

UNDERSTANDING THE IMPACT OF INSOMNIA DISORDER

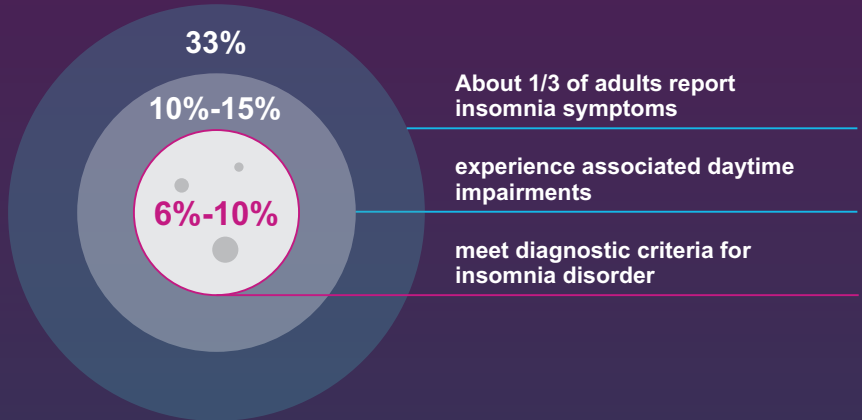
Insomnia disorder is characterized by difficulty falling asleep, staying asleep, or both, despite an adequate opportunity to sleep.¹

Diagnostic criteria for insomnia disorder include²:

- Symptoms**
Difficulty falling asleep or staying asleep or waking too early in the morning that leads to dissatisfaction with sleep quantity or quality
- Impairment**
Sleep disturbance that leads to impairment in social, work, educational, behavioral, or other areas of functioning, or that may cause significant distress
- Chronicity**
Experiencing sleep difficulty while having adequate opportunity to sleep, at least 3 nights per week for at least 3 months

Although Many Adults Experience Insomnia Symptoms, Only a Small Percentage Meet Diagnostic Criteria for Insomnia Disorder

Prevalence of Insomnia Symptoms and Diagnosis in the Adult Population²



Insomnia Is Associated With Several Risk Factors and an Increased Risk for Certain Comorbidities

Risk Factors

- Advancing age²
- Female³
- Medical comorbidities such as chronic pain, restless legs syndrome, GERD, respiratory issues⁴
- Poor sleep hygiene practices (eg, excessive caffeine use, irregular sleep schedules)²
- Psychiatric disorders such as anxiety and depression^{2,3}

Comorbidities

- Mood disorders⁵
- Type 2 diabetes⁶
- Cardiovascular disease^{7,8}
- Breast cancer⁹
- Behavioral and cognitive impairment¹⁰
- Heart failure¹¹

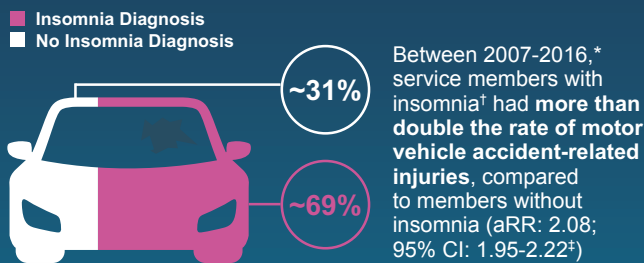
INSOMNIA CAN NEGATIVELY IMPACT NEXT-DAY FUNCTION

Inadequate sleep from insomnia can have next-day consequences¹²: • Fatigue • Impaired Cognitive Function and Memory • Daytime Sleepiness

Insomnia Symptoms Have Been Associated With an Increased Risk of Motor Vehicle Accidents and Falls^{13,14}

Motor Vehicle Accidents

Motor Vehicle Accident (MVA)-Related Injuries in Active Component Service Members Between 2007–2016* (n=5,587)



A retrospective cohort study compared incidence rates of motor vehicle accident (MVA)-related injuries between service members with diagnosed insomnia[†] and an unexposed cohort (N=172,062) (January 1, 2007–December 31, 2016).

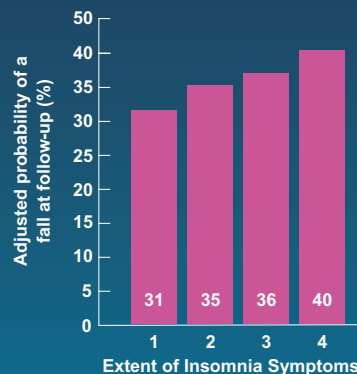
*MVA-related injury during the 365-day follow-up period was defined as an outpatient or inpatient encounter that included any of the MVA-related ICD-9 or ICD-10 external cause of injury codes, or NATO Standardization Agreement (STANAG 2050) hospitalization cause of injury and trauma codes.

[†]An incident case of insomnia was defined by records of two outpatient medical encounters within 90 days of each other or one hospitalization with a diagnosis of insomnia in any diagnostic position, in a non-deployed healthcare setting using ICD-9 or ICD-10 codes.

[‡]Adjusted for covariates.

Falls

Positive Relationship of the Extent of Insomnia Symptoms and Risk of Falling



Older adults who fell reported a greater number of insomnia symptoms compared with those who did not fall

A composite score (0–4) for the number of insomnia symptoms was created. A higher score reflected a greater burden of insomnia symptoms.

Data from the Health and Retirement Study (HRS) patients were asked about their extent of insomnia symptoms (n=6,882) (2006–2014).

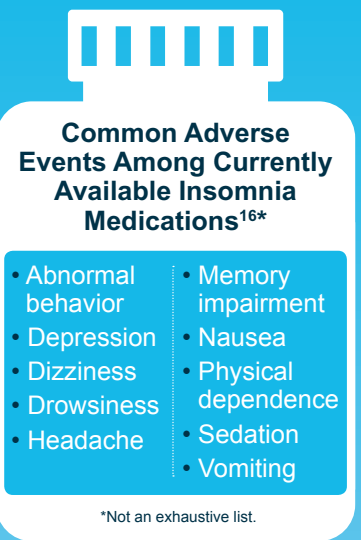
INSOMNIA MEDICATIONS MAY FURTHER CONTRIBUTE TO NEXT-DAY IMPAIRMENT

For patients already being treated for insomnia, the next-day impact may be due to the residual effects of their insomnia medications. These effects can manifest as¹⁵:

Headache Grogginess Difficulty Remembering Difficulty Concentrating

Approximately
80%

of US adults taking medications for insomnia report experiencing **negative next-day effects** related to **medication use**.¹⁵



Common Adverse Events Among Currently Available Insomnia Medications^{16*}

- Abnormal behavior
- Depression
- Dizziness
- Drowsiness
- Headache
- Memory impairment
- Nausea
- Physical dependence
- Sedation
- Vomiting

*Not an exhaustive list.

THE FDA, AGS, AND AASM HAVE ISSUED SAFETY WARNINGS, GUIDANCE, AND RECOMMENDATIONS RELATED TO INSOMNIA MEDICATIONS

Food and Drug Administration (FDA)¹⁷

The FDA requires a new **boxed warning** regarding rare but serious injuries and deaths resulting from various complex sleep behaviors that have occurred with certain prescription insomnia medications.

American Geriatrics Society (AGS) Beers Criteria¹⁸

The use of **certain classes of drugs for the treatment of insomnia** are to be avoided in older adults due to increased risk of side effects.

American Academy of Sleep Medicine (AASM)¹⁹

The AASM guidelines do not recommend some medications for insomnia treatment due to the harms outweighing the benefits.

UNMET NEEDS PERSIST FOR PATIENTS WITH INSOMNIA DISORDER

For more information and resources on insomnia, visit dayafterinsomnia.com

References: 1. Institute of Medicine. Sleep disorders and sleep deprivation: an unmet public health problem. Washington, DC: National Academies Press; 2006. 2. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Association; 2013. 3. Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med Rev*. 2002;6(2):97-111. 4. Kaur H, Bollu PC. Chronic Insomnia. [Updated 2019 Feb 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. <https://www.ncbi.nlm.nih.gov/books/NBK526136/>. Accessed June 10, 2019. 5. Hertenstein E et al. Insomnia as a predictor of mental disorders: A systematic review and meta-analysis. *Sleep Med Rev*. 2019;43:96-105. 6. LeBlanc ES et al. Insomnia is associated with an increased risk of type 2 diabetes in the clinical setting. *BMJ Open Diabetes Res Care*. 2018;6(1):e000604. 7. Li M et al. Insomnia and risk of cardiovascular disease: a meta-analysis of cohort studies. *Int J Cardiol*. 2014;176(3):1044-1047. 8. Javaheri S, Redline S. Insomnia and risk of cardiovascular disease. *Chest*. 2017;152(2):435-444. 9. Sen A et al. Insomnia and the risk of breast cancer: the HUNT study. *Psychosom Med*. 2017;79(4):461-468. 10. Garbarino S et al. Co-morbidity, mortality, quality of life and the healthcare/welfare/social costs of disordered sleep: a rapid review. *Int J Environ Res Public Health* 2016;13(8). 11. Laugsand LE et al. Insomnia and the risk of incident heart failure: a population study. *Eur Heart J*. 2014;35(21):1382-1393. 12. Leger D, Poursain B. An international survey of insomnia: under-recognition and under-treatment of a polysymptomatic condition. *Curr Med Res Opin*. 2005;21(11):1785-1792. 13. Erickson EA, Stahlman S, McNellis MG. Insomnia and motor vehicle accident-related injuries, active component, U.S. Armed Forces, 2007-2016. *MSMR*. 2017;24(12):2-11. 14. Chen TY, Lee S, Buxton OM. A greater extent of insomnia symptoms and physician-recommended sleep medication use predict fall risk in community-dwelling older adults. *Sleep*. 2017;40(11). 15. Fitzgerald T, Vietri J. Residual effects of sleep medications are commonly reported and associated with impaired patient-reported outcomes among insomnia patients in the United States. *Sleep Disord*. 2015;2015:607148. doi:10.1155/2015/607148. 16. Equihua AC, De la herrán-Arita AK, Drucker-colin R. Orexin receptor antagonists as therapeutic agents for insomnia. *Front Pharmacol*. 2013;4:163. doi:10.3389/fphar.2013.00163. 17. FDA requires stronger warnings about rare but serious incidents related to certain prescription insomnia medicines [press release]. Food and Drug Administration. April 30, 2019. 18. 2019 American Geriatrics Society Beers Criteria® Update Expert Panel. *J Am Geriatr Soc*. 2019;67(4):674-694. 19. Sateia MJ 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):307-349.

