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Management of Insomnia Disorder in Adults: Current State of the Evidence

Clinician Summary ARCHIVED | Aug 1, 2017

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Focus of This Summary

This is a summary of a systematic review that evaluated current evidence regarding the effectiveness, comparative effectiveness, and adverse effects of management strategies for insomnia disorder in adults. The systematic review synthesized evidence from 169 randomized controlled trials and 12 observational studies published through January 2015. This summary is provided to assist in informed clinical decisionmaking. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background

Insomnia involves dissatisfaction with sleep quantity or quality and is associated with difficulty initiating sleep, maintaining sleep, returning to sleep after early morning waking, or a combination thereof. Diagnostic criteria for insomnia disorder require that sleep symptoms cause clinically significant distress or impairment in functioning, occur despite adequate opportunity for sleep, and are experienced on a chronic basis (at least 3 nights per week for at least 3 months).[1]

Many treatments are available for insomnia symptoms, including sleep hygiene education, behavioral and psychological interventions, prescription medications, over-the-counter medications and supplements, and complementary and alternative medicine (CAM) treatments.

Psychological and behavioral interventions include cognitive behavioral therapy for insomnia (CBT-I), brief or multicomponent behavioral therapy, stimulus control, relaxation training, and sleep restriction (Appendix). Guidelines[2,3] recommend CBT-I as first-line treatment for all adults with chronic insomnia disorder.

The U.S. Food and Drug Administration (FDA) has approved several prescription drugs for insomnia, typically for short-term use. These include nonbenzodiazepine hypnotics (zaleplon, zolpidem, eszopiclone), an orexin receptor antagonist (suvorexant), a melatonin agonist (ramelteon), some benzodiazepines (e.g., triazolam, temazepam), and an antidepressant (doxepin).

The systematic review assessed the efficacy, comparative effectiveness, and adverse effects of a broad range of management strategies for insomnia disorder in adults.

Conclusions

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Psychological and Behavioral Therapy: Effectiveness (Table 1)

- CBT-I improved global and sleep outcomes in the general adult population (low to moderate strength of evidence [SOE]). Effectiveness was demonstrated across modes of delivery and was sustained in the long term (at least 6 months) for some outcomes (low to moderate SOE).
- CBT-I also appeared to improve global and some sleep outcomes in older adults and in patients with pain conditions and insomnia (low SOE for most outcomes).

Psychological and Behavioral Therapy: Adverse Effects

Evidence was insufficient regarding the adverse effects of psychological and behavioral interventions.

Pharmacological Therapy: Effectiveness (Table 2)

- Nonbenzodiazepine hypnotics (eszopiclone and zolpidem) and an orexin receptor antagonist (suvorexant) improved some outcomes among the general adult population in primarily short-term (up to 3 months) studies (low to moderate SOE).
- The antidepressant doxepin improved global and some sleep outcomes, primarily in older patients (low to moderate SOE).
- Evidence regarding the long-term efficacy of pharmacological therapies for insomnia disorder is very limited.

Pharmacological Therapy: Adverse Effects (Table 3)

- Evidence regarding the long-term (more than 3 months) safety of pharmacological therapies for insomnia disorder is limited. Nevertheless, observational studies suggest a possible association between hypnotics and fractures, head injuries, dementia, and cancer.
- FDA labels warn of several potential severe adverse effects for all insomnia medications.

Overview of Clinical Research Evidence

The effects of insomnia treatment can be assessed in various ways. Outcome measures include:

- **Sleep outcome measures**: These assess specific sleep parameters (sleep-onset latency, time awake after sleep onset, total sleep time, and sleep efficiency) or sleep quality.
- **Global outcome measures**: These assess improvements in both sleep and accompanying daytime dysfunction or distress (e.g., fatigue or sleepiness, depressed mood, reduced quality of life). The Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI) are common global outcome instruments.

Intervention	General Adult Population: Global Outcomes	General Adult Population: Sleep Outcomes	Adults 55 Years of Age and Older: Global Outcomes	Adults 55 Years of Age and Older: Sleep Outcomes	Adults With Pain Conditions: Global Outcomes	Adults With Pain Conditions: Sleep Outcomes
CBT-I[b]	Improves ([evidence low] to [evidence medium])	Improves ([evidence medium])	May improve ([evidence low])	Reduces awake time after sleep onset ([evidence medium])	May improve ([evidence low])	May improve some outcomes ([evidence low])
				May improve other outcomes ([evidence low])		

BBT = brief behavioral therapy; CBT-I = cognitive behavioral therapy for insomnia; MBT = multicomponent behavioral therapy

[a] Controls included treatment as usual, attention control (i.e., sleep hygiene or sleep education), "wait-list" management, placebo or sham treatment, or no treatment.

[b] The effectiveness of CBT-I was demonstrated across modes of delivery: in-person as an individual, in-person as a group, telephone, Web-based, and based on a self-help book.

[c] These results refer to stimulus control alone. Stimulus control is also often a component of CBT-I, MBT,

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Intervention	General Adult Population: Global Outcomes	General Adult Population: Sleep Outcomes	Adults 55 Years of Age and Older: Global Outcomes	Adults 55 Years of Age and Older: Sleep Outcomes	Adults With Pain Conditions: Global Outcomes	Adults With Pain Conditions: Sleep Outcomes
CBT-I (studies lasting ≥ 6 months)	May improve ([evidence low])	Improves sleep efficiency ([evidence medium]) May improve other outcomes ([evidence low])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])
Stimulus Control[c]	([evidence insufficient])	May improve some outcomes ([evidence low])	([evidence insufficient])	May improve total sleep time ([evidence low])	([evidence insufficient])	([evidence insufficient])
MBT or BBT	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	May improve some outcomes ([evidence low])	([evidence insufficient])	([evidence insufficient])

BBT = brief behavioral therapy; CBT-I = cognitive behavioral therapy for insomnia; MBT = multicomponent behavioral therapy
[a] Controls included treatment as usual, attention control (i.e., sleep hygiene or sleep education), "wait-list" management, placebo or sham treatment, or no treatment.
[b] The effectiveness of CBT-I was demonstrated across modes of delivery: in-person as an individual, in-person as a group, telephone, Web-based, and based on a self-help book.
[c] These results refer to stimulus control alone. Stimulus control is also often a component of CBT-I, MBT, and BBT.

Table 1: Effectiveness of Psychological and Behavioral Interventions for Insomnia Disorder When Compared With a Control[a]: Main Findings

Drug Type	Drug Name	General Adult Population: Global Outcomes	General Adult Population: Sleep Outcomes[a]	Adults 55 Years of Age and Older: Global Outcomes	Adults 55 Years of Age and Older: Sleep Outcomes[a]
Nonbenzodiazepine Hypnotics	Eszopiclone	May improve ([evidence low])	Improves sleep onset latency and total sleep time ([evidence medium]) May reduce time awake after sleep onset ([evidence low])	May improve ([evidence low])	May improve some outcomes ([evidence low])
	Zolpidem[b]	May improve ([evidence low])	Improves latency, total sleep time, and sleep quality ([evidence medium]) May reduce time awake after sleep onset ([evidence low])	([evidence insufficient])	May improve sleep onset latency ([evidence low])
	Zolpidem ER	May improve ([evidence low])	May improve some outcomes ([evidence low])	([evidence insufficient])	([evidence insufficient])

ER = extended release
[a] Sleep outcomes include sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, and sleep quality.
[b] Data are from studies of routine use of zolpidem 10 mg or 15 mg or as-needed use of zolpidem 10 mg for the general adult population and zolpidem 5 mg for the older adult population.
[c] Other antidepressants include trazodone, amitriptyline, and mirtazapine, none of which are approved by the U.S. Food and Drug Administration (FDA) for insomnia.
[d] Other benzodiazepines include drugs approved by the FDA for insomnia (estazolam, flurazepam, lorazepam, quazepam, and triazolam) and drugs not approved by the FDA for insomnia (alprazolam and clonazepam).

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Drug Type	Drug Name	General Adult Population: Global Outcomes	General Adult Population: Sleep Outcomes[a]	Adults 55 Years of Age and Older: Global Outcomes	Adults 55 Years of Age and Older: Sleep Outcomes[a]
	Zaleplon	([evidence insufficient])	Improves sleep quality ([evidence medium]) Probably has no effect on total sleep time ([evidence low])	([evidence insufficient])	([evidence insufficient])
Orexin Receptor Antagonists	Suvorexant	Improves ([evidence medium])	Improves latency and total sleep time ([evidence medium]) Reduces time awake after sleep onset ([evidence medium])	([evidence insufficient])	([evidence insufficient])
Melatonin Agonists	Ramelteon	([evidence insufficient])	May improve sleep quality ([evidence low]) Probably has no effect on other outcomes ([evidence low])	([evidence insufficient])	May improve sleep onset latency ([evidence low])
Antidepressants	Doxepin	([evidence insufficient])	May improve some outcomes ([evidence low])	May improve ([evidence low])	Improves total sleep time ([evidence medium]) May improve other outcomes ([evidence low])

ER = extended release
[a] Sleep outcomes include sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, and sleep quality.
[b] Data are from studies of routine use of zolpidem 10 mg or 15 mg or as-needed use of zolpidem 10 mg for the general adult population and zolpidem 5 mg for the older adult population.
[c] Other antidepressants include trazodone, amitriptyline, and mirtazapine, none of which are approved by the U.S. Food and Drug Administration (FDA) for insomnia.
[d] Other benzodiazepines include drugs approved by the FDA for insomnia (estazolam, flurazepam, lorazepam, quazepam, and triazolam) and drugs not approved by the FDA for insomnia (alprazolam and clonazepam).

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Drug Type	Drug Name	General Adult Population: Global Outcomes	General Adult Population: Sleep Outcomes[a]	Adults 55 Years of Age and Older: Global Outcomes	Adults 55 Years of Age and Older: Sleep Outcomes[a]
	Others[c]	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])
Benzodiazepines	Temazepam	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])
	Others[d]	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])
Over-the-Counter Sleep Medications and Supplements	Diphenhydramine, doxylamine, melatonin	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])	([evidence insufficient])

ER = extended release
[a] Sleep outcomes include sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, and sleep quality.
[b] Data are from studies of routine use of zolpidem 10 mg or 15 mg or as-needed use of zolpidem 10 mg for the general adult population and zolpidem 5 mg for the older adult population.
[c] Other antidepressants include trazodone, amitriptyline, and mirtazapine, none of which are approved by the U.S. Food and Drug Administration (FDA) for insomnia.
[d] Other benzodiazepines include drugs approved by the FDA for insomnia (estazolam, flurazepam, lorazepam, quazepam, and triazolam) and drugs not approved by the FDA for insomnia (alprazolam and clonazepam).

Table 2: Effectiveness of Pharmacological Interventions for Insomnia Disorder When Compared With Placebo: Main Findings
Note: Most studies of pharmacological interventions were small and of short duration (less than 3 months).

Drug Class	Drug	Common Effects[a]	Serious Effects[b]

CNS = central nervous system
[a] Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug.
[b] Adverse effects accompanied by warnings or precautions statements in the FDA labels.

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Drug Class	Drug	Common Effects[a]	Serious Effects[b]
Nonbenzo-diazepine Hypnotics	**Eszopiclone**	Somnolence, unpleasant taste in the mouth, headache, dizziness, dry mouth, rash, anxiety, hallucinations, respiratory infection	• CNS depressant effects and next-day psychomotor impairment • Increased CNS effects in older adults • Sleep-driving and other complex behaviors while not fully awake • Worsening depression or suicidal thoughts • Falls and severe injuries because of drowsiness • Severe anaphylactic or anaphylactoid reactions • Possible respiratory depression in people with severe lung disease or sleep apnea • Withdrawal symptoms if abrupt dose reduction or discontinuation
	Zolpidem	Somnolence, headache, malaise, vertigo, dizziness, diarrhea	• CNS depressant effects and next-day psychomotor impairment • Increased CNS effects in older adults • Sleep-driving and other complex behaviors while not fully awake • Worsening depression or suicidal thoughts • Falls and severe injuries because of drowsiness • Severe anaphylactic or anaphylactoid reactions • Possible respiratory depression in people with severe lung disease or sleep apnea • Withdrawal symptoms if abrupt dose reduction or discontinuation

CNS = central nervous system

[a] Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug.

[b] Adverse effects accompanied by warnings or precautions statements in the FDA labels.

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Drug Class	Drug	Common Effects[a]	Serious Effects[b]
	Zaleplon	Headache, drowsiness, dizziness, paresthesias, difficulty with coordination	• CNS depressant effects and next-day psychomotor impairment • Increased CNS effects in older adults • Sleep-driving and other complex behaviors while not fully awake • Worsening depression or suicidal thoughts • Falls and severe injuries because of drowsiness • Severe anaphylactic or anaphylactoid reactions • Possible respiratory depression in people with severe lung disease or sleep apnea • Withdrawal symptoms if abrupt dose reduction or discontinuation
Benzodiazepines	**Temazepam**	Drowsiness, dizziness, headache, nervousness, nausea	• Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) • Worsening depression or suicidal thoughts in people with primary depression • Severe anaphylactic or anaphylactoid reactions • Possible profound sedation, respiratory depression, coma, and death with concomitant opioid use • Possible adverse effects in people with severe lung disease or sleep apnea

CNS = central nervous system

[a] Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug.

[b] Adverse effects accompanied by warnings or precautions statements in the FDA labels.

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Drug Class	Drug	Common Effects[a]	Serious Effects[b]
Orexin Receptor Antagonists	**Suvorexant**	Somnolence, fatigue, dry mouth	• CNS depressant effects and next-day psychomotor impairment • Sleep-driving and other complex behaviors while not fully awake • Sleep paralysis, hypnagogic or hypnopompic hallucinations, cataplexy-like symptoms • Worsening depression or suicidal thoughts • Possible respiratory depression in people with severe lung disease or sleep apnea
Melatonin Agonists	**Ramelteon**	Somnolence, fatigue, headache, dizziness, worsened insomnia, nausea	• Potential impairment of activities requiring complete mental alertness after drug ingestion • Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) • Worsening depression or suicidal thoughts • Severe anaphylactic or anaphylactoid reactions • Decreased testosterone and increased prolactin levels • Possible adverse effects in people with severe sleep apnea

CNS = central nervous system
[a] Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug.
[b] Adverse effects accompanied by warnings or precautions statements in the FDA labels.

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Drug Class	Drug	Common Effects[a]	Serious Effects[b]
Antidepressants	**Doxepin**	Drowsiness, nausea, upper respiratory tract infection	• CNS depressant effects, with impaired alertness and motor coordination that may persist the next day • Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) • Potential addictive effects when combined with CNS depressants or sedating antihistamines • Worsening depression or suicidal thoughts • Possible respiratory depression in people with severe lung disease or sleep apnea

CNS = central nervous system
[a] Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug.
[b] Adverse effects accompanied by warnings or precautions statements in the FDA labels.

Table 3: Adverse Effects of Pharmacological Interventions for Insomnia Disorder: Systematic Review Findings and U.S. Food and Drug Administration Label Information

Strength of Evidence Scale[†]

High: [evidence high]
High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.

Moderate: [evidence medium]
Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.

Low: [evidence low]
Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.

Insufficient:[evidence insufficient]
Evidence is either unavailable or does not permit a conclusion.

[†]The overall evidence grade was assessed based on the ratings for the following domains: study limitations, directness, consistency, precision, and reporting bias. Other domains were considered, as appropriate: dose-response association, plausible confounding, and strength of association (i.e., magnitude of effect). For additional details on the methodology used to assess strength of evidence, please refer to: Owens DK, Lohr KN, A

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al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—

Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577.

Other Findings

- Observational studies of long-term harms of pharmacological agents showed possible increased risks of the following:
  - **Hypnotics in general**: dementia, cancer
  - **Zolpidem**: head injury or fracture requiring hospitalization, hip fracture, cancer
  - **Ramelteon**: prolactinoma
  - **Temazepam**: death, cancer
- In observational studies, the effects of hypnotics on mortality were mixed.

Gaps in Knowledge and Other Issues

- Evidence regarding the effects of insomnia interventions in most patient subgroups was limited. Participants in general adult population trials were predominantly middle-aged, healthy, female, and white.
- Reporting on quality of life and functioning was very limited.
- Evidence for comparative effectiveness evaluations was low or insufficient.
- Evidence was insufficient regarding the effectiveness of most single behavioral interventions, such as sleep hygiene education, relaxation techniques, and sleep restriction.
- Evidence was insufficient regarding the adverse effects of psychological and behavioral interventions. Some studies reported participant withdrawals, which may reflect feasibility issues (e.g., treatments are time-consuming) rather than physical or psychological harms.
- Studies of pharmacological interventions rarely lasted more than 6 weeks. Evidence regarding their longer-term efficacy and safety is limited or lacking.
- Outcome reporting and intervention effect sizes varied among studies of pharmacological therapy, and a large placebo response was observed in some studies.
- Evidence was insufficient to assess the efficacy or comparative effectiveness of CAM interventions.

Key Points for Clinician and Patient and Caregiver Discussions

- CBT-I appears to be effective and safe as treatment for insomnia disorder.
  - Guidelines from professional organizations such as the American College of Physicians and the American Academy of Sleep Medicine recommend CBT-I as the first-line treatment for all adults with chronic insomnia disorder.
  - Web-based CBT-I may be an option for individuals without access to a therapist trained in CBT-I techniques.
  - Additional resources for CBT-I information include the American Academy of Sleep Medicine and the National Sleep Foundation.
  - A list of specialists certified by the American Board of Sleep Medicine in behavioral sleep medicine (including CBT-I) is available on its Web site.
- Some medications appear to be effective for insomnia in the short term (e.g., up to 3 months), but they have numerous potential side effects, some of which are serious.
- In light of the limited evidence regarding long-term benefits and the potential for serious adverse effects, medications should be used for insomnia disorder with caution.

Source

The information in this summary comes from Brasure M, MacDonald R, Fuchs E, Olson CM, Carlyle M, Diem S, Koffel E, Khawaja IS, Ouellette J, Butler M, Kane RL, Wilt TJ. Management of Insomnia Disorder. Comparative Effectiveness Review No. 159. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I.) AHRQ Publication No. 15(16)-EHC027-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2015.

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[2]Qaseem A, Kansagara D, Forciea MA, et al. Ann Intern Med. 2016 Jul 19;165(2):125-33. PMID: 27136449.
[3]Morgenthaler T, Kramer M, Alessi C, et al. Sleep. 2006 Nov;29(11)1415-9. PMID: 17162987.

Appendix

Treatment	Definition
Sleep Hygiene Education	Education of patients about health and environmental factors to improve sleep (e.g., avoiding/limiting caffeine, nicotine, and alcohol; maintaining a regular sleep schedule; avoiding napping; exercising regularly; maintaining a quiet and dark bedroom).
Stimulus Control	Therapy to change behaviors associated with bed or the bedroom and to establish consistent sleep patterns (e.g., using the bedroom for sleep only; going to bed only when tired).
Sleep Restriction	Interventions to limit time in bed to sleep time and to gradually increase time in bed as sleep efficiency improves.
Relaxation Training	Training to reduce somatic tension and to control bedtime thoughts that impair sleep.
Brief Behavioral Therapy (BBT)	Therapy that combines stimulus control and sleep restriction strategies.
Multicomponent Behavioral Therapy (MBT)	Therapy combining various behavioral interventions but not cognitive therapy.
Cognitive Therapy	Interventions to change patients' thinking about sleep by identifying, challenging, and replacing dysfunctional beliefs and attitudes (e.g., challenging notions about requisite amounts of sleep and about how sleep is out of their control; thought journaling).
Cognitive Behavioral Therapy for Insomnia (CBT-I)	Multimodal combination of treatments, including cognitive therapy, behavioral interventions (sleep restriction, stimulus control, or both), and education (sleep hygiene).
Table adapted from: Morgenthaler T, Kramer M, Alessi C, et al.; American Academy of Sleep Medicine. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of Sleep Medicine report. Sleep. 2006 Nov;29(11):1415-9. PMID: 17162987; and Buysse DJ. Insomnia. JAMA. 2013 Feb 20;309(7):706-16. PMID: 23423416.	

Appendix Table 1: Psychological and Behavioral Interventions for Insomnia Disorder

Project Timeline

Management of Insomnia Disorder

Oct 25, 2013 Topic Initiated

Apr 3, 2014 Research Protocol ARCHIVED

Dec 30, 2015 Systematic Review

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