

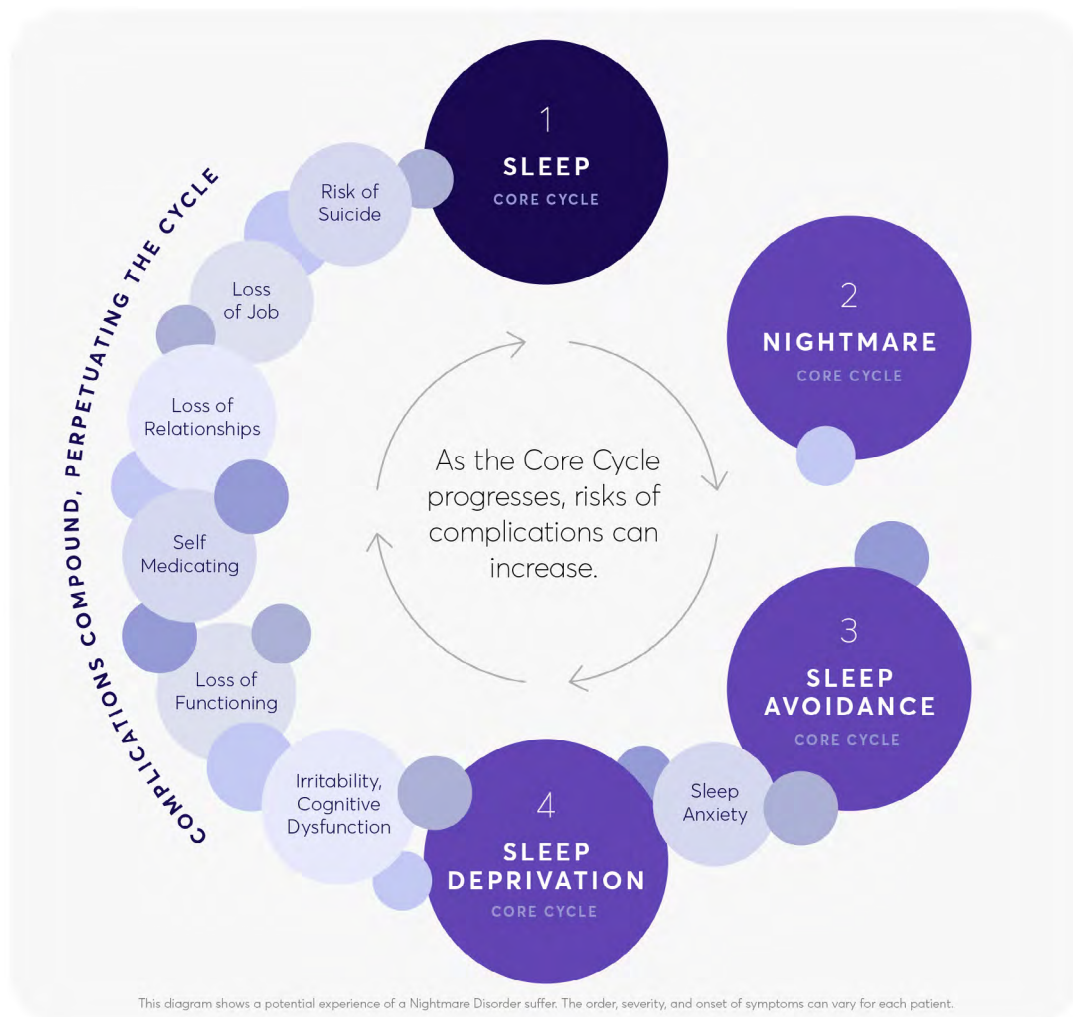
NIGHTMARES AND THE IMPACT ON PATIENTS

The Impact of Nightmares

Frequent nightmares disrupt sleep and often lead to chronic sleep deprivation. This sleep deprivation is associated with considerable social, financial, and health-related costs.¹ Sleep deprivation and sleep fragmentation related to nightmares are associated with cognitive performance deficits, a decreased positive mood, impaired learning, and attention deficits. A study by Li et al² demonstrated that insomnia symptoms, sleep-disordered breathing symptoms, and consequences of low-quality sleep—daytime fatigue and sleepiness, morning headache, and difficulty getting up in the morning—are well-correlated with increased nightmare frequency. This study found that insomnia correlated most strongly with nightmares. Psychiatric disorders, especially mood disorders, are also associated with frequent nightmares in multiple studies.³⁻⁵

FIGURE A

Nightmare Disorder Patient Experience

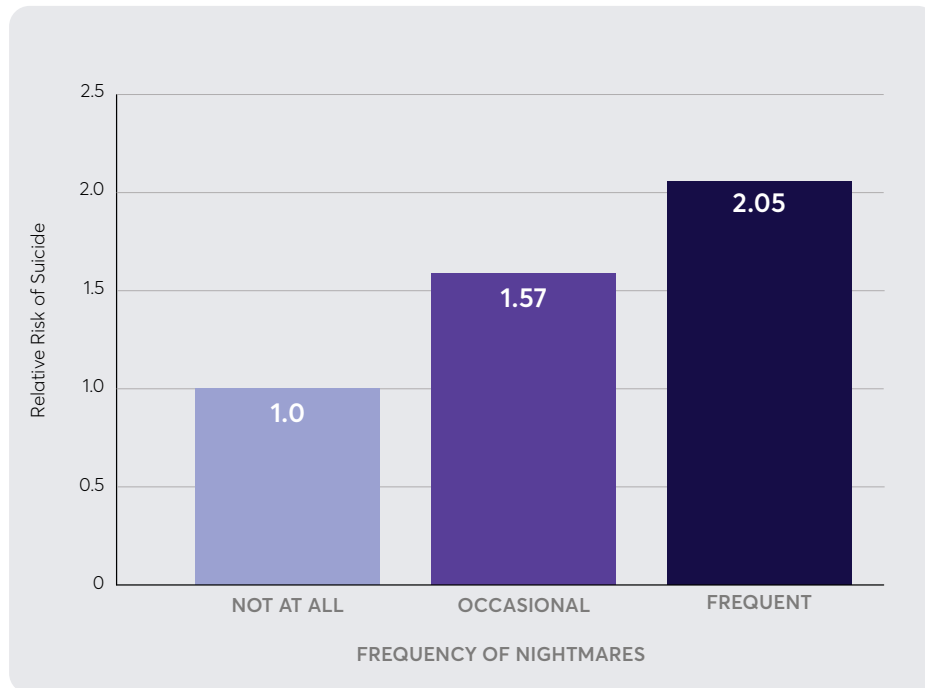


Suicide and Nightmares

Suicide is the 10th leading cause of death from all causes in the United States. Approximately 48,000 people die by suicide in the United States alone.⁶ The suicide rate in the U.S. Armed Forces has been rising in recent years, and in 2008, the military's suicide rate surpassed that of the general population.⁷ The suicide rate in 2016 for veterans was roughly double that of the non-veteran U.S. population.⁸ Frequent nightmares have been demonstrated to be an independent risk factor for repeated suicide attempts.⁹ Other research demonstrates this clear association between suicidality and nightmares.¹⁰⁻¹² Depressed patients with nightmares have been found to be more suicidal than those without nightmares.¹³ Tanskanen and colleagues conducted a large, prospective population-based study to evaluate the risk of suicide among adults with nightmares over a 20-year period. They found those with frequent nightmares at baseline were 57% more likely to die by suicide than those without nightmares (Figure B). These studies, taken together, demonstrate that nightmares are a unique predictor of suicidal ideation, suicide attempts, and completed suicide.

FIGURE B

Suicide Risk and Nightmare Frequency



Adapted from Tanskanen et al. Nightmares as predictors of suicide. *Sleep* 2001.

Important Safety Information

INTENDED USE/INDICATION FOR USE

The NightWare digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from post-traumatic stress disorder (PTSD). It is intended for home use.

CONTRAINDICATIONS

If you have acted out your nightmares (i.e. sleepwalking, violence) do not use NightWare and contact your Healthcare Provider.

WARNINGS

- NightWare is not a standalone therapy for PTSD. The device should be used in conjunction with prescribed medications for PTSD and other recommended therapies for PTSD-associated nightmares and nightmare disorder, according to relevant consensus guidelines.
- If daytime sleepiness occurs, contact your Healthcare Provider.
- If you feel drowsy, do not drive or operate heavy machinery. Contact your health care provider.
- If the watch vibration causes awakenings not associated with nightmares, please contact your Healthcare Provider.

- If nightmares persist, worsen, or recur, contact your Healthcare Provider.
- If skin irritation occurs, discontinue use of the watch and contact your Healthcare Provider.
- Your watch may disturb your bedpartner. Try not to expose your bedpartner to the watch at night.
- Do not wear the watch too tightly, it should feel comfortable and snug, not tight on your wrist.
- Wear the watch only when you are planning to go to sleep; do not wear it while reading or watching TV in bed as this may trigger false alerts.
- Use the NightWare watch every night.
- Not intended for use by individuals under age 22.
- The long term safety and effectiveness of the NightWare device has not been established.
- The long term effects of the NightWare device use on the sleep architecture have not been established.

PRECAUTIONS:

- Do not drop or crush the smartphone or watch.
- Be sure to charge the smartphone and watch every day.

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