Insights from a User Meeting on NightWare for PTSD-Related Nightmares: Patient Selection and Criteria

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Abstract:

NightWare is a digital therapeutic device designed to help individuals suffering from nightmare disorder and post-traumatic stress disorder (PTSD). This white paper summarizes the insights gained from a user meeting attended by sleep medicine doctors, psychiatrists, and other clinicians who have used NightWare in their practice. The meeting focused on key aspects of patient selection, including the challenges associated with identifying patients who could benefit from NightWare, and the importance of careful patient screening to ensure the device is appropriate for their condition. The users also discussed the effectiveness of NightWare in reducing nightmare frequency and severity, and its potential as an adjunct therapy for patients with PTSD. Additionally, the meeting addressed concerns related to patient stigma and misconceptions about the impact of PTSD on military careers. Overall, the insights gained from this meeting provide valuable guidance for clinicians who are considering NightWare as a treatment option for patients with nightmare disorder or PTSD.

Introduction:

- NightWare utilizes smartwatch technology and proprietary algorithms to detect and interrupt PTSD-related nightmares during sleep.
- The user meeting provided key insights and recommendations for the clinical application of NightWare to improve treatment outcomes.

Nightmares are a common symptom in patients with PTSD, and they can significantly affect quality of life, mental health, and overall well-being. NightWare is a medical device that uses smartwatch technology and proprietary algorithms to detect and interrupt PTSD-related nightmares during sleep. A user meeting was conducted to discuss the clinical application of NightWare, with clinicians sharing their experiences and insights on the use of the device. This white paper summarizes the key insights and recommendations discussed during the user meeting for clinicians who did not attend.

Participants:

The meeting was moderated by COL (Ret.) Brian Robertson, MD, Chief Medical Officer of NightWare and attended by 5 clinicians supporting active-duty military personnel representing psychiatry, sleep medicine, psychology, and family medicine. Clinicians preferred to not disclose their names.

Clinical Assessment Tools:

- The Nightmare Disorder Index (NDI) is a useful tool for assessing nightmare frequency and severity, although its question on duration may be less useful.
- Data from NightWare itself can be a valuable resource for clinicians to track patient progress and make informed treatment decisions.

The user meeting discussed various clinical assessment tools used to assess the response to treatment in patients with PTSD-related nightmares. The Nightmare Disorder Index (NDI) was identified as a useful tool by one clinician. It was noted that the NDI is a simple and easy-to-use questionnaire with four questions that can provide useful information about the frequency and severity of nightmares. However, it was also noted that the fifth question on the NDI, which asks about the duration of nightmares, may not be clinically useful.

Another clinician mentioned that they prefer to follow up with patients by talking to them rather than using a questionnaire response. They ask patients to bring in their phone or watch and look at the data to assess the number of interventions, whether they are going up or down, the overall impression, and the impression of spouses. The data from the device was found to be a useful tool for clinicians to track the patient's progress and make informed decisions.

Patient Selection:

- Good candidates for NightWare include patients who have not responded to other treatments, have difficulty adhering to traditional treatments, or are motivated to use technology.
- Alcohol use, sleep anxiety, and menstrual cycle impacts should be considered and addressed to optimize treatment outcomes with NightWare.

There were several factors that participants identified other clinicians should consider when selecting patients who could benefit from NightWare.

First, patients who suffer from PTSD-related nightmares and have not responded well to other treatments could be good candidates for NightWare. NightWare may be especially useful for patients who are not good candidates for medication due to concerns about side effects or who have had limited success with other treatments like CBT. NightWare can help regardless of trauma. Patients with combat trauma, sexual trauma, and childhood trauma can all benefit from NightWare.

Secondly, patients who have difficulty adhering to traditional treatments like CBT or who may not have easy access to specialized care could benefit from NightWare. This could include patients who live in rural or remote areas, patients who have limited mobility or transportation, or patients who work unconventional hours that make it difficult to attend appointments.

Thirdly, patients who are motivated to use technology and are willing to engage with the device as part of their treatment plan could be good candidates for NightWare. This may include younger patients or patients who are comfortable using technology as part of their daily lives.

It was also noted that alcohol use can be a significant contributor to poor outcomes with NightWare. Clear communication between clinician and patient is essential for optimizing outcomes regarding alcohol and NightWare. Further, clinicians should do their best to coach patients to help them avoid sleep anxiety. It can also be important to educate patients on the impacts that menstrual cycles can have on nightmares.

It is important to note that while NightWare may be beneficial for some patients, it is not appropriate for everyone. Clinicians should carefully consider the individual needs and preferences of each patient before recommending NightWare as a treatment option. Additionally, clinicians should ensure that patients are fully informed about the device, its potential benefits and limitations, and the level of engagement required to use it effectively.

Follow-Up Plans:

- Patients should use NightWare for at least 2-3 weeks before the first follow-up appointment, with subsequent follow-ups tailored to individual needs and clinical resources.
- When patients transition from military to civilian care, accurate data transfer is critical to ensure continued and appropriate care.

The user meeting also discussed follow-up plans for patients using NightWare. It was recommended that patients should use the device for at least two to three weeks before the first follow-up appointment. The duration between follow-up appointments may vary depending on the patient's individual needs and the availability of clinical resources. Clinicians may follow up with patients every two to three weeks if they are working with patients with PTSD, but if they are dealing with nightmares themselves, the recommended follow-up period was at least two to three weeks, and possibly up to a month.

When the patient leaves the military and moves to a civilian network provider, it is essential to transfer access to their data to their new provider. The device's data and patient information must be accurately shared with the new provider to ensure that the patient receives appropriate and continued care.

Use of PCL-5:

- Question two on the PCL-5 can be useful for assessing nightmare frequency and severity in PTSD patients.
- The PCL-5 is a widely used tool in clinical practice for patients with PTSD and can be incorporated into standard procedures.

The PCL-5 is a widely used clinical assessment tool that is used to assess PTSD symptoms. It was mentioned during the user meeting that question two on the PCL-5, which asks about repeated disturbing dreams of the stressful experience, can be useful to assess the frequency and severity of nightmares in patients with PTSD. The PCL-5 was noted to be a commonly used tool in clinical practice for patients with PTSD, with clinicians using it in their standard procedures.

Stigma and Misconceptions:

- Clinicians must address the stigma surrounding PTSD treatment and reassure patients that seeking help and using NightWare will not adversely affect their military career.
- Efforts to educate patients and the public about PTSD are important to reduce stigma and misconceptions.

The user meeting also discussed the stigma associated with behavioral health and PTSD in the military community. It was noted that many patients are reluctant to seek treatment for fear of losing their military career, clearance, or the stigma associated with PTSD. One clinician pointed out that untreated PTSD can lead to more problems with work performance and security clearances; having a PTSD diagnosis does not, in itself, endanger your career. It was emphasized that clinicians need to reassure patients that seeking behavioral health care and using NightWare will not adversely affect their military career. It was also noted that the stigma associated with PTSD still exists, despite the efforts of clinicians to educate patients and the public.

Conclusion:

The user meeting provided valuable insights into the clinical application of NightWare for patients with PTSD-related nightmares. The NDI, PCL-5, and patient data collected from the device were identified as useful clinical assessment tools to assess the frequency and severity of nightmares and track patient progress. Follow-up plans for patients should be individualized based on patient needs and clinical resources.

Clinicians should also be aware of the potential concerns that patients may have regarding seeking treatment for PTSD. As discussed during the user meeting, many patients are worried that seeking treatment for PTSD may negatively impact their military career, result in loss of clearance, or carry a stigma. In fact, it is more likely that untreated PTSD symptoms are a much larger threat to military careers than the PTSD diagnosis. It is important for clinicians to work with patients to address these concerns and normalize seeking treatment for PTSD. The NightWare device may be particularly beneficial for patients who are hesitant to seek traditional therapy due to these concerns. Clinicians should also be aware of the potential for patients to discontinue use of the NightWare device prematurely, particularly if they do not see immediate results. Patients should be informed that it may take some time for the device to calibrate to their individual sleep patterns and that continued use may be necessary to achieve optimal results.

Overall, the user meeting provided valuable insights into the clinical use of the NightWare device for the treatment of PTSD-related nightmares. Clinicians should consider incorporating the device into their treatment plans, particularly for patients who have not responded to traditional therapies or who are hesitant to seek treatment. The device should be used in conjunction with ongoing therapy and regular follow-up assessments to monitor progress and ensure optimal treatment outcomes. Further research is needed to better understand the

long-term efficacy and safety of the device, but early results are promising and suggest that it may be a valuable tool in the treatment of PTSD-related nightmares.

Meeting insights will be incorporated into the <u>NightWare Clinical Treatment Guidelines</u> 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 <u>nightwareprofessionaleducation@nightware.com</u> or visit the Prescriber Resources section at <u>www.nightware.com</u>.