NIGHTWARE

DIGITAL THERAPEUTIC

TAKE SLEEP BACK. MOVE LIFE FORWARD.

Please refer to page 6 for safety and indication information.
The IFU can be found at www.NightWare.com.

PTSD/PTS* NIGHTMARES

There have been no FDA cleared therapies specifically for nightmares associated with PTSD. The majority of patients with PTSD report sleep disturbances, mostly nightmares and insomnia. Frequent nightmares disrupt sleep and often lead to chronic sleep deprivation. The resulting sleep deficiencies are associated with considerable social, financial and health related costs — even suicide.

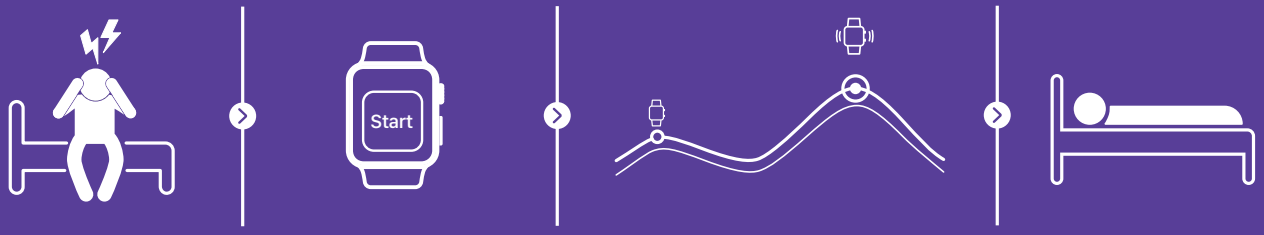
Key facts about nightmares:

- Nightmares affect 2–8% of the general population[1] — a number that is thought to be higher among members of the military.
- 72% of patients with PTSD have comorbid nightmares
- Nightmares are present in many patients with depression, insomnia and especially PTSD
- Frequent nightmares are independent risk factors for suicide[2]

Current nightmare treatments[3]

- A drug indicated for hypertension is the most commonly prescribed treatment for nightmares
- Imagery Rehearsal Therapy and other forms of re-scripting therapy
- Cognitive Behavioral Therapy

When a patient presents with recurring nightmares, NightWare can be prescribed to help improve the patient's sleep quality. NightWare is designed to disrupt nightmares and improve sleep.



Patient with nightmares experiencing poor quality of sleep and distress

Prescribed NightWare which delivers therapy through the iPhone and Apple Watch provided in the kit

Patient data collected and evaluated to create custom sleep profile that provides interventions to interrupt nightmares

Patient gets better quality of sleep

* For many Veterans, the use of the word "Disorder" serves as a barrier to receiving care. They believe that the symptoms associated with the trauma they experienced are not a "Disorder." For the purpose of supporting the needs of all Veterans, Nightware recognizes that many use PTS instead of PTSD.

WHAT IS NIGHTWARE AND HOW DOES NIGHTWARE WORK[1]?

NightWare is the first and only FDA cleared digital therapeutic to interrupt nightmares and improve sleep quality.

- NightWare must be prescribed by a physician. It is not an app available for download.
- NightWare's platform uses artificial intelligence (AI) algorithms to interrupt nightmares
- It pairs cloud-based AI with the easy-to-use Apple Watch® and iPhone® provided in the kit
- The Apple Watch's heart rate sensor, accelerometer and gyroscope collect signals that are consistent with a nightmare
- NightWare calculates a patient's unique "stress index"† to develop personalized treatment
- Interrupts nightmares via vibrotactile feedback through the prescribed Apple Watch

"I was headed for a catastrophic collision."

Robert Guithues, U.S. Army (Retired)
Combat Tours: Iraq and Afghanistan
NightWare User Since 2014*

"For 3 months I wasn't sleeping due to nightmares and I was dealing with the pain of a spinal injury. Due to the sleep deprivation and physical pain I was out of it. There were times I couldn't remember the details of my 30 minute drive to work. I became hypervigilant - sleeping with my weapon nearby because I had lost mental clarity. I knew I needed help. I didn't like who I had become. I'm glad I was able to find NightWare. It has been a godsend."

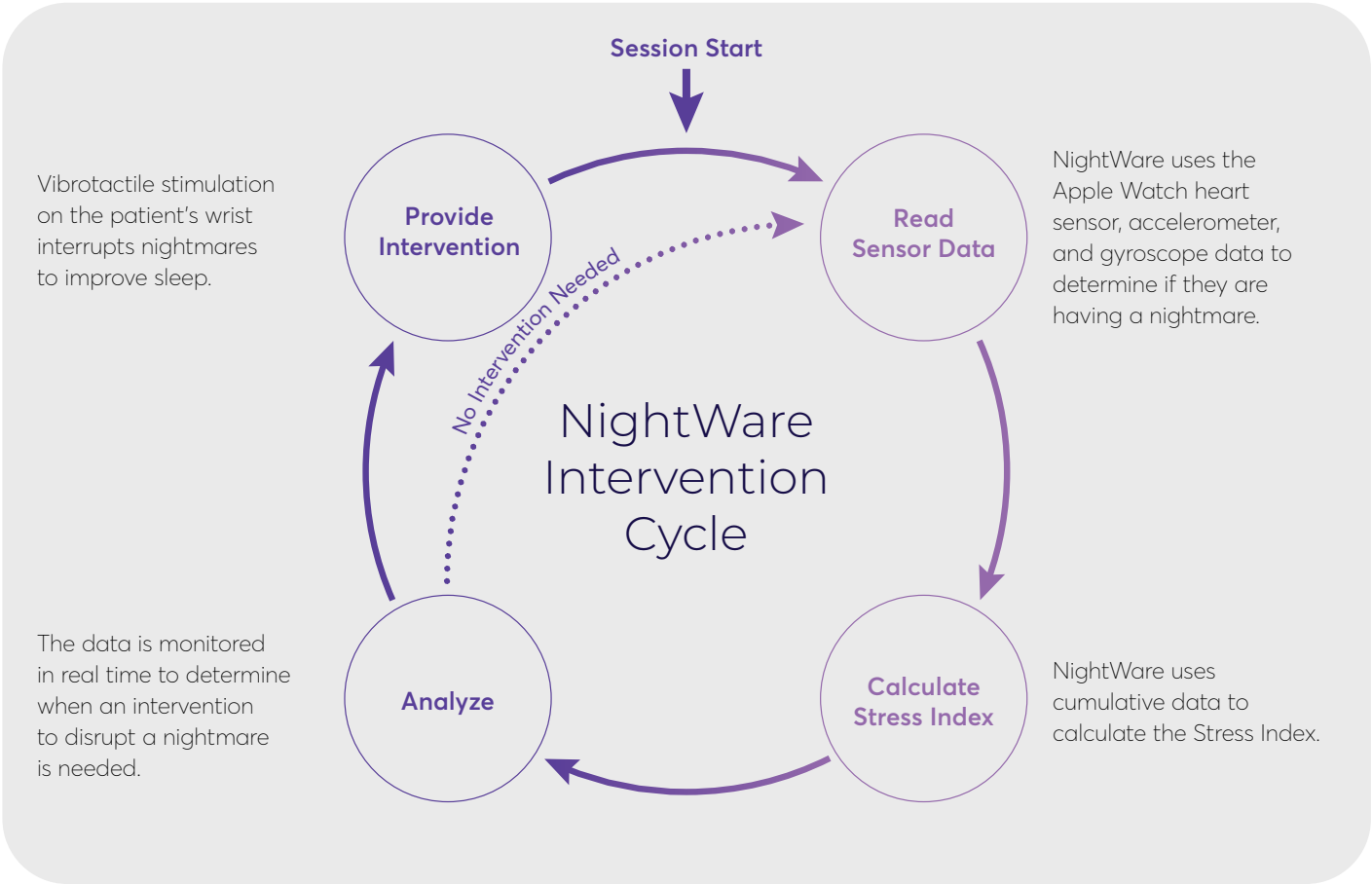
* Participant in clinical trial

† Stress Index is a device-specific measurement and does not represent a clinically validated measure of stress.

BENEFITS OF NIGHTWARE

- Non-pharmaceutical/non-invasive treatment option with a low-risk safety profile
- Safe to use with other therapies
- Clinical trials were conducted with Veterans and are ongoing
- Works fast — within a few days or weeks to improve sleep quality

NightWare improves sleep by interrupting nightmares when they happen. It is a non-invasive treatment option for those suffering from persistent nightmares.



CLINICAL SUPPORT

NightWare demonstrated efficacy in placebo-controlled clinical trials[1]

NightWare's safety and efficacy is supported by a double-blind, sham controlled, randomized clinical trial (NW101002). 70 participants were enrolled in the trial. Patients in the sham group wore the device, but no vibratory stimulation was provided. The evidence demonstrated the probable benefits outweighed the probable risks.

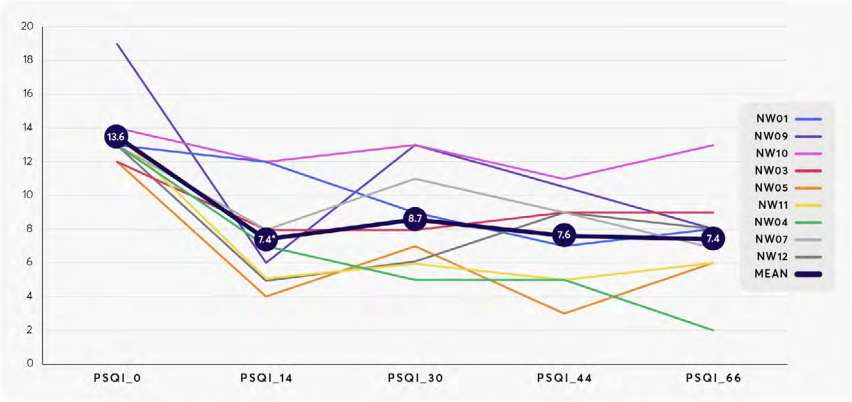
Summary:^

- The primary measure of relative efficacy was the difference in mean PSQI change between NightWare and placebo arms. The difference observed between the active and sham groups was 1 point.†
- 3.2-point improvement on the Pittsburgh Sleep Quality Improvement Scale in an ongoing randomized controlled trial*
- Exceeds the minimal clinically important difference
- The PSQI-A improvement was more than double that of the sham device*
- PSQI-A measures important differences in sleep quality directly related to PTSD

In an open-label pilot study[4] of NightWare in 9 subjects, there was a large effect size of a 6-point improvement in the Pittsburgh Sleep Quality Index (PSQI), a well-validated measure of sleep quality [Figure 1].

FIGURE 1

Total PSQI at Biweekly Assessments

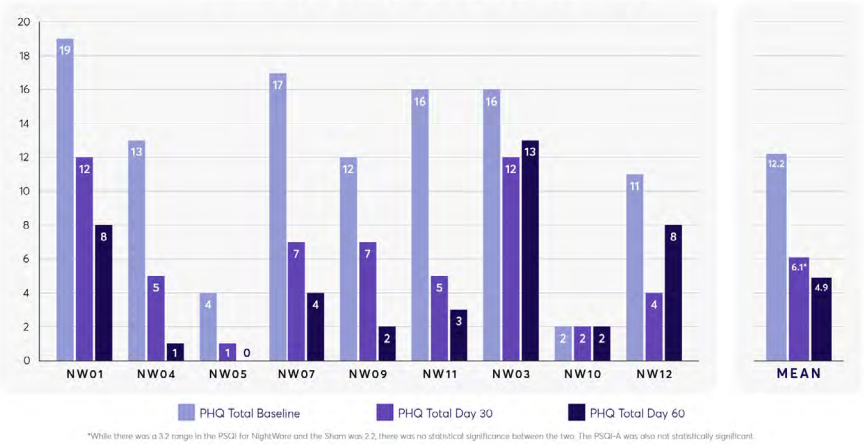


*While there was a 3.2 range in the PSQI for NightWare and the Sham was 2.2, there was no statistical significance between the two. The PSQI-A was also not statistically significant.

Additionally, the Patient Health Questionnaire 9 (PHQ-9), a standard questionnaire to measure the severity of depressive symptoms demonstrated a 6-point improvement [Figure 2].

FIGURE 2

Total PHQ at Monthly Assessments



*While there was a 3.2 range in the PSQI for NightWare and the Sham was 2.2, there was no statistical significance between the two. The PSQI-A was also not statistically significant.

^ These are interim data. Clinical trials are ongoing.
† These results were not statistically significant
* While there was a 3.2 range in the PSQI for NightWare and the Sham was 2.2, there was no statistical significance between the two. The PSQI-A was also not statistically significant.

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.

REFERENCES

NightWare. (2020). Provider Instructions for Use: FDA Instructions for Use. Hopkins, MN. NightWare.

1. Sjöström N, Hetta J, Waern M. Persistent nightmares are associated with repeat suicide attempt: a prospective study. Psychiatry Res. 2009;170(2-3):208–211.
2. Department of Veterans Affairs, Department of Defense. VA/DoD clinical practice guidelines for the management of posttraumatic stress disorder and acute stress disorder. 2017. https://www.healthquality.va.gov/guidelines/MH/ptsd/VADoDPTSDCPGFinal.pdf Accessed 25 Apr 2020.
3. Data on file at NightWare.

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