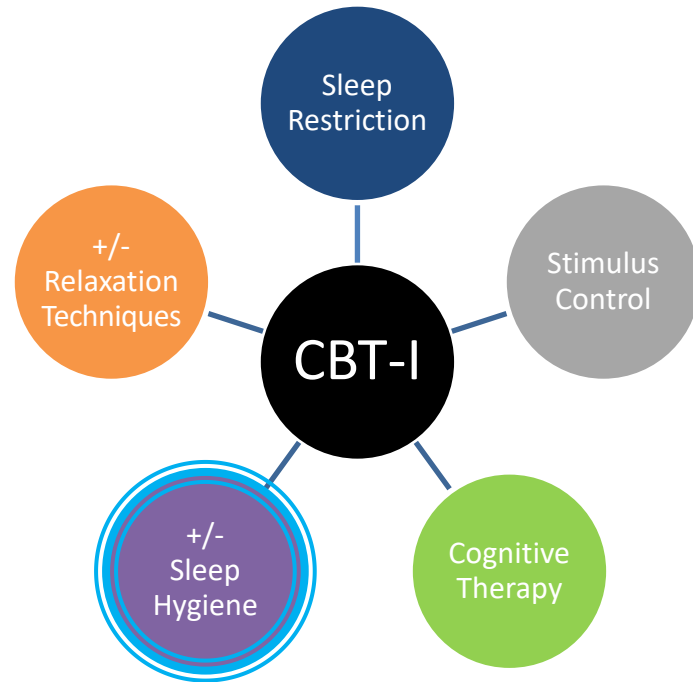
Think *“Even if it takes a little while to fall asleep, I’ll be ok tomorrow”*

Edinger JD et al. *J Clin Sleep Med.* 2021 Feb;17(2):255-262.
Sutton EL. *Ann Intern Med.* 2021 Mar;174(3):ITC33-ITC48.
Ng L and Cunningham D. *Aust Prescr.* 2021 Aug;44(4):124-8.

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Sleep Hygiene *Use as part of comprehensive CBT-I plan*

Goal: Promote healthy sleep behaviors & environment



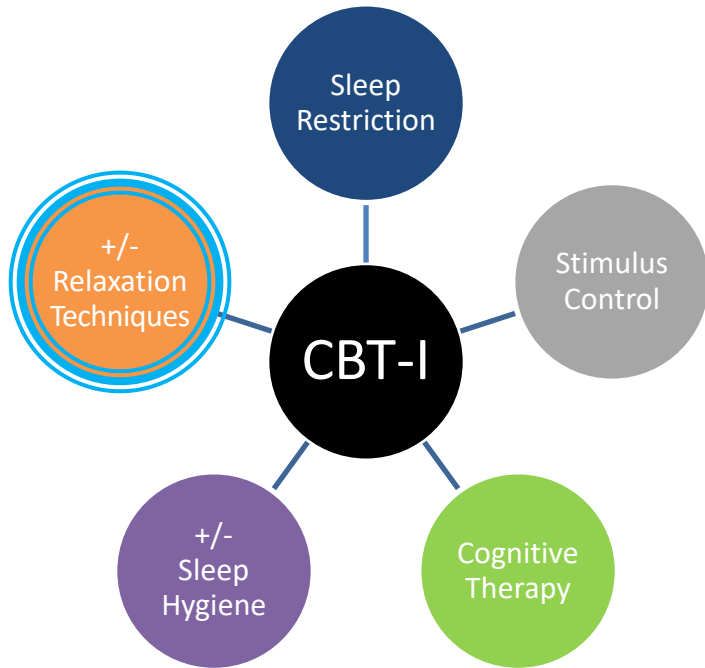
- Keep regular sleep/wake schedule
- Avoid naps
- Exercise regularly during the day
- Avoid caffeine, alcohol & nicotine before bed
- Avoid exposure to bright light & screens 2 hours before bed
- Maintain cool, comfortable & conducive sleep environment
- Use bed for only sleep & sex

Hauri PJ. *Clin Chest Med.* 1998 Mar;19(1):157-68.
Chung KF et al. *Fam Pract.* 2018 Jul;35(4):365-75.
Edinger JD et al. *J Clin Sleep Med.* 2021 Feb;17(2):255-262.
Sutton EL. *Ann Intern Med.* 2021 Mar;174(3):ITC33-ITC48.
Ng L and Cunningham D. *Aust Prescr.* 2021 Aug;44(4):124-8.

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Relaxation Techniques *Optional component of CBT-I*

Goal: Reduce mental activity and muscle tension before bed



- Deep abdominal breathing
- Progressive muscle relaxation
- Guided imagery
- Meditation

Barriers to CBT-I

Knowledge Barriers

- Clinician lack of familiarity
- Patients have familiarity with medications as a treatment

System Barriers

- Shortage of trained CBT-I practitioners
- Cost
- Time

System Barriers to CBT-I

Demand >> Supply

- lack of trained sleep psychologists
- majority located in or near major cities

Cost

- can be expensive
- not always covered by insurance

Time-consuming Intervention

- on average 6-8 sessions
- Varies between 30-90 minutes

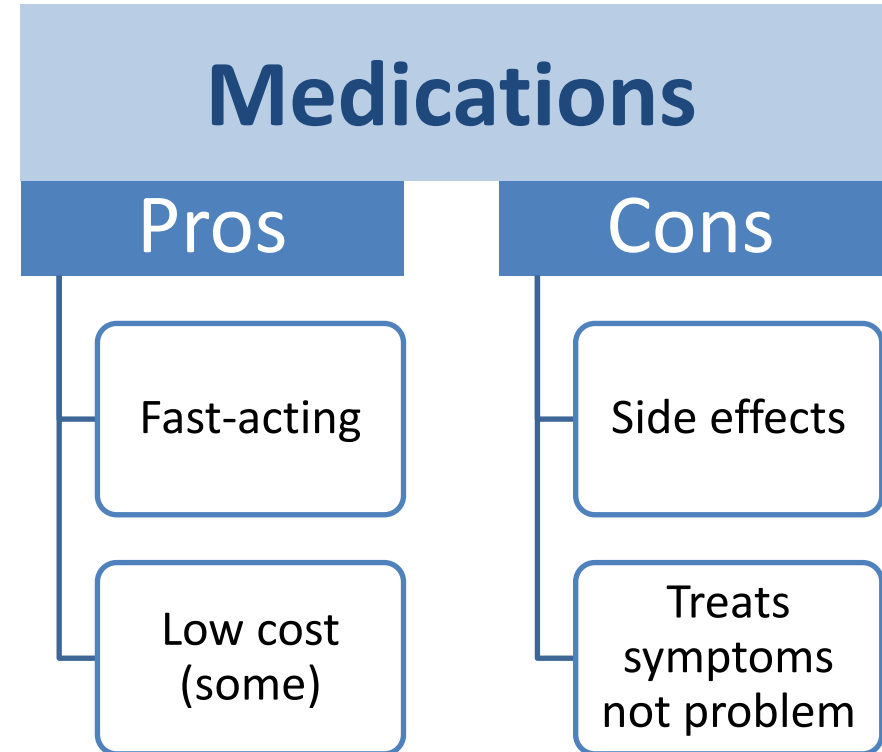
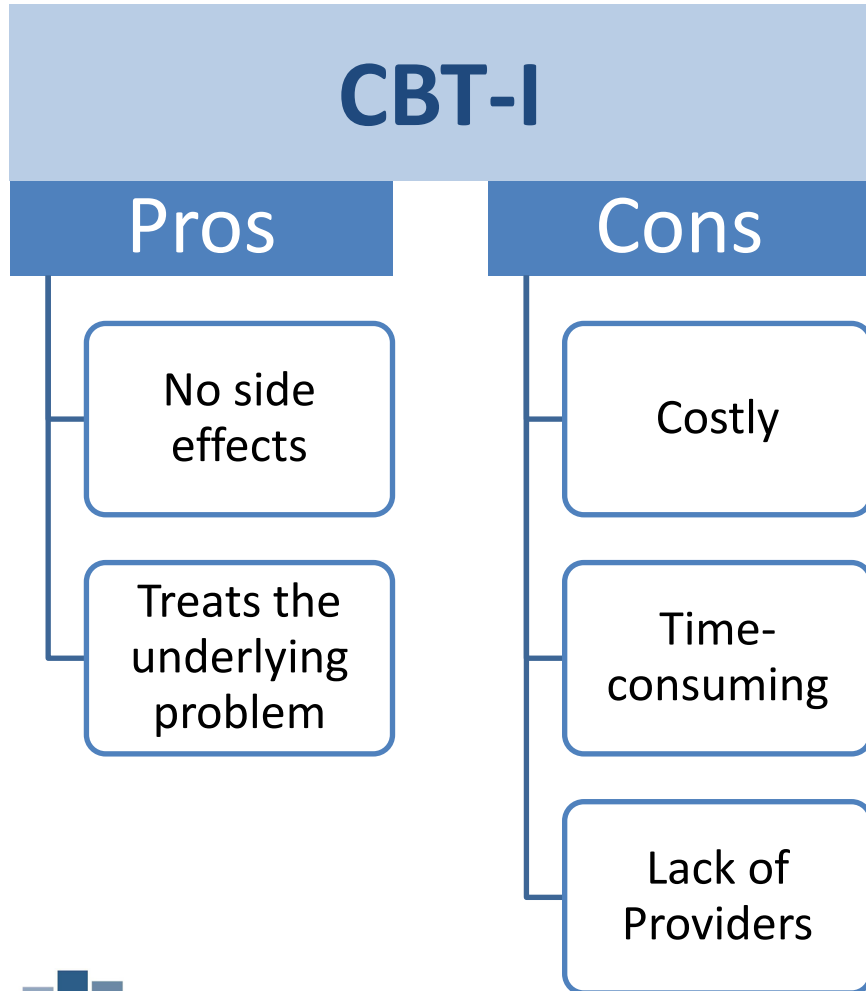
Solutions to System Barriers

- Telehealth delivery is non-inferior to in-person
- Digital CBT-I (dCBT-I) is
 - Effective
 - Interactive
 - App-based
 - Free versions available
 - Alternative delivery - shown to outweigh the benefits of medication therapy alone

Comparison of Digital vs Traditional CBT-I

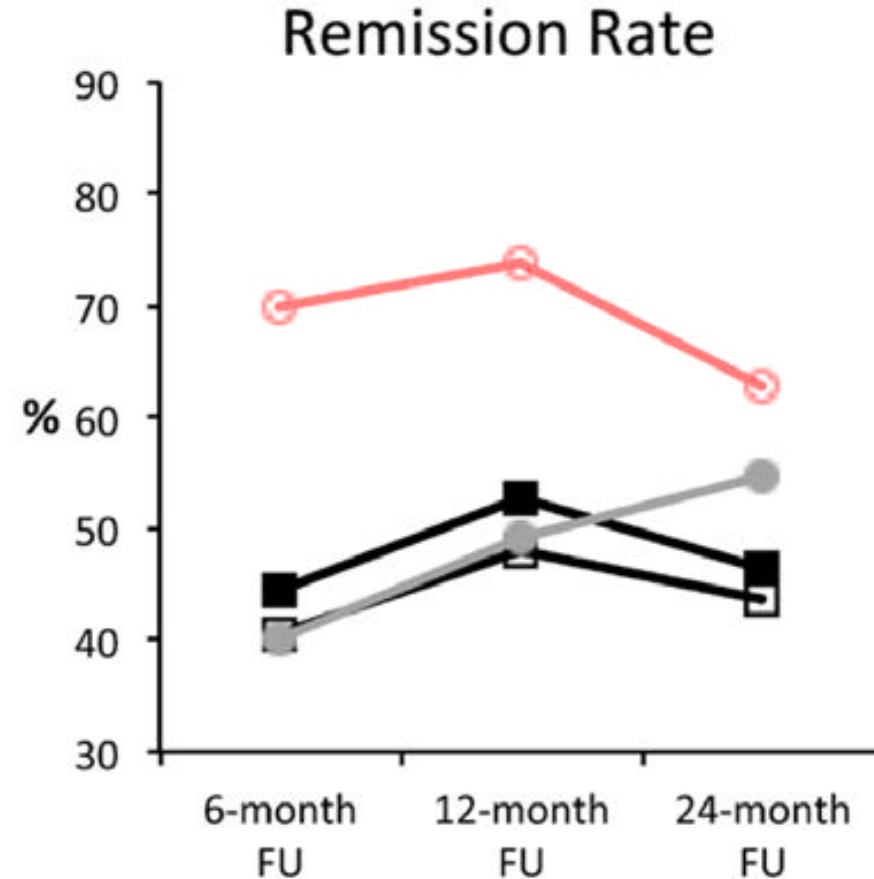
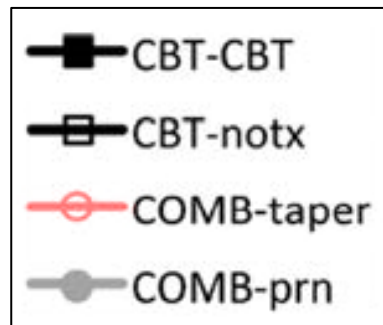
Sleep parameter	dCBT-I effect	CBT-I effect
Sleep onset latency	↓ 11 minutes	↓ 19 minutes
Wake after sleep onset	↓ 20 minutes	↓ 26 minutes
Total sleep time	↑ 20 minutes	↑ 8 minutes
Sleep efficiency	↑ 7%	↑ 10%

Pros and Cons of Treatment Options



CBT-I Can Support Medication Tapering

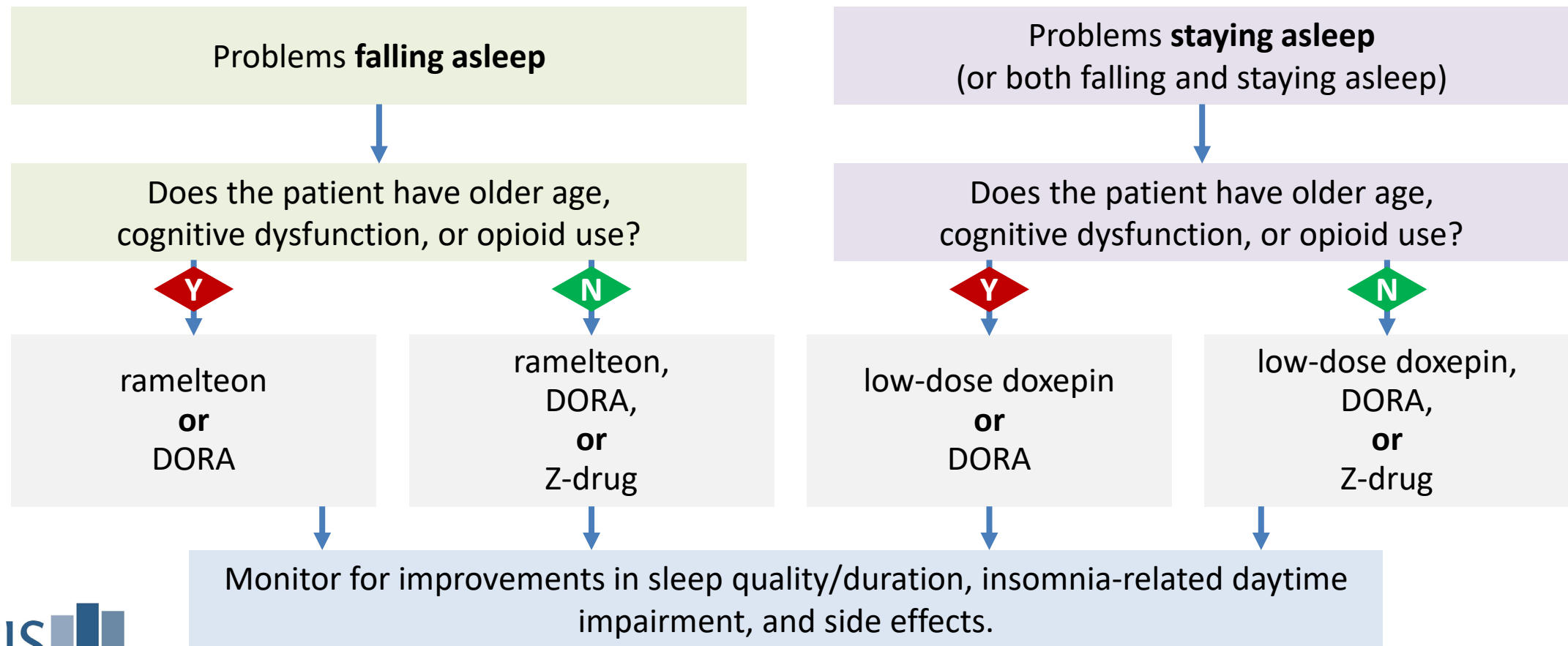
Extending CBT-I while tapering medications produces better sustained improvements compared to an as-needed medication approach.



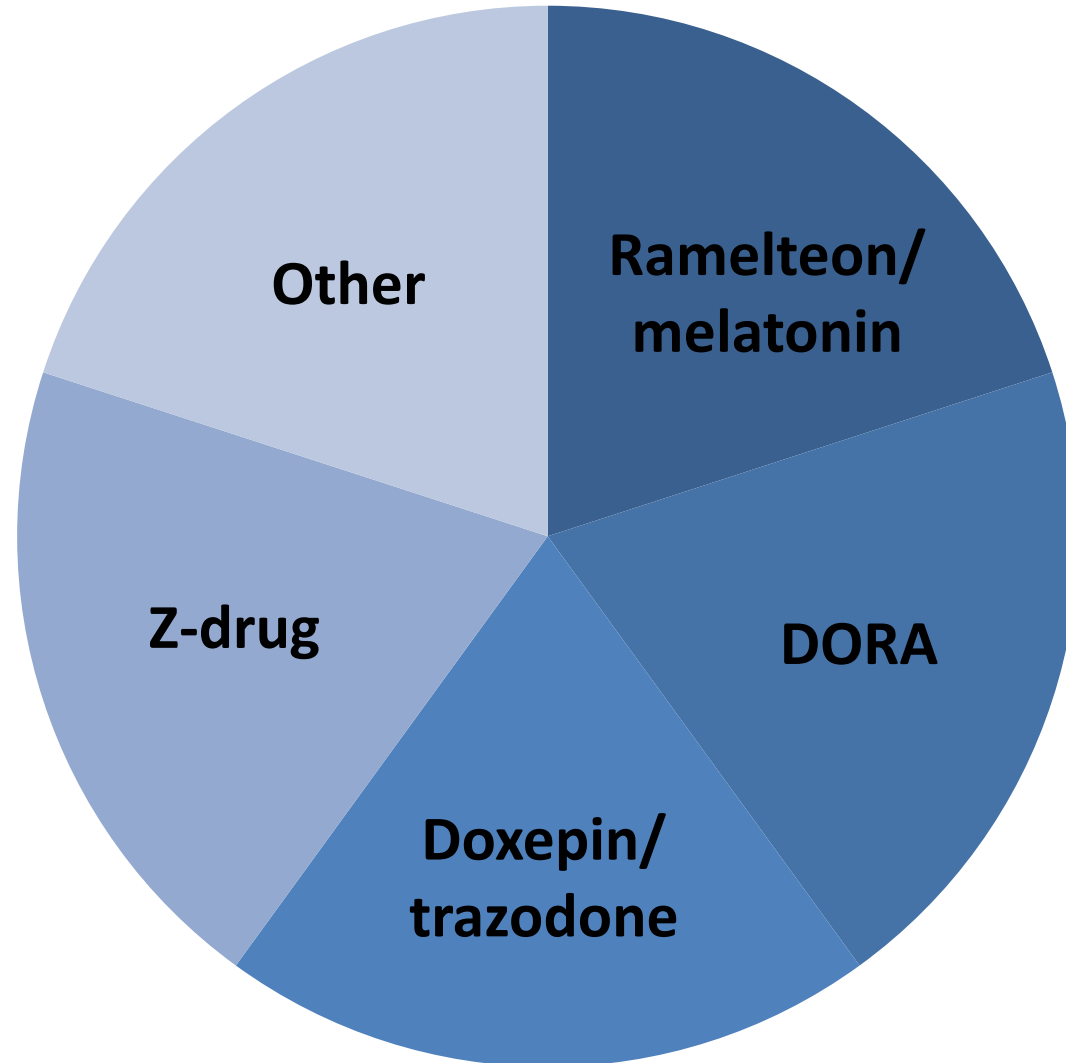
Medication Management

Selecting and Managing Medications

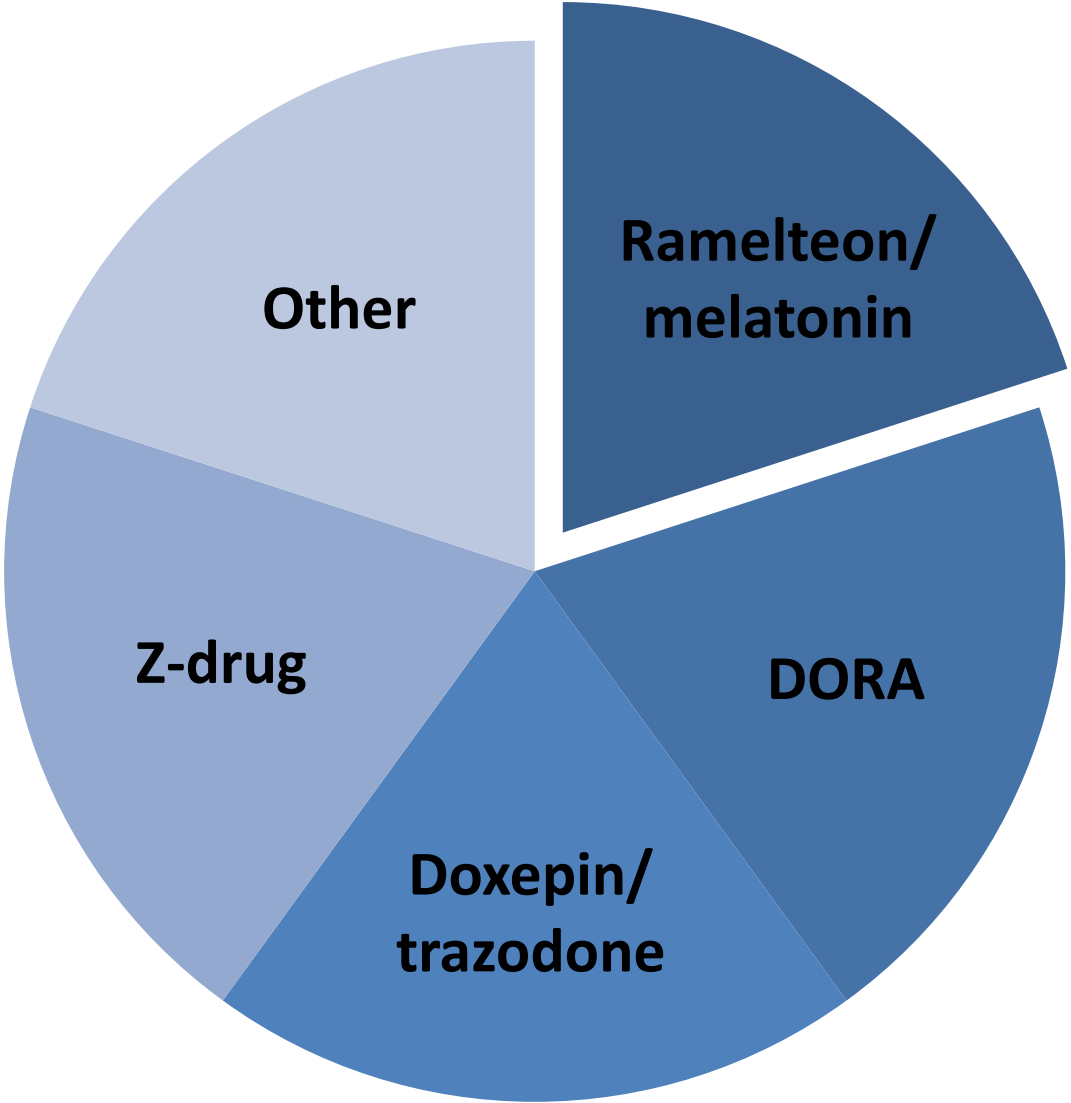
If a decision is made to use medication for insomnia, choose based on primary complaint and patient-specific characteristics.



Prescribing for Insomnia



Prescribing ...



Ramelteon (Prescription Melatonin Analog)

Mechanism

- Ramelteon (Rozerem) is a prescription melatonin receptor agonist
- Compared to melatonin it is 17-times more potent at melatonin receptors

Dose: 8mg

Benefits:

- Reduction in sleep latency by 13 minutes greater than placebo
- Benefits shown to endure at 12 months

Side effects:

- Dizziness, nausea, fatigue, somnolence

Considerations:

- Does not improve sleep maintenance or duration
- Delayed absorption when taken with or immediately after a high fat meal

OTC Melatonin

Dosing: 1-5 mg typically

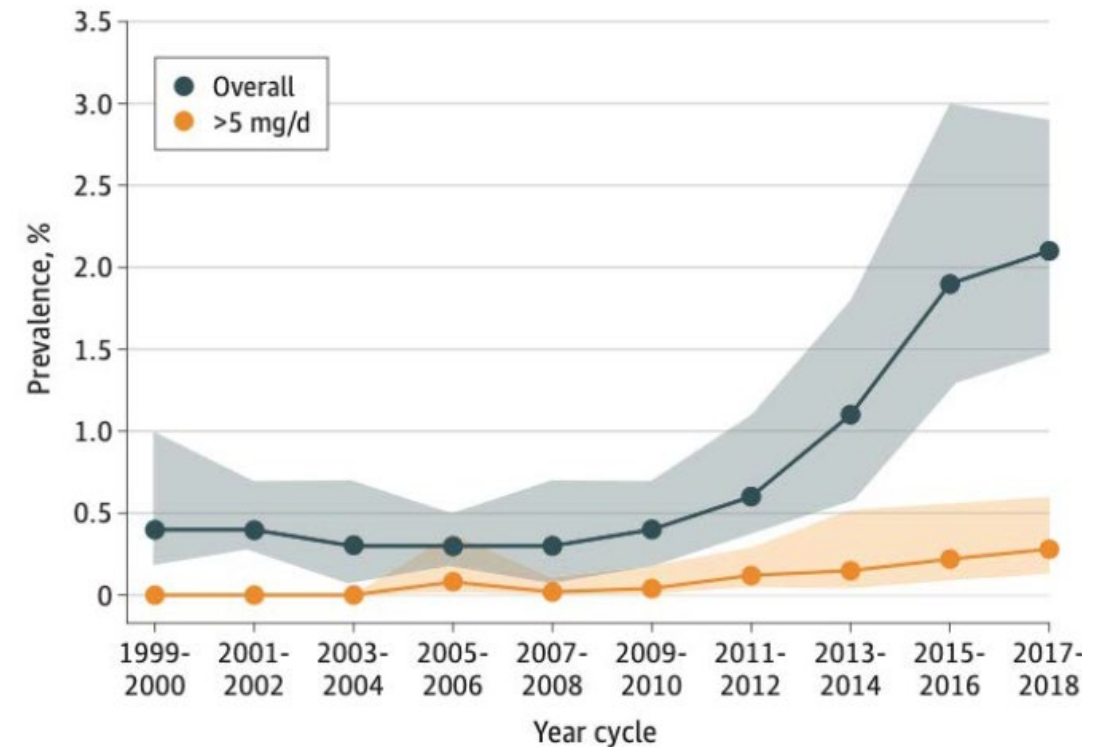
Side effects:

- Vivid dreams, nightmares, dizziness, sleepiness, headaches, stomach cramps

Considerations:

- As a dietary supplement, the ingredients are less regulated (dose and presence of additives)
- Actual dose of melatonin and advertised ingredients may be inaccurate

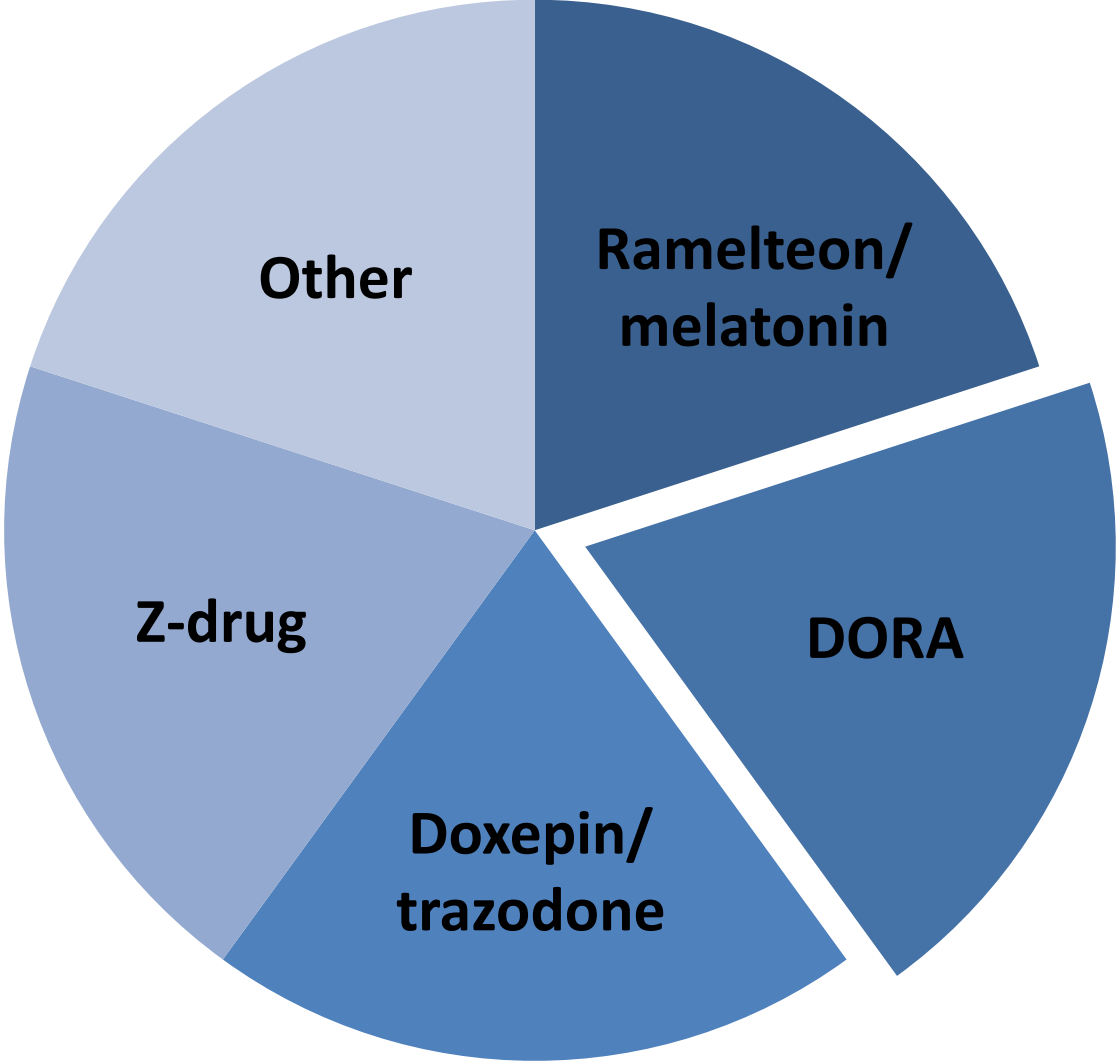
Figure. Trends in Reported Weighted Prevalence of Overall Melatonin Use and Melatonin Use Greater Than 5 mg/d Among US Adults



Costello RB et al. *Nutr J*. 2014 Nov 7;13:106.
Erland LA and Saxena PK. *J Clin Sleep Med*. 2017 Feb;13(2):275-81.
Li J et al. *JAMA*. 2022 Feb;327(5):483-5.

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Prescribing ...



Dual Orexin Receptor Antagonists (DORAs)

Mechanism:

- Facilitate sleep by decreasing the wake drive (orexin/hypocretin) rather than inducing sedation
 - Half-life: daridorexant (Quviviq) = 8hrs; lemborexant (Dayvigo) = 12hrs; suvorexant (Belsomra) = 18hrs

Benefits:

- Improve sleep onset and sleep maintenance
- Reduced next-day impairment compared to other sleep aids
- No evidence of rebound insomnia, withdrawal symptoms, or serious safety problems

DORAs - Safety

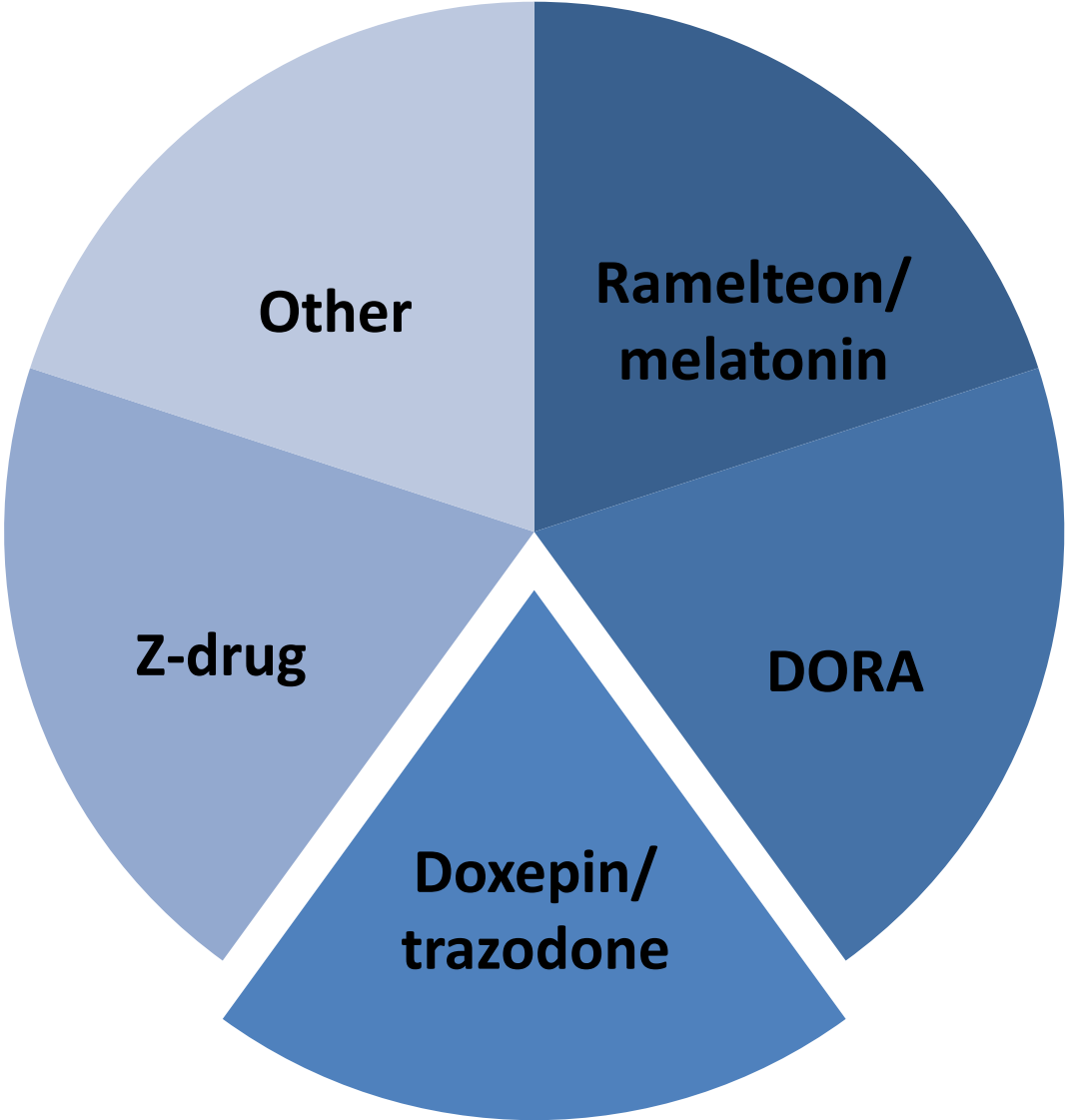
Side effects:

- Somnolence is the most common side effect
- Possible dose-dependent impairment in alertness and attention (e.g., next morning driving)
- Fewer side effects and adverse events compared to zolpidem

Considerations:

- Currently schedule IV controlled substance, but no evidence to suggest dependence/abuse potential
- Do not cause rebound insomnia with discontinuation
- Medications NOT on Beers list to avoid in elderly

Prescribing ...



Doxepin

Mechanism:

- Tricyclic antidepressant with insomnia indication at low dose

Dose: 3-6mg

Benefits: compared to placebo

	All – 3mg	Age > 65 – 3mg	All – 6mg	Age > 65 – 6mg
Wake after sleep onset	↓ 20 min	↓ 23 min	↓ 28 min	↓ 34 min
Total sleep time	↑ 25 min	↑ 30 min	↑ 30 min	↑ 38 min

Doxepin – Side Effects and Considerations

Side effects:

- somnolence, headache

Considerations:

- Benefits most pronounced in older adults
- Doses exceeding 25 mg not indicated for sleep (anticholinergic side effects)
- Cost varies between dosage forms (for a 30-day supply):
 - doxepin 3 mg (Silenor): \$553
 - doxepin 3 mg (generic): \$55
 - doxepin 3 mg (10 mg/ML liquid): \$63 per 120 mL bottle - \$5 a month

Trazodone

Mechanism:

- Serotonin antagonist and reuptake inhibitor, anti-histamine-1

Dose: 50-150mg

Effect on sleep: compared to placebo

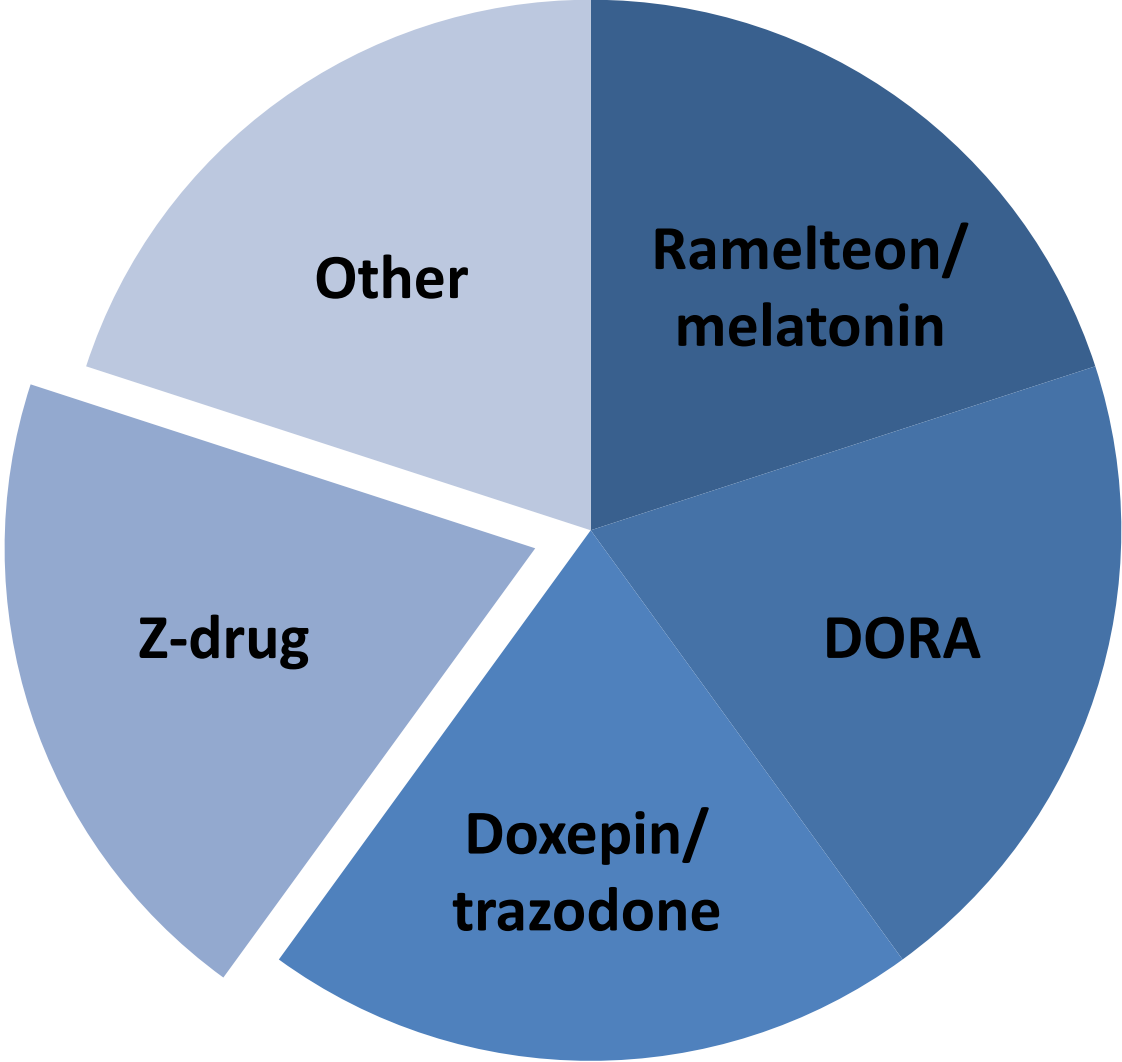
Sleep latency*	↓ 10 min
Wake after sleep onset*	↓ 8 min
Quality of sleep	<i>No improvement</i>

* Did not meet statistical significance

Side effects:

- headache, somnolence, orthostatic hypotension, cognitive or motor impairment
 - NOT approved by the FDA for treatment of insomnia (off-label use)
 - AASM recommends against use of trazodone for sleep-onset or –maintenance insomnia

Prescribing ...



Benzodiazepine receptor agonists (BZRAs, “Z drugs”)

Mechanism: benzodiazepine receptor agonist

- Cause CNS depression and have sedative (but not anxiolytic) effects by enhancing inhibitory effects of gamma-aminobutyric acid (GABA)

Benefits:

- Less abuse potential than benzodiazepines
- Improve sleep onset, sleep time and sleep quality

	Zolpidem (Ambien)	Eszopiclone (Lunesta)	Zaleplon (Sonata)
Sleep latency*	5-12 min	14 min	10 min
WASO*	25 min	10-14 min	N/A
Total sleep time	29 min	25-57 min	N/A
Sleep quality*	Moderate improvement	Moderate-to-large impr.	No improvement

* All outcome vs. placebo; N/A – not available

Buscemi N et al. *J Gen Intern Med.* 2007 Sep;22(9):1335-50.
Sateia MJ et al. *J Clin Sleep Med.* 2017 Feb;13(2):307-49.
Samara MT et al. *Acta Psychiatr Scand.* 2020 Jul;142(1):6-17.

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BZRA Safety - General

Side effects:

- Dizziness, somnolence, drowsiness, complex sleep-related behaviors

Considerations:

- AVOID in older adults and those **with cognitive impairment**
- Caution regarding **next-morning impairment** for activities that require complete mental alertness (e.g., driving, operating heavy machinery, etc.)
- All sedative hypnotics associated with **sleepwalking and other complex behaviors** including sleep-driving and -eating
 - **Tell patients to discontinue use immediately** and avoid use of any medications in the same class if any such episodes occur

BZRA Safety – Specific Populations

- Women require reduced doses relative to men given slower elimination time
 - FDA changed recommended doses based on this data (post-marketing)
- No race-, ethnicity-, or BMI-related association with elimination time
- Older adults (age ≥ 65) have always required lower doses due to absorption and elimination rate, but the American Geriatrics Society advises **against** use of this class at *any* dose in older adults

Greenblatt DJ et al. *J Pharmacol Exp Ther.* 2000 May;293(2):435-43.

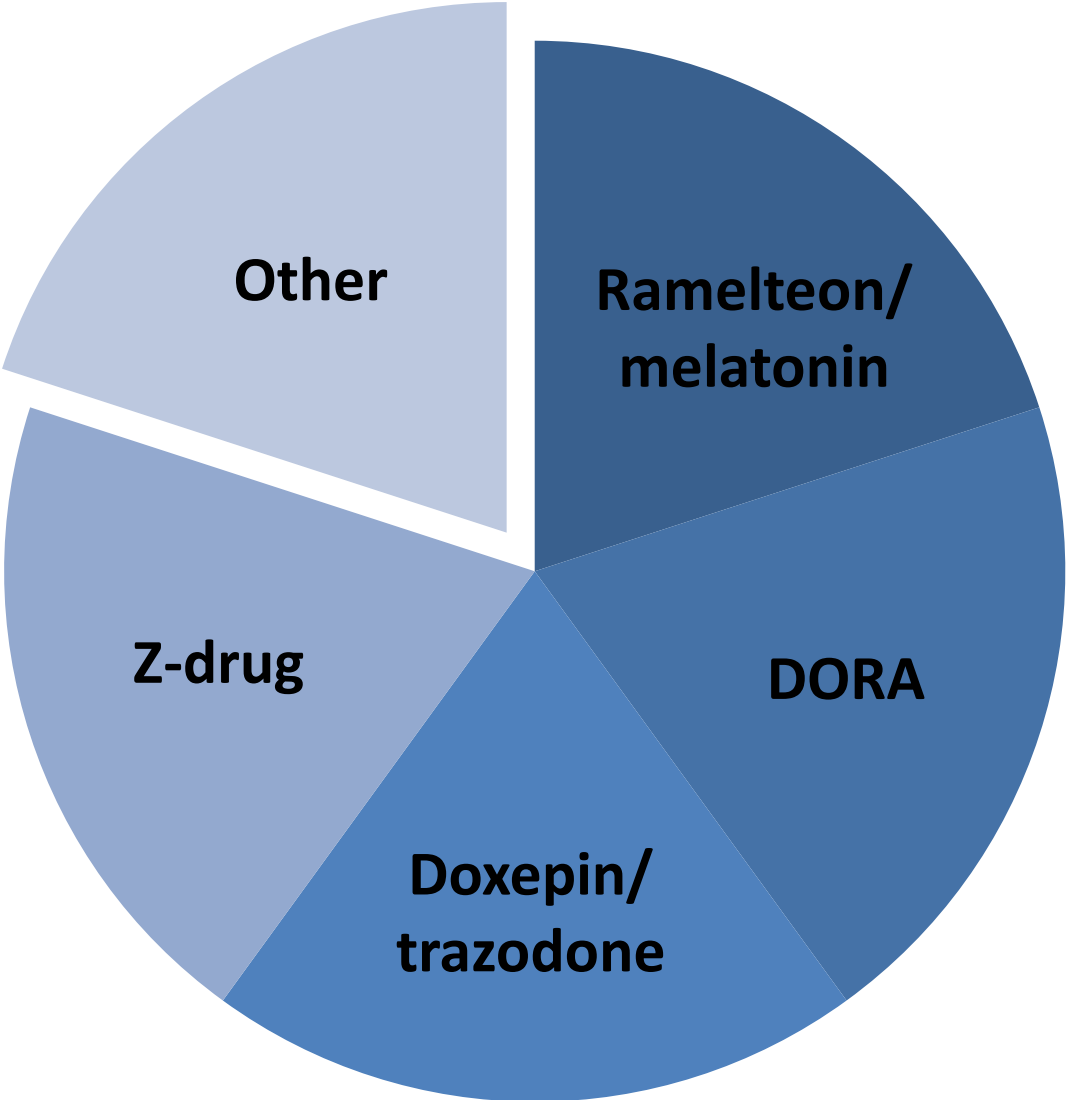
Verster JC and Roth T. *Traffic Inj Prev.* 2012;13(3):286-92.

Pergolizzi JV Jr et al. *Sleep Disord.* 2014;2014:527109.

2023 American Geriatrics Society Beers Criteria^R Update Expert Panel. *J Am Geriatr Soc.* 2023 Jul;71(7):2052-2081.

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Prescribing ...



Benzodiazepines

Mechanism:

- Enhance inhibitory effects of gamma-aminobutyric acid (GABA) causing central nervous system depression & sedative and anxiolytic effects

Benefits:

- Sleep latency decreased and sleep quality increased compared to placebo

Benzodiazepines with an FDA Indication for Insomnia

	Dose	Half-life	Sleep onset	Sleep maintenance
Estazolam	1-2mg – adults 0.5mg – older adults	Intermediate (10-24h)	✓	✓
Flurazepam	15-30mg – adults 15mg – older adults	Long (120-160h in older adults)	✓	✓
Temazepam	7.5-30mg – adults 7.5-15mg – older adults	Intermediate (8-15h)	✓	✓
Triazolam	0.125-0.25mg – all	Short (2-5h)	✓	
Quazepam	7.5-15mg – adults 7.5mg – older adults	Long (40h)	✓	✓

Note: “older adult” = age ≥ 65

Benzodiazepine Side Effects

Possible risks of benzodiazepines



Feel tired or drowsy



Problems with memory and thinking



Depression, mood changes, irritability, anger



Worsening of PTSD symptoms



- Become dependent on the medicine
- Withdrawal symptoms



- Worsening of COPD and sleep apnea
- Pneumonia



- Car crash
- Arrest for driving while impaired



- Unsteady walking
- Falls, broken bones, or concussion



Overdose—especially when combined with alcohol, strong pain medicine (opioids), non-prescribed medicines



- Birth defects
- Withdrawal symptoms in newborn



The key to success

The best way to reduce or stop benzodiazepines is to work with your provider to very slowly decrease your dose. This may take months, but it is the safest approach.

Benzodiazepines

Considerations:

- Have misuse potential and cause tolerance and withdrawal
- Rebound insomnia and next day somnolence noted
- Decrease REM sleep
- Complex sleep behavior can occur
- Should be avoided in older adults and those with cognitive impairment
- Long-term treatment is not recommended (>4 weeks)

Challenges to Understanding the Role of Cannabis on Sleep

- Heterogeneity in formulations and doses, many of which are not regulated
- Impact on sleep is dependent on dose, composition, and frequency of use
- Dose (“high” versus “low”) is not clearly defined or consistent among studies



IN SHORT – no good data to inform us on its use for sleep

Overview of Outcomes with Meds

		Total sleep time	Sleep latency	Wake after sleep onset	Sleep quality
Melatonin	Melatonin/Ramelteon		✓		✓
DORAs	Daridorexant	✓	✓	✓	✓
	Suvorexant	✓	✓	✓	✓
	Lemborexant	✓	✓	✓	✓
Sedating anti-depressants	Doxepin	✓	✓	✓	✓
	Trazodone				
BZRAs	Eszopiclone	✓	✓	✓	✓
	Zaleplon	✓	✓		✓
	Zolpidem	✓	✓	✓	✓
Benzos	Temazepam	✓	✓	✓	✓
	Triazolam		✓		✓
Cannabis	Cannabis		✓		

CASE STUDY: Nancy

Chief complaint: not sleeping

- 69 yo female
- PMHx: HTN, lipids, DJD-knee
- OTC product no longer helping
- “What do you think about marijuana gummies for sleep, doc?”



Social History:

- Married, lives with husband
- Retired 5 yr ago
- Never smoker
- ETOH about 3x/month

Meds:

- Bisoprolol/HCT
- Atorvastatin
- Naproxen BID prn
- OTC doxylamine ½ tab (12.5mg) nightly

Safer Practice Prescribing

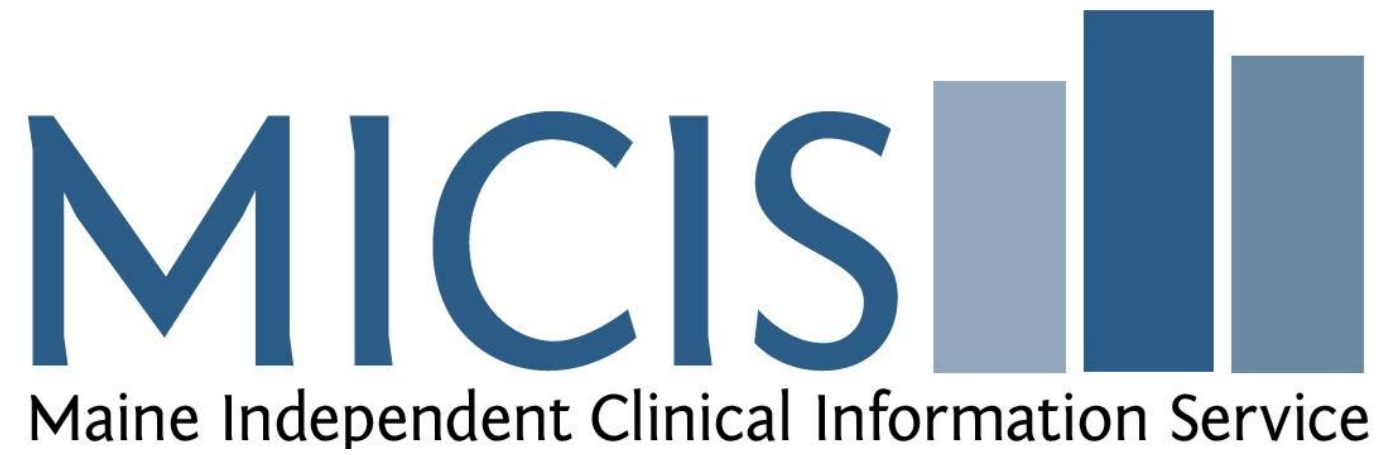
- Prescribe medications in conjunction with cognitive behavioral approach
- Use the lowest effective dose
- Avoid refills – schedule regular follow-ups
 - Most medications are only recommended for short-term use
- Avoid combining with other sedating medications or alcohol
- Use caution in older adults
- Instruct patients on proper timing of medications (i.e., half-life and expected duration)
- Assess for complex sleep-related behaviors and next-day impairment

Putting It All Together

- Tools to assess insomnia: sleep diary, questionnaires, actigraphy +/- or wearable technology, + polysomnography (PSG) or home sleep testing (HST)
- Recommend CBT-I first for chronic insomnia treatment
 - CBT-I vs. medication--sustained benefit long-term
 - CBT-I can support medication tapering/de-prescribing
- Medications are less effective as monotherapy (i.e. without CBT-I)
 - Evaluate safety profiles when selecting medications
- Limit prolonged medication use whenever possible; consider withdrawal in long-term users
 - Use an individualized risk-benefit analysis
 - Ramelteon, DORAs, doxepin may be more appropriate if longer-term use is needed

How to Get Education Credit

- If your institution is providing credit, you will follow your usual process.
- If MICIS is providing credit, please fill out the online survey within 2 weeks and a credit document will be emailed from the Maine Medical Association.



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