Insights from a User Meeting on NightWare for PTSD-Related Nightmares: Impacts of Medications and Co-Morbidities

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Abstract:
This paper consolidates key insights from a user meeting discussing the use of NightWare, an innovative digital therapeutic device for Nightmare Disorder - a condition characterized by frequent distressing nightmares causing significant distress and functional interference. Despite a range of existing treatments, many patients remain unresponsive, thus necessitating innovative solutions such as NightWare. The user meeting, attended by clinicians from sleep medicine, psychiatry, psychology, and internal medicine, and moderated by COL (Ret.) Brian Robertson, MD, Chief Medical Officer of NightWare, yielded important findings. Discussions focused on the impact of medications and comorbidities on NightWare's efficacy, emphasizing that drugs altering heart rates could challenge the device's functioning until the algorithm adjusts, and comorbidities like insomnia and obstructive sleep apnea could disrupt sleep patterns, potentially reducing effectiveness. Hence, the concurrent management of these conditions alongside NightWare's use is crucial. Moreover, patient adherence to the device, necessitating its use for at least 50% of nights, significantly influenced treatment outcomes. Additionally, common patient FAQs were addressed, clarifying device usage and data security concerns. This paper serves as a resource for clinicians treating Nightmare Disorder, providing practical insights into optimizing the use of NightWare and improving patient outcomes.

Introduction:
Nightmares are unsettling dreams that not only interrupt sleep but can also lead to significant emotional distress and hindrance in everyday activities. The DSM-5 identifies Nightmare Disorder as a condition characterized by frequent, troubling nightmares resulting in substantial distress or interference in societal, vocational, or other aspects of life. There are multiple treatment options for Nightmare Disorder, however, a large number of patients prove unresponsive to these treatments, leading to considerable health problems. NightWare presents an innovative, non-invasive, and non-drug related wearable digital therapeutic that employs smartwatch technology to identify and interrupt nightmares during sleep. This paper aims to consolidate and present the learnings from a NightWare user meeting and explore their potential impact for healthcare professionals treating individuals with Nightmare Disorder.

Participants:
The meeting was moderated by COL (Ret.) Brian Robertson, MD, Chief Medical Officer of NightWare and attended by five clinicians supporting active duty military personnel representing sleep medicine, psychiatry, psychology, and internal medicine. Clinicians preferred to not disclose their names.

Methods:
The user meeting was attended by sleep medicine doctors, psychiatrists, and other healthcare providers who treat patients with nightmare disorder. The meeting was designed to gather feedback from prescribers about the use of NightWare in clinical practice, including impact of medications on NightWare and impact of comorbidities on NightWare. The meeting was structured as a moderated discussion, and the insights gained were recorded and summarized.

Results:
The user meeting generated several insights that have important implications for clinicians who treat patients with nightmare disorder. These insights are organized into the following categories: impacts of medication on NightWare efficacy, effect of comorbidities on NightWare efficacy, patient adherence and compliance, and patient FAQs.

Impacts of medication on NightWare efficacy:

- **Medications, especially those affecting heart rate, can affect NightWare's efficacy until algorithm adjusts**
- **Need for clear communication about patient's medication changes**

The clinicians' discussion highlighted a crucial aspect of NightWare's efficacy—its interaction with medications. Many medications can alter the resting and sleeping heart rate for users. Such alterations can pose challenges to NightWare, which operates by monitoring and understanding a patient's unique sleep patterns to alleviate nightmares. For example, beta-blockers can lower the heart rate for patients taking them. This change would interfere with the Stress Index threshold calculated by the NightWare algorithm. Therefore, any changes in a patient's medication regimen might necessitate a readjustment period for NightWare to relearn the patient's sleep patterns, highlighting the need for clear communication about medication changes to patients using NightWare.

Effect of comorbidities on NightWare:

- **Comorbidities like OSA and insomnia can affect NightWare's effectiveness**

- **Concurrent treatment of comorbid conditions optimizes NightWare's benefits**

The clinicians further discussed the interaction of NightWare with comorbidities like insomnia and obstructive sleep apnea (OSA), which are common among PTSD patients. These conditions can disrupt sleep patterns and hence skew the sleep data needed for the calculated Stress Index threshold. For instance, insomnia can interfere with the device's ability to accurately analyze sleep patterns, potentially reducing its effectiveness. Similarly, OSA can lead to fragmented sleep, making it difficult for NightWare to discern and accurately interrupt nightmares. Consequently, the clinicians highlighted the importance of treating these comorbid conditions concurrently to maximize NightWare's benefits. The discussion underscores the need for a holistic approach to treatment, encompassing medication management, treatment of comorbidities, and the utilization of NightWare.

Patient adherence and compliance:

- **For best outcomes, NightWare should be used more than 50% of nights**
- **Patient education leads to better compliance and outcomes**

Patient compliance to treatment is an important concern. Optimal outcomes through the use of NightWare require daily usage, or at least 50% of nights. Therefore, clinicians must emphasize this during consultations to ensure the best therapeutic outcomes, while concurrently managing comorbidities and adjusting medications as needed.

Patient FAQs:

- **Location services are turned off**
- **Devices cannot be overcharged**
- **Ensure iPhone is connected to WiFi for optimal treatment**

Regarding device use, patients expressed concerns about data security, overcharging, and device connection. In light of this, clinicians should clarify that location services are turned off by default, devices can't be overcharged, and Wifi is required for updating the stress index and threshold.

Conclusion:

This user meeting on NightWare provided valuable insights into the utilization of this digital therapeutic device for Nightmare Disorder, particularly for PTSD-related nightmares. The meeting underscored the impact of medications and comorbidities on the device's efficacy and highlighted the importance of patient adherence for optimal outcomes. Understanding the

interaction between NightWare and medications that influence heart rate, managing comorbid conditions such as insomnia and obstructive sleep apnea, and ensuring patient adherence to the device usage guidelines are pivotal aspects of improving treatment outcomes. Moreover, clinicians' ability to address common patient concerns and misconceptions about the device plays a significant role in ensuring compliance and optimizing outcomes. The insights from this meeting hold valuable implications for healthcare professionals treating Nightmare Disorder and nightmares associated with PTSD.

Meeting insights will be incorporated into the NightWare Clinical Treatment Guidelines which provides prescribing clinicians the best practices for maximizing outcomes through utilizing NightWare. If you would like to request access to this document you may email nightwareprofessionaleducation@nightware.com or visit the Prescriber Resources section at www.nightware.com.