Insufficient Sleep and Nightmares

Sleep Hygiene and Beyond

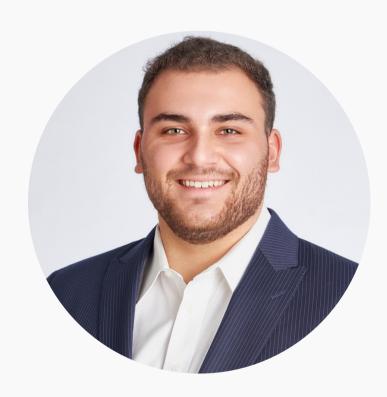
INTRODUCTIONS



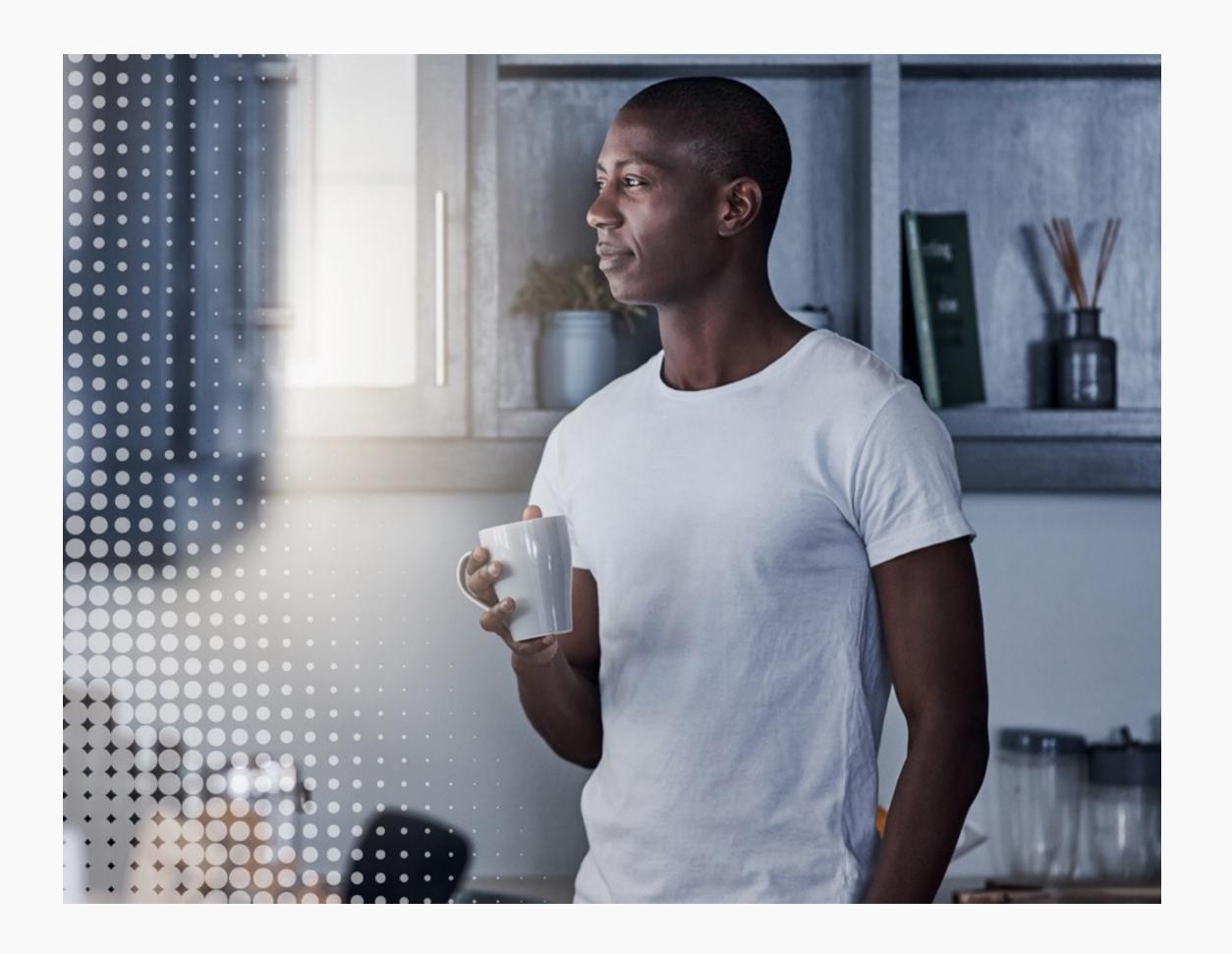
Brian Robertson, MD Chief Medical Officer NightWare



Kenneth Rayl, MBA
Director of Clinical Affairs
NightWare



Brant Newman
Business Development
NightWare



IT'S ABOUT MORE THAN JUST SLEEP

YOU ARE NOT ALONE!

UP TO 80% OF SERVICE MEMBERS WITH PTSD SUFFER FROM NIGHTMARE DISORDERS

Importance of Sleep in PTSD Patients

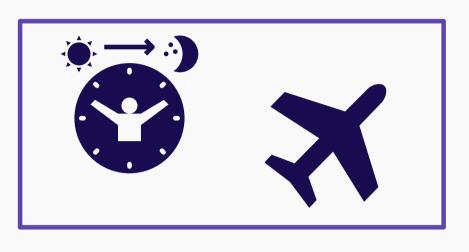
- Disturbed Sleep Patterns in PTSD Patients:
 - Nearly 100% experience sleep disturbances
 - Nightmares and insomnia are most common issues
- Benefits of Improved Sleep
 - Reduced Anxiety: Direct link between sleep quality and anxiety levels
 - Better Mood: Less irritability, mood swings, and potential depression
 - Enhanced Memory & Concentration: Sleep is vital for cognitive functions
 - Improved Physical Health: Sleep affects overall health, reducing risks like heart disease, obesity, and diabetes
 - Reduced Hyperarousal: Decreased symptoms making relaxation easier

Insufficient Sleep and Nightmares

A Global

& U.S. Public Health Problem

Causes of Insufficient Sleep are Complex



Occupation

Shift Work, Prolonged Working Hours, Jet Lag, Early School Start Times, Military Service



Lifestyle

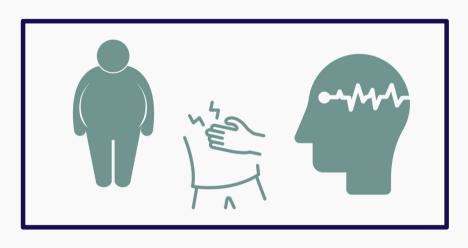
Irregular Sleep Schedules, Stress, Video Games, Alcohol, Caffeine & Nicotine Use



Medical/Psychological

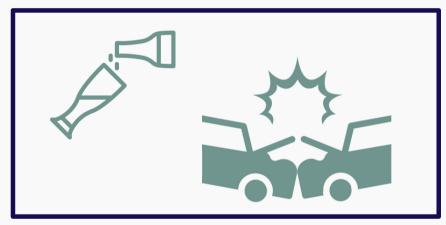
Insomnia, Sleep Apnea, Restless Leg Syndrome, Narcolepsy, Nightmares, Anxiety, Depression, PTSD

Insufficient Sleep Leads To Significant Health Problems



Health Problems

Obesity, Diabetes, Heart Disease, Cancer, Suicidal Thoughts, Depression, Anxiety, Cold & Flu



Risky Behaviors

Impaired Function, Memory Problems, Poor Reaction Time, Increased Incidence Of Accidents, Substance Abuse



Mortality Risk

A greater risk of mortality is seen in both men and women when recommend hours of sleep is not achieved

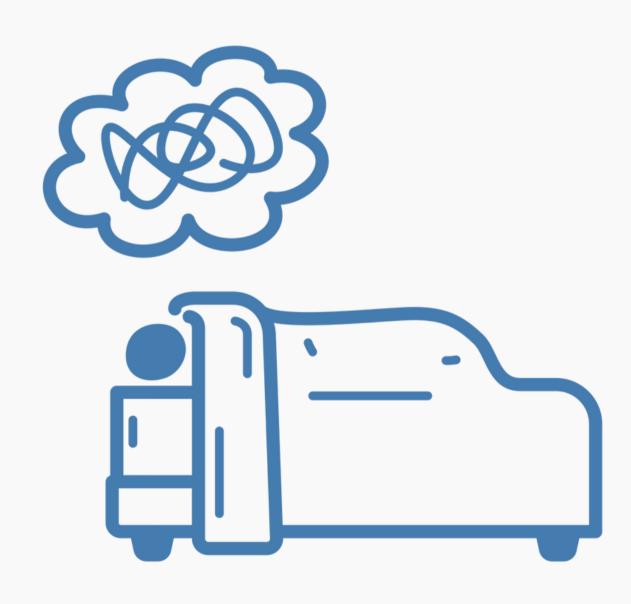
What is Nightmare Disorder?

- 1. Repeated frightening dreams that impact quality of life
- 2. Nightmare disorder can range from mild to severe
- 3. Nightmare disorder can be short-term (<1 year) or chronic
- 4. Very common in patients diagnosed with PTSD

What are Nightmares?

Nightmares are:

- Complex, vivid, well-remembered dreams that are frightening and can cause you to awake suddenly
- Symptoms often include: sweating, shortness of breath and arm/leg movements and feelings of fear, anger, shame and/or sadness
- Frequently associated with stressful or traumatic events and/or medications



UP TO 70% OF ADULTS SUFFERING FROM MENTAL HEALTH CONDITIONS REPORT RECURRENT NIGHTMARES



compared to 3.4-11% without mental health conditions

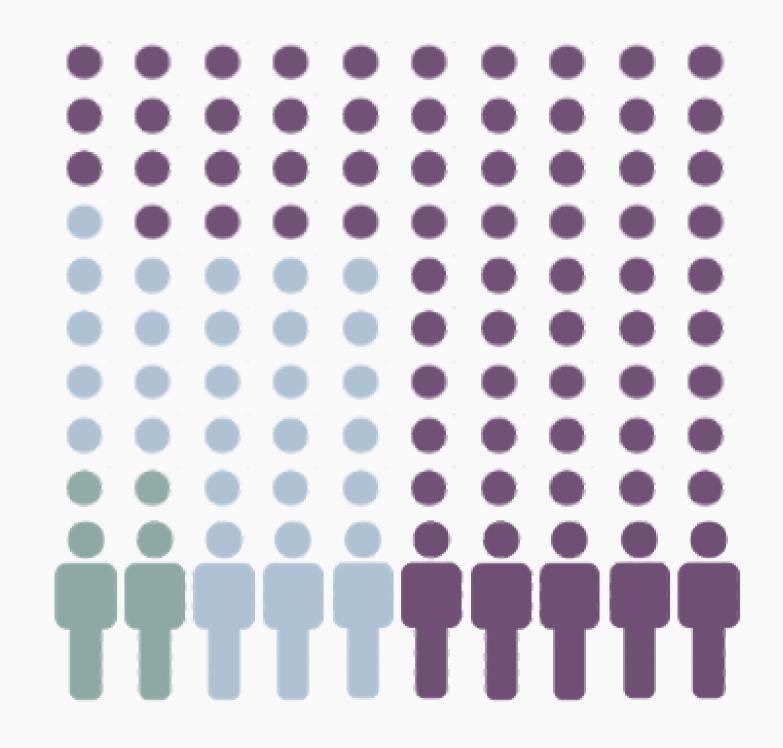
PTSD, post traumatic stress disorder

1. Singh S et al. Cureus 2018; 10(12): e3807. 2. Nadorff MR et al. J Clin Sleep Med 2015; 11(7):747-750. 3. Gieselmann A, et al. J Sleep Res 2019; 28:e12820. 4. Swart ML, et al Psychother Pyschosom 2013; 82:267-268.

NIGHTMARES ARE UNDERDIAGNOSED!

Study:

- Retrospective sample of active duty patients in a military sleep clinic
- Nightmares significantly associated with:
 - Insomnia
 - Depression
 - Anxiety
 - o PTSD
- 3.9% of the 493 patients reported nightmares
- 31.2% had clinically significant nightmares
- <u>Approximately 85% of patients with nightmares</u>
 <u>go undiagnosed</u>



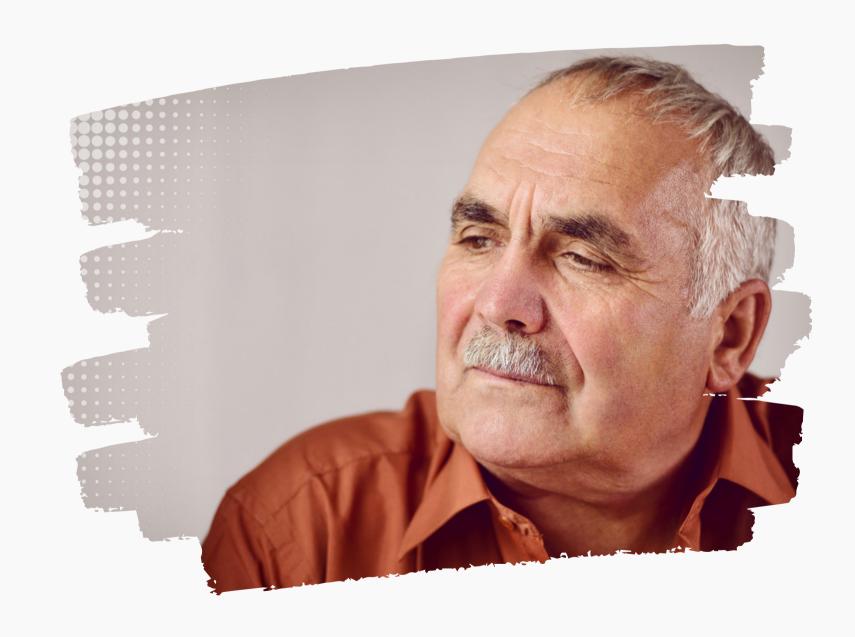
Self-Reported

Have Nightmares

No Nightmares

Nightmares and Suicide

- Nightmares linked to increased suicidality in patients with depression and mood disorders
- 72% of women with depression who experience frequent nightmares show higher suicidal tendencies compared to those without nightmares
- Nightmares are an independent risk factor for suicidal ideation, attempts, and death



The "Hidden" Effects of Nightmares

Sleep Anxiety
Delayed Sleep
Insufficient Sleep



- Job Problems
- Relationship Challenges
- Increased Risk of Suicide

Memory Problems
Emotional Challenges
Difficulty With Tasks





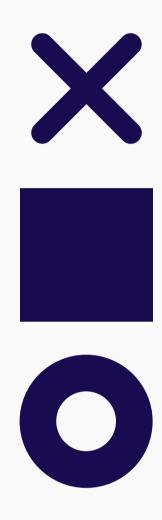




MENTAL DECLINE

PERSONAL CHALLENGES

PEOPLE WITHOUT WEEKLY DISTRESSING DREAMS/NIGHTMARES DEMONSTRATED A SIGNIFICANTLY LOWER RISK FOR MENTAL DECLINE AND DEVELOPING DEMENTIA COMPARED TO THOSE WITH WEEKLY DISTRESSING DREAMS, WITH THE LATTER GROUP SHOWING A 4.0-FOLD RISK FOR MENTAL DECLINE AND A 2.2-FOLD RISK FOR DEVELOPING DEMENTIA.



aOR, adjusted odds ratio;

1. Otaiku Al. The Lancet.com 2022;52:101640

The Prevalence of Nightmares in Veterans and PTSD Patients

Combat Exposure & Nightmares

- Personnel who underwent combat report more recurrent nightmares
- Case Study: World War II Veterans
 - Men: 7.2% reported frequent nightmares
 - Women: 7% reported frequent nightmares
 - Civilian average: 3.7% with nightmares

PTSD & Nightmares

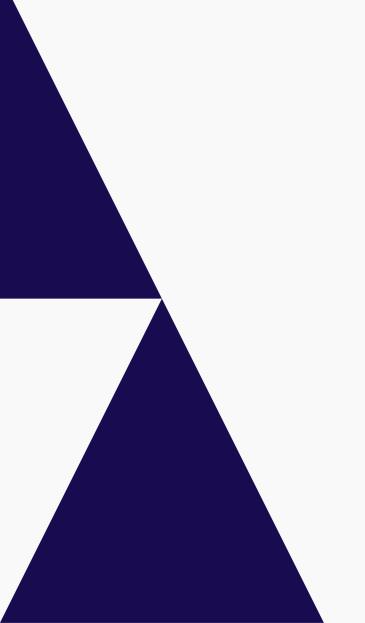
- 50-80% of PTSD patients experience trauma-related nightmares
- 52.4% of combat veterans with PTSD report frequent nightmares

Comparison with other groups

- Combat veterans without PTSD: 4.8%
- Civilians: 3.4%

Nightmare Disorder

Etiology



Etiology of Nightmares

Distress

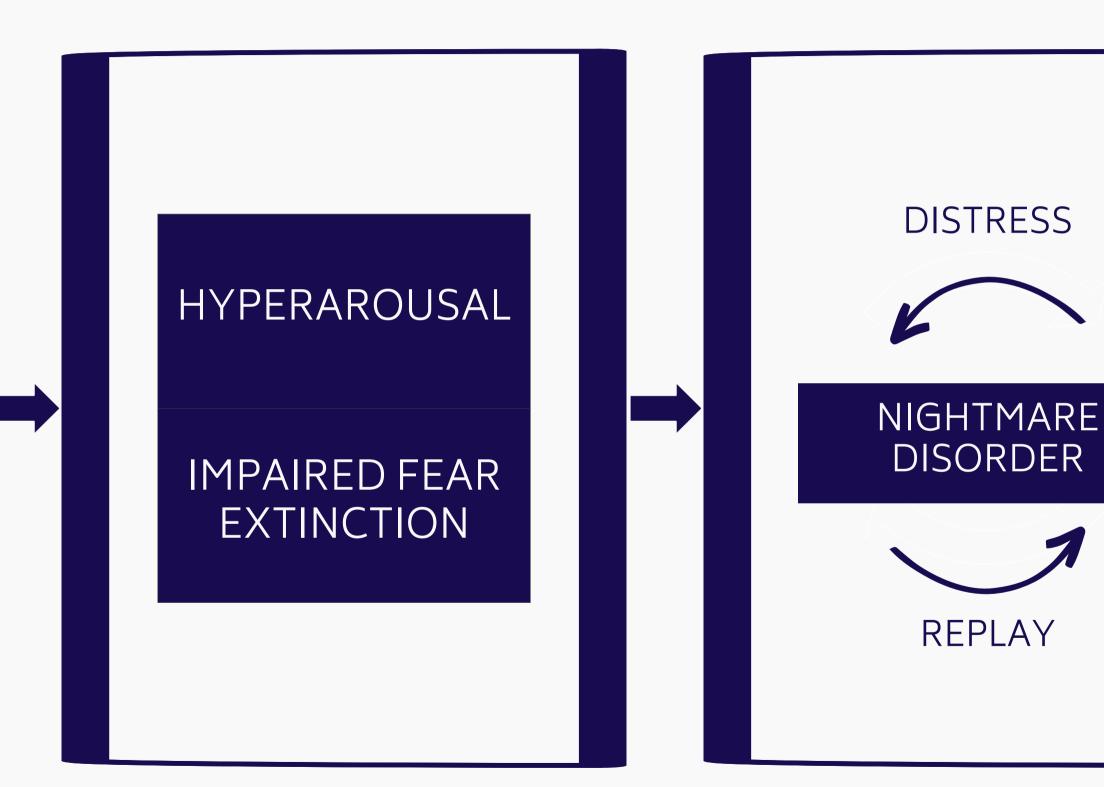
 (i.e., traumatic experiences, childhood adversity, and trait susceptibility)

Cognitive factors

 (i.e., maladaptive beliefs, thought suppression)

Physiologic factors

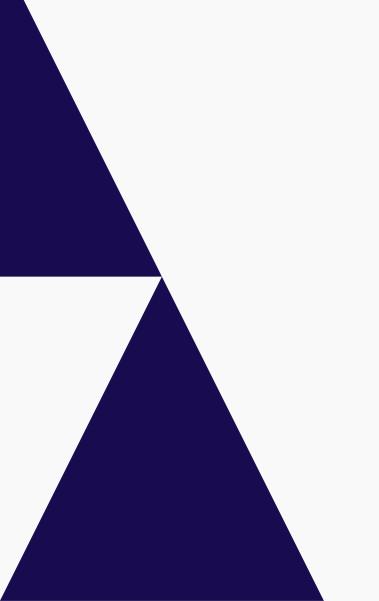
 (i.e., chemosensory pathways, hypoxia, medications)





Nightmare Disorder

Patient Journey



Insufficient Sleep

Are You At Risk?

ASK YOURSELF

How many hours do you sleep on an average night?

During the past month, how would you rate your sleep quality overall?

Do you go to bed and wake up at the same time every day, even on weekends?

How likely is it that you would fall asleep during the daytime without intending to or that you would struggle to stay awake while you are doing things?

How often do you have trouble going to sleep or staying asleep?

During the past 2 weeks, for about how many days did you have loud snoring?

Insufficient Sleep

Treatments for Nightmare Disorder (ND)

Healthy Sleep Habits

ESTABLISH A RELAXING BEDTIME ROUTINE

- Turn off electronic devices at least 30 minutes before bedtime
- Don't eat a large meal before bedtime. If hungry at night, eat a light, healthy snack
- Avoid consuming caffeine in the afternoon or evening
- Avoid consuming alcohol before bedtime
- Reduce your fluid intake before bedtime

DON'T GO TO BED UNLESS YOU ARE SLEEPY

- If you don't fall asleep after 20 minutes, get out of bed. Go do a quiet activity without a lot of light exposure. It is especially important to not get on electronics
- Use your bed only for sleep and sex

MAKE YOUR BEDROOM QUIET AND RELAXING

- Keep the room at a comfortable, cool temperature
- Limit exposure to bright light in the evenings





- Get up at the same time every day, even on weekends or during vacations
- Set a bedtime that is early enough for you to get at least 7-8 hours of sleep



EXERCISE REGULARLY + MAINTAIN A HEALTHY DIET



- Exercise at moderate intensity for at minimum of 30 minutes a day, five days each week
- Focus on a variety of nutrient-dense foods



Current Therapies for Nightmare Disorder

- Therapies you may be aware of:
 - Medical management with prazosin
 - Imagery Rehearsal Therapy (IRT)
 - Cognitive Behavioral Therapy (CBT)
 - Exposure, relaxation, and rescripting therapy (ERRT)
 - Eye movement desensitization & reprocessing (EMDR)
- NightWare*
 - Is the only FDA cleared therapy for the temporary reduction in sleep disturbances related to Nightmare Disorder in adults 22 years and older.**
 - Leverages an Apple watch and a smartphone, along with a propriety algorithm to reduce the impact of nightmares and improve sleep quality.
 - Do not use NightWare if you have been known to "act out" your nightmares (i.e. sleepwalking, violence, etc).



The effects of NightWare use on reduction of social, emotional or cognitive issues discussed in this presentation have not been evaluated in clinical trials.

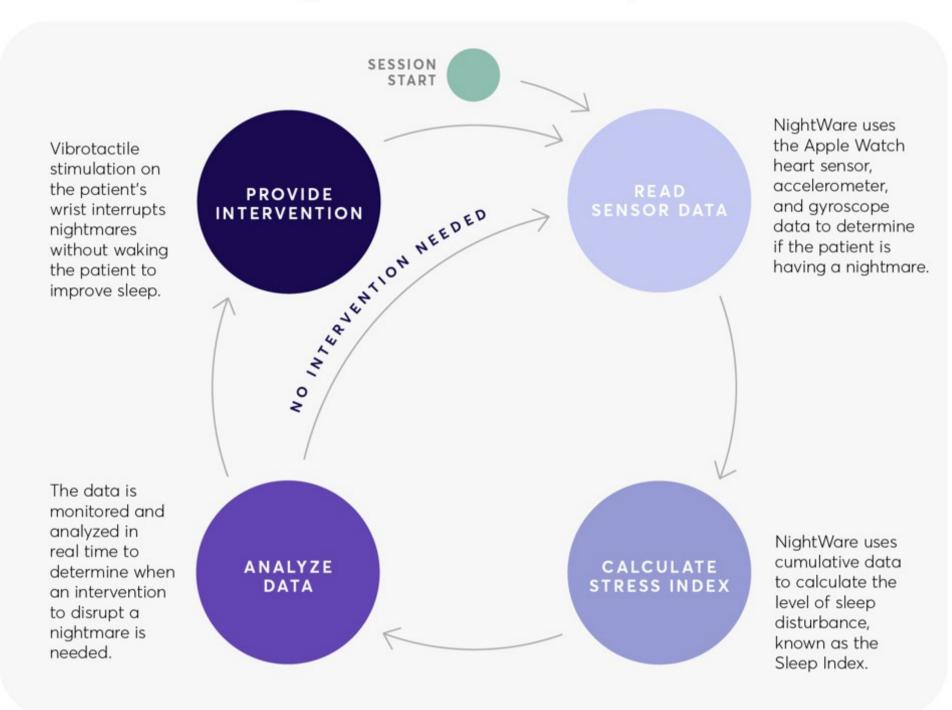
^{*}NightWare is not approved for the treatment o PTSD or to improve quality of life.

^{**}U.S. Food and Drug Administration, Center for Drug Evaluation and Research. NightWare Kit (including Apple iPhone, Apple Watch, Apple iPhone Charging Cable, Apple Watch Charging Cable) DEN200033, May 27,2020. Retrieved April 27,2023, from http://janeganter.com/crastudentwriters/cite_fda_approval_ltr.pdf

THE ONLY FDA INDICATED DEVICE OR DRUG FOR NIGHTMARES ASSOCIATED WITH PTSD OR NIGHTMARE DISORDER

- Improves sleep by interrupting nightmares without waking the patient
- Precision, custom algorithm unique to each patient
- Positive safety profile and avoids drug interactions
- Impact typically within two weeks
- De Novo 510(k) cleared Nov 2020
 - Submitted safety and efficacy data
- FDA Breakthrough Status

NightWare Intervention Cycle





SCIENTIFIC INVESTIGATIONS

A randomized sham-controlled clinical trial of a novel wearable intervention for trauma-related nightmares in military veterans

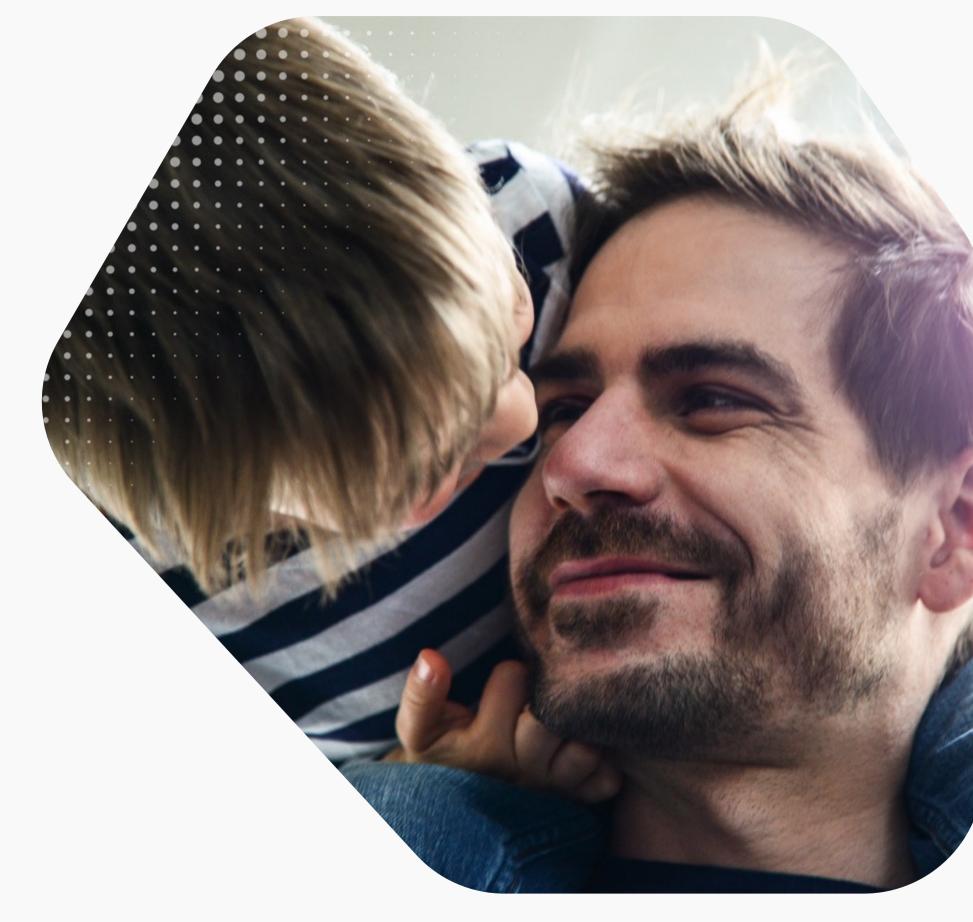
Nicholas D. Davenport, PhD^{1,2}; J. Kent Werner, MD, PhD^{3,4,5}

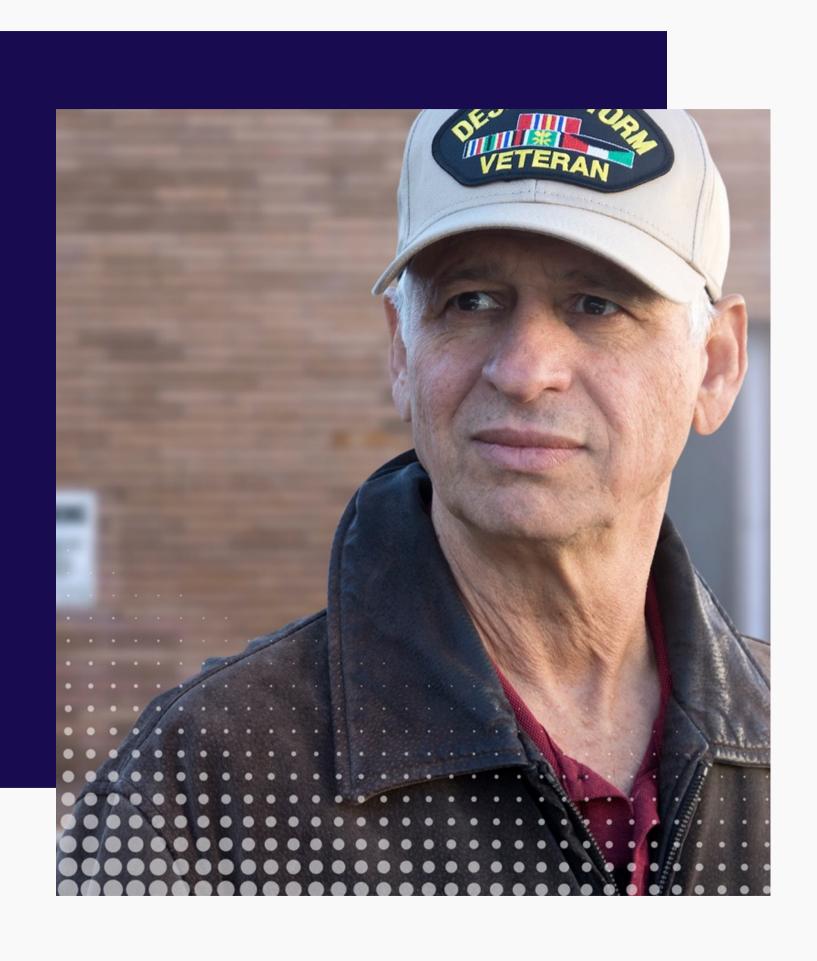
OUR STUDY SHOWED IN AS LITTLE AS 30-DAYS, IMPROVEMENTS IN SLEEP QUALITY OCCUR IF DEVICE IS USED AT LEAST 50% OF THE TIME

- a. Improved sleep quality
- b. Increased sleep duration
- c. Decreased time to fall asleep

NIGHTWARE USER EXAMPLE #1

- Major, active duty
- Alcohol abuse prior to sleeping to mask nightmares
- Upon getting sober, nightmares started again and sleep quality decreased
- Ineffective medical treatment
- NightWare stopped nightmares and improved sleep
- Patient is still sober*





NIGHTWARE USER EXAMPLE #2

- First Sergeant, 20+ years of service
- Severe traumatic nightmares nightly
- Ineffective medical treatment
- NightWare stopped nightmares and improved sleep

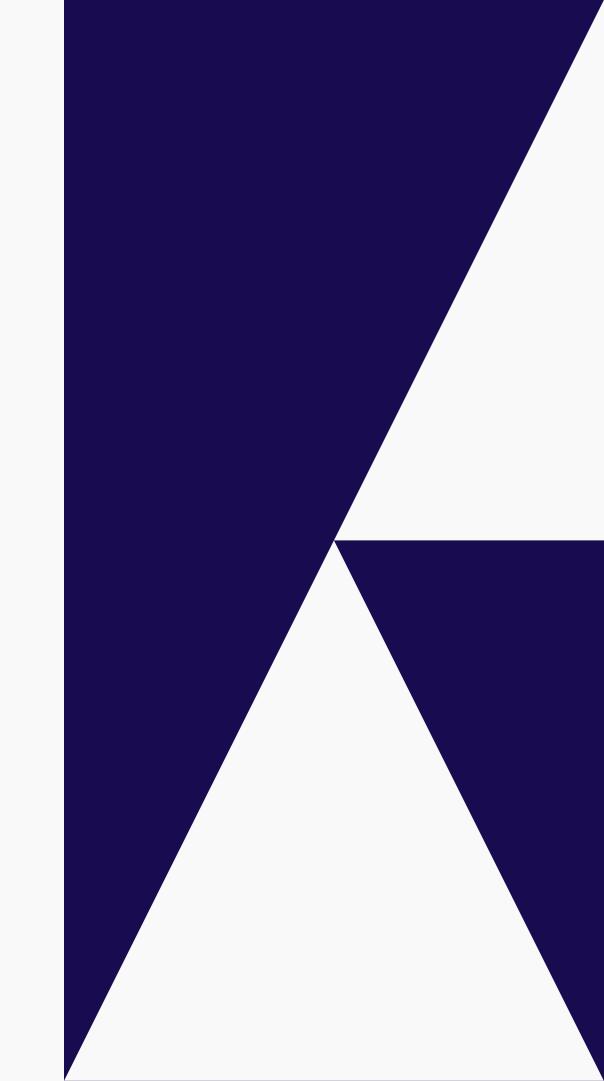
NIGHTWARE USER EXAMPLE #3

- Green Beret, 20+ years of combat deployments
- Severe traumatic nightmares nightly
- Awaken in the middle of the night sweating and short of breath
- Decreased sleep quality for spouse
- Ineffective medical treatment
- NightWare stopped nightmares
- Improved sleep for patient and spouse
- Patient now only has pleasant dreams



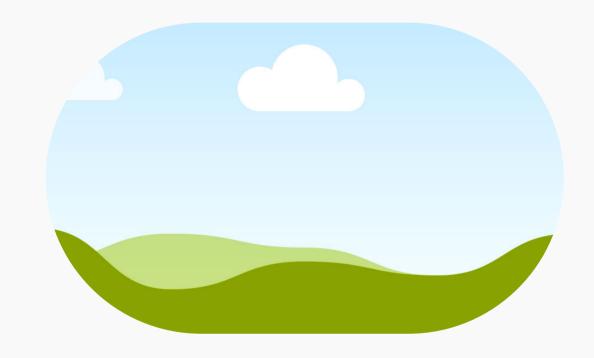
Summary

Wake Up!

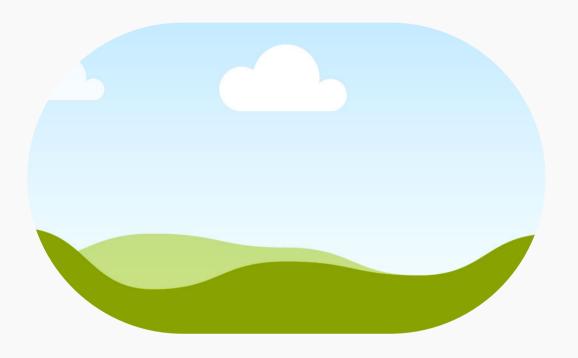


SUMMARY

Progress not perfection



Chronic nightmares and lack of sleep affect your ability to function during the day



Sleep quality from chronic nightmares can be improved – seek help if you have nightmares



Wake up and go to bed at the same times every day

Should You Seek Treatment for Your Sleep Problems?

ASK YOURSELF

How many hours do you sleep on an average night? If less than 6 hours...talk to your doctor.

During the past month, how would you rate your sleep quality overall? If fair or poor sleep quality...talk to your doctor.

Do you go to bed and wake up at the same time every day, even on weekends? No...talk to your doctor.

How likely is it that you would fall asleep during the daytime without intending to or that you would struggle to stay awake while you are doing things? If likely or very likely...talk to your doctor.

How often do you have trouble going to sleep or staying asleep? If more than twice per week...talk to your doctor.

During the past 2 weeks, for about how many days did you have loud snoring? If some or most of the time...talk to your doctor.



Request a quote through NightWare's authorized government distributor, Sleep Management (dba VieMed):

- Request a quote via email: government@viemed.com
- Item #100001-NightWare Digital Therapeutic System

Note: Once submitted, quotes are generated within 24 business hours.

Submit consult and quote to Prosthetics:

- Please ensure that the official Sleep Management (dba VieMed) quote accompanies the consult when submitting to Prosthetics
- For questions, contact Sleep Management's (dba VieMed) customer service department

Sleep Management (dba VieMed) VieMed NPI: 1336166347 Phone: 833-735-1192 Fax: 800-358-1907 government@viemed.com

Justification in Notes:

- Example-Device is designed to disrupt nightmares and improve sleep.
- Example-Device is a non-invasive treatment option for those suffering from persistent nightmares.

For further questions or to request informational flyers, please contact Brant Newman at brant@nightware.com

NIGHTWARE'S CURRENT RESEARCH STUDY PROVIDES A POTENTIAL WAY FOR PATIENTS TO TRY NIGHTWARE

01 -----

If you are interested in participating in this research project, the following sites are currently conducting the research study:

- Cleveland, OH VA (phone: 763-453-1241)
- Walter Reed National Military Medical Center (phone: 612-250-6692,email: NightwareWRNMMC@hjf.org)

02 -----

The following sites will be activated in the next few months:

- Charleston, SC VA
- Savannah, GA VA
- Ann Arbor, MI VA

Thank you

