https://doi.org/10.5664/jcsm.10338

JCSM | Journal of Clinical Sleep Medicine

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]

[1]Research, Minneapolis VA Health Care System, Minneapolis, Minnesota; [2]Departments of Psychiatry and Psychology, University of Minnesota, Minneapolis, Minnesota; [3]Center for Neuroscience and Regenerative Medicine, Uniformed Services University, Bethesda, Maryland; [4]Department of Neurology, Uniformed Services University, Bethesda, Maryland; [5]Sleep Disorders Center, Walter Reed National Military Medical Center, Bethesda Maryland

Study Objectives: Persistent nightmares are common among individuals exposed to trauma and are especially prevalent among veterans. While behavioral and pharmacological interventions are available, they have demonstrated limited efficacy. Innovations in wearable technology provide a potential avenue to match or exceed these existing treatments by directly targeting nightmare physiology.

Methods: We conducted a randomized, sham-controlled study to determine the efficacy of a novel wearable device–based application in 65 veterans with impaired sleep secondary to trauma-related nightmares. Changes in measures of sleep quality, posttraumatic stress disorder/depression symptoms, and quality of life across the 30-day trial were compared between the Active and Sham systems.

Results: Both groups demonstrated statistically significant within-person improvement on all measures. While the Active system was generally associated with stronger magnitude of improvement, none of the comparisons of individual measures across conditions reached statistical significance. However, a post-hoc analysis excluding participants with low frequency of usage demonstrated significantly better improvement in perceived sleep quality with the Active device than Sham.

Conclusions: Overall, these results provide preliminary evidence that a wearable device may improve self-reported sleep quality for veterans reporting frequent trauma-related nightmares, especially in compliant users.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Traumatic Nightmares Treated by NightWare (To Arouse Not Awaken) (TNT/NW); URL: https://www.clinicaltrials.gov/ct2/show/NCT04040387; Identifier: NCT04040387.

Keywords: veterans, nightmares, trauma, post-traumatic stress disorder, sleep quality

Citation: Davenport ND, Werner JK. A randomized sham-controlled clinical trial of a novel wearable intervention for trauma-related nightmares in military veterans [published online ahead of print, 2022 Oct 28]. *J Clin Sleep Med*. doi: 10.5664/jcsm.10338

BRIEF SUMMARY

Current Knowledge/Study Rationale: Nightmares are common among people exposed to trauma and can lead to significant distress. Current treatments for nightmares are of limited efficacy and include the potential for adverse side effects. We provide a preliminary assessment of a novel wearable technology application intended to improve sleep quality by reducing the number and intensity of nightmares.

Study Impact: While still preliminary, results indicate that wearable technology could be a viable alternative to medication or behavioral therapy for the treatment of trauma-related nightmares.

INTRODUCTION

Sleep disruptions, including insomnia and nightmares, are the most commonly reported features of posttraumatic stress disorder (PTSD),[1,2] frequently emerging prior to the onset of full clinical criteria[3] and persisting for decades, even when additional symptoms have been successfully treated.[4] Moreover, trauma-related sleep disturbances are associated with a range of mental and physical health conditions, including depression, suicide, and lower overall quality of life (for review see references[5]). Nightmares, defined as dreams that trigger emotional distress and objective physiological signs such as tachycardia, palpitations, and diaphoresis,[6,7] are especially associated with longer duration and greater severity of PTSD symptoms[2] and have been linked to a 5-fold increase in risk for high suicidality.[8] Military veterans, especially those exposed to combat, may be disproportionately vulnerable to these outcomes given the increased rate of PTSD[9] and comorbid mental health conditions, including depression and substance dependence.[10]

The most prominent pharmacologic treatment for trauma-related nightmares is prazosin, an α-1 adrenergic antagonist used in the treatment of hypertension. Early trials of prazosin in veterans demonstrated improvement in distressing dreaming, insomnia, and overall PTSD symptomatology,[11–13] though the magnitude of improvement relative to placebo in more recent trials has been variable.[14–17] While generally well tolerated, side effects among patients have included dizziness, headache, drowsiness, fatigue, weakness, heart palpitations, and nausea.[18] Moreover, medications require ongoing clinical monitoring to maintain efficacy.

Of the several variants of cognitive behavioral therapy recommended as behavioral interventions for treatment of nightmares, image rehearsal therapy (IRT) has emerged as especially specific to nightmares.[19] Reported effects of IRT, in which threatening elements of recurrent nightmares are identified and replaced by non-threatening variations, on nightmares and related symptoms are generally moderate but significantly greater than wait-list control conditions[16] and do not differ from prazosin when compared directly.[20] However, dropout rates of 25%–40% limit the interpretability of effects and reflect the substantial burden required of the patient and clinician (eg, time, emotional distress, etc).[2]

Digital health interventions (DHI) have recently emerged as a prominent form of personalized medicine, providing the potential to overcome limitations of traditional treatment options by targeting specific symptoms within an individual. The flexibility of DHI, along with the widespread availability and daily use of personal technology, provide substantial opportunity to provide more targeted intervention with fewer clinical resources than traditional options. DHI applications to date have demonstrated efficacy in reducing insomnia in veterans by implementing an individualized sleep restriction approach[21] and treatment of PTSD symptoms through administration of daily light therapy.[22] However, no DHI options have directly targeted the physiology associated with nightmares. The NightWare system (Minneapolis, MN) is a novel wearable intervention that uses heart rate and motion data from a commercially available smart watch to disrupt physiological signs of distress through haptic feedback, usually without noticeably awakening the patient. Expanding on preliminary results from an open-label pilot, which demonstrated improvement in sleep quality, as well as in mental health symptoms and quality of life,[23] we conducted a randomized controlled trial to evaluate the efficacy of NightWare relative to a sham system. We hypothesized that interventions would reduce the perceived frequency of nightmares and result in improved self-reported sleep quality compared to sham. Additionally, we hypothesized that improved sleep would be associated with reductions in self-reported mental health symptoms.

METHODS

Participants

A total of 72 veterans with trauma-related sleep disturbances were enrolled in this randomized controlled trial. Potential participants were identified based on VA medical records of veterans with current or past diagnoses of PTSD and documented history of nightmares. Additional inclusion criteria include trauma history, frequent nightmares (> 7 in the previous month), total score of at least 20 on the Posttraumatic Stress Disorder Checklist-5,[24] and poor overall sleep quality as indicated by a score of at least 10 on the Pittsburgh Sleep Quality Index (PSQI[25]). Exclusion criteria included diagnosis of obstructive sleep apnea, current drug or alcohol abuse, specific medications known to affect sleep or dreams (eg, beta-blockers, prazosin), and lack of access to wireless internet (for device functionality). Potential participants were also screened for suicidality using the Columbia Suicide Severity Rating Scale[26] and excluded if risk was determined to be high (ie, ideation with intent in past month, preparatory actions or attempt in past 3 months). All potential participants with moderate or high suicide risk were provided access to appropriate clinical resources.

Eligible participants completed an informed consent process and provided written consent. The study protocol was reviewed and approved by the Minneapolis Veterans Affairs Health Care System Institutional Review Board.

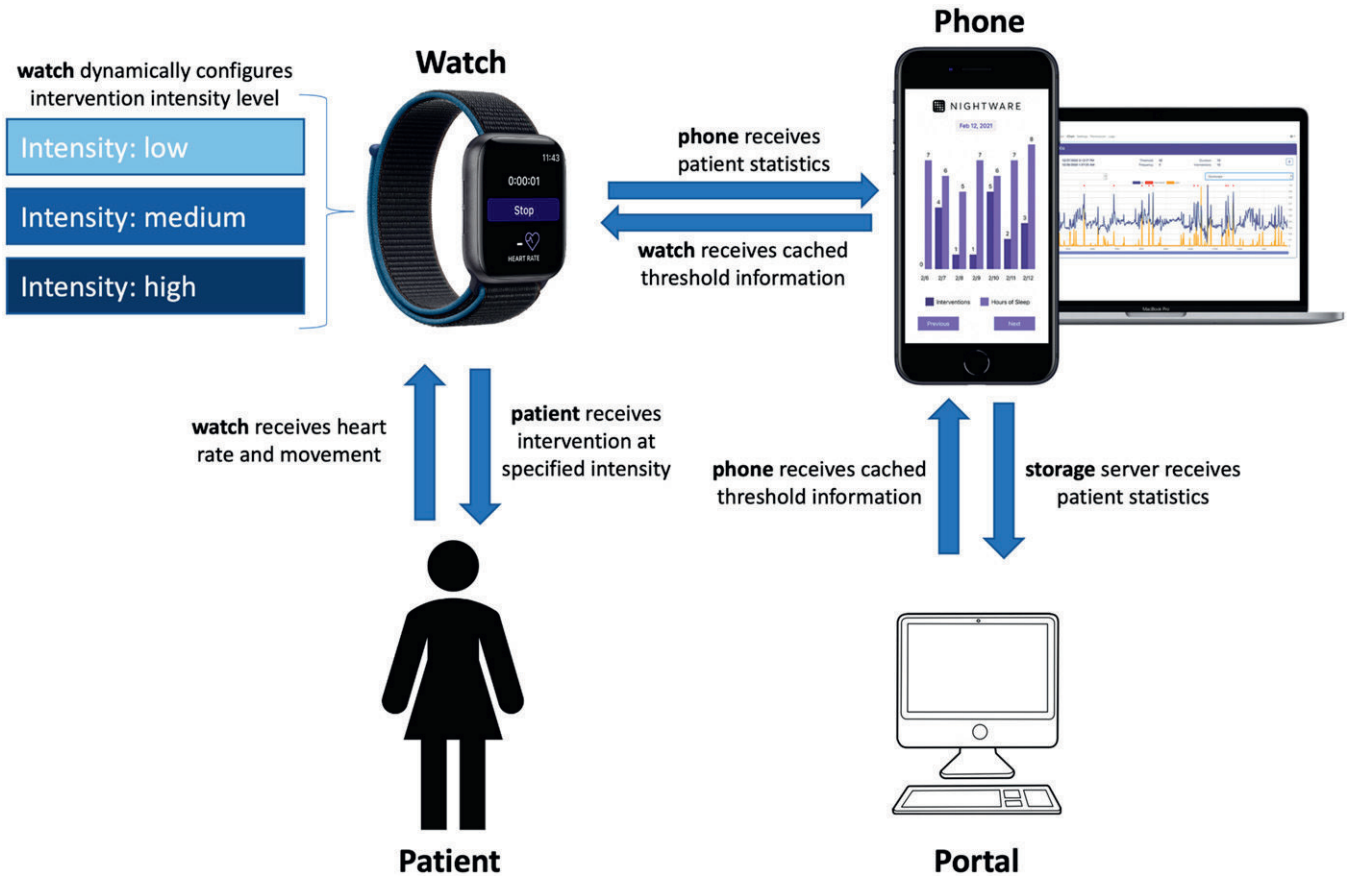
Measures

Upon enrollment, participants completed a baseline study visit consisting of self-report questionnaires assessing sleep quality, mental health, and related symptoms. These questionnaires were repeated at completion visits scheduled to occur 30 +/− 7 days after baseline, though some visits occurred beyond 37 days due to participants rescheduling. At each visit, overall sleep quality was assessed using the PSQI, a widely used instrument that summarizes 7 components of sleep quality, and the PTSD Addendum,[27] which specifically probes sleep problems associated with PTSD. Impact of sleep quality on activities of daily life was assessed using the 10-item Functional Outcomes of Sleep Questionnaire,[28] and characteristics of nightmares (eg, frequency, severity) were assessed using the Trauma-Related Nightmare Survey.[29] Because the goals of this study were both to improve sleep quality and reduce nightmares, we utilized a new instrument focusing on these outcomes as an additional measure of self-reported sleep quality, asking participants "how long did you sleep" (0–9 hours), "how deeply did you sleep" (0 = None, 1 = Very Poor, 4 = Average, 8 = Excellent, 9 = Perfect), and "how well were nightmares prevented" (same scale) over the prior week, each rated on a 9-point Likert scale and summed to produce the NightWare Likert (NWL). Finally, to determine whether usage of the device was associated with changes in PTSD or depression symptoms, we administered the Posttraumatic Stress Disorder Checklist-5 and Patient Health Questionnaire-9.[30]

Intervention

The NightWare smartphone application uses data (eg, movement, heart rate, position) from a connected smartwatch to calculate a "stress index" and determine an individualized threshold putatively distinguishing normal sleep from distressed sleep (see **Figure 1**). The intervention threshold was determined automatically, and adaptively adjusted over time, for each participant by a proprietary algorithm based on the prior 1,000 minutes of recorded data. Subsequently, detection of a stress index above the threshold prompts the smartwatch to vibrate at an intensity and duration intended to disrupt the physiologic process, potentially terminating or preventing a distressing dream without compromising the perceived quality of sleep. The haptic interventions (ie, vibrations) occur as 3 preconfigured patterns (low, medium, high) stored in the smartwatch and range in duration from 3 to 5 seconds. The initial intervention uses the low-intensity vibration pattern consisting of 3 sets of 2 successive quarter-second taps to the wrists, with sets separated by a half-second pause. If the stress index remains above the intervention threshold, subsequent interventions use the medium- and high-intensity vibration patterns consisting

Figure 1—NightWare device.



of 3 and 5 sets, respectively, of 3 successive quarter-second taps followed by a quarter-second pause. Once the stress index drops below the threshold, the vibration intensities reset, and the next intervention will be low intensity.

Study design, blinding procedures, and randomization

We conducted a randomized, double-blind, sham-controlled trial. Participants were randomly assigned to either an Active (n = 36) or Sham (n = 36) condition using stratified permuted block randomization to reduce spurious influence of baseline PSQI (10–14 vs 15+). Participants were provided a smartphone-smartwatch pair preloaded with study software to ensure standardization of equipment. The Active and Sham software were identical in interface and functionality with the exception that the Sham software did not deliver haptic stimulation upon detection of distressed sleep. Participants and study staff were blind to the version of software installed on each phone. During the first week of participation, usage and functionality questions (eg, "Did the watch wake you up last night?", "Did you have a nightmare last night?") were administered by phone or text to all participants to encourage compliance and troubleshoot technical problems. Basic usage data (ie, app start and stop times) for each participant were automatically compiled daily throughout the trial for ongoing monitoring of usage frequency. To simulate usage outside of direct clinical supervision, no minimum frequency was enforced, allowing participants to self-regulate.

Statistical analyses

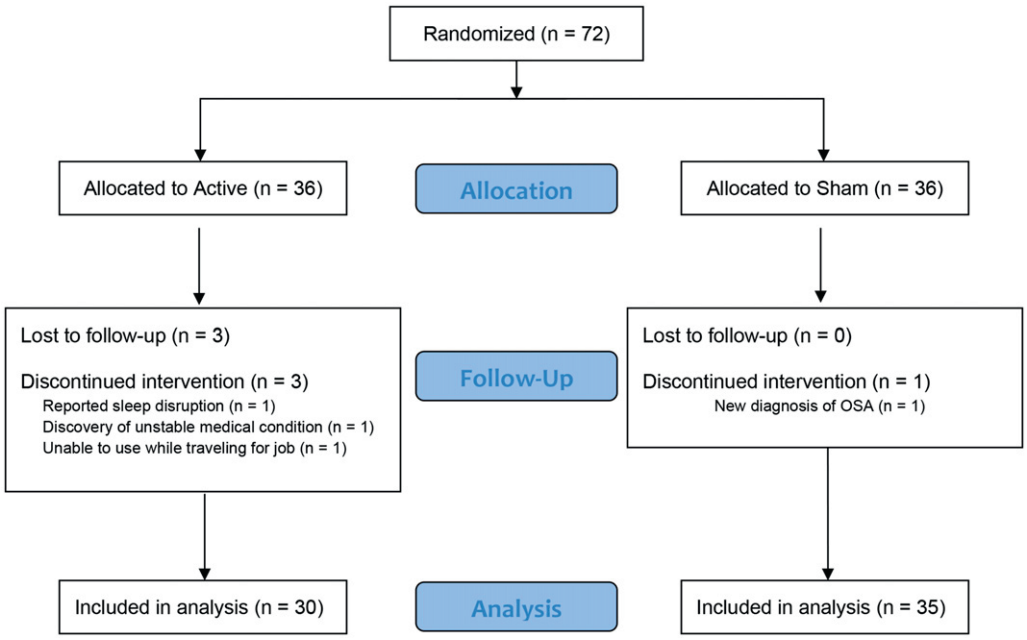
Baseline demographic characteristics and self-report measures were compared between the Active and Sham arms using 2-sample *t* tests (continuous variables) and Chi-square tests (discrete variables). Longitudinal change on each self-report measure was computed as the difference between values measured at completion minus baseline. Significance of change within each condition was computed using 1-sample *t* tests, and changes were compared across conditions using 2-sample *t* tests. Each set of tests was corrected for multiple comparisons using a false discovery rate[31] of q = .05 at alpha = .05.

RESULTS

Baseline characteristics

More than 90% of enrolled participants completed the trial (**Figure 2**), resulting in a final sample size of n = 65 (30 Active, 35 Sham). While a disproportionate number of participants who did not complete the trial had been randomized to the Active

Figure 2—CONSORT diagram.



OSA = obstructive sleep apnea.

group (6 vs 1; $\chi^2 = 3.96$, $P = .047$), only 1 withdrawal was attributed to the device (disruption of sleep). The remaining cases were due to life events (n = 1), development of an exclusionary condition (n = 2), or lost to follow-up (n = 3). The participants who did not complete the trial were all male but otherwise did not differ from the overall initial sample on any baseline measure (all $P > .5$). Baseline demographic characteristics and self-report measures for veterans who completed are presented in **Table 1** and **Table 2**. No differences between randomization conditions were observed on any demographic variable or baseline self-report measure.

Among participants who completed the trial, frequency of use was generally high (**Figure 3**), with 73.8% of participants using the device more days than not and nearly half (47.7%) using the device at least 5 times per week, on average. Average frequency of use did not differ between Active and Sham conditions (62% vs 67% of nights during trial; $P = .32$, d = 0.25).

Longitudinal changes

The Active condition was associated with significant improvement on all measures (**Table 3**). The Sham condition was also associated with significant improvement on PSQI, Trauma-Related Nightmare Survey, Posttraumatic Stress Disorder Checklist, and NWL, after correcting for multiple comparisons. While the effects associated with the Active condition were consistently of greater magnitude than those associated with Sham (**Figure 4**), no difference between conditions reached statistical significance, indicating that the effects of the intervention could not be distinguished from those of other contributions to treatment response (eg, expectations, motivation, individual differences) with the current sample size.

To determine whether under-utilization contributed to underestimation of effects, analyses were repeated after excluding the 17 participants (9 Active, 8 Sham) who used the device fewer than 50% of nights (median usage: Active 33%, Sham 39%). Within this "high usage" subsample (median usage: Active 74%,

Table 1—Demographic characteristics.

Variable	Active (n = 30)	Sham (n = 35)	*P*
Age: years, mean (SD)	46.8 (15.5)	45.6 (13.2)	.743
Sex: n (%)			.159
Men	16 (53%)	21 (60%)	
Women	14 (47%)	11 (31%)	
Transgender	0 (0%)	3 (9%)	
Ethnicity: n (%)			.473
Hispanic or Latino	1 (3%)	4 (11%)	
Not Hispanic or Latino	27 (90%)	29 (83%)	
Unknown	2 (7%)	2 (6%)	
Race: n (%)			.365
American Indian or Alaskan Native	1 (3%)	1 (3%)	
Black or African American	3 (10%)	1 (3%)	
White	25 (83%)	31 (89%)	
Other	1 (3%)	0 (0%)	
Unknown	0 (0%)	2 (6%)	

SD = standard deviation.

Table 2—Baseline characteristics.

Variable	Active (n = 30)	Sham (n = 35)	*P*
PSQI	14.5 (3.3)	13.7 (2.8)	.34
PHQ-9	12.5 (5.2)	12.8 (5.3)	.84
PCL	44.0 (13.5)	47.2 (12.5)	.33
TRNS	42.8 (7.5)	43.0 (6.6)	.93
FOSQ*	12.1 (3.2)	13.4 (2.8)	.10
PSQI-A	9.7 (3.8)	10.6 (4.1)	.37
NWL	10.5 (3.5)	10.6 (2.6)	.83

All measures are presented as mean (standard deviation). *n = 27 Active, 33 Sham due to missing data. FOSQ = Functional Outcomes of Sleep Questionnaire, NWL = NightWare Likert, PCL = Posttraumatic Stress Disorder Checklist, PHQ-9 = Patient Health Questionnaire, PSQI = Pittsburgh Sleep Quality Index, PSQI-A = PTSD Addendum to PSQI, TRNS = Trauma-Related Nightmare Scale.

Sham 75%), the Active condition was associated with significantly greater improvement, compared to Sham, on the PSQI (4.1 vs 1.9; $P = .016$, d = 0.72) and NWL (6.1 vs 2.7; $P = .002$, d = 0.94). As seen in **Figure 4**, the degree of change associated with the Sham condition in this subset was similar to that of the entire sample, indicating that additional usage of an inactive device had little effect. In contrast, the effect of the Active device on the PSQI and NWL was markedly stronger among the "high usage" subset than the whole sample, indicating that higher usage of the Active system is associated with greater effectiveness. Notably, when changes on the individual components of the PSQI were compared separately (**supplemental material**), the components of greatest improvement were Sleep Latency ($P = .018$, d = 0.71) and Sleep Disturbances ($P = .030$, d = 0.66).

DISCUSSION

In a sample of veterans with a history of PTSD and self-reported traumatic nightmares, we conducted a 30-day randomized controlled trial of a novel digital intervention intended to improve sleep quality by reducing the frequency and intensity of nightmares. Both the Active and Sham conditions demonstrated statistically significant improvement relative to baseline on measures of sleep quality, mental health, and quality of life. Neither the primary nor secondary outcomes were statistically different between conditions in this study. However, post-hoc analysis examining participants who used the device on a majority of nights revealed significant effects of the Active system compared to Sham on the primary outcome of overall sleep quality (ie, PSQI) as well as on the NWL.

Although the underlying mechanisms of nightmares remains elusive, there is growing evidence of a role for autonomic dysregulation.[32–34] The NightWare DHI is the first to automatically target these events by providing haptic feedback in response to heart rate and movement changes. Given that the 2 areas of greatest relative improvement on the PSQI were Sleep Latency and Disruptions (**supplemental material**), it is plausible that the device has the primary effect of reducing sleep-related autonomic arousal, allowing more rapid sleep onset and fewer waking events. This effect could occur through the hypothesized mechanism of disrupting the sleep stage in which distress is present, facilitating transition to a nonstressful sleep state, and thus extinguishing the stress response, though more refined measurements of sleep physiology (eg, polysomnography) would be required to test this hypothesis directly. While it is possible that reductions in anxiety about sleep could be induced simply by the belief or expectation of efficacy, rather than effects of the device itself, this would be

Figure 3—Distribution of usage frequency in each study arm.

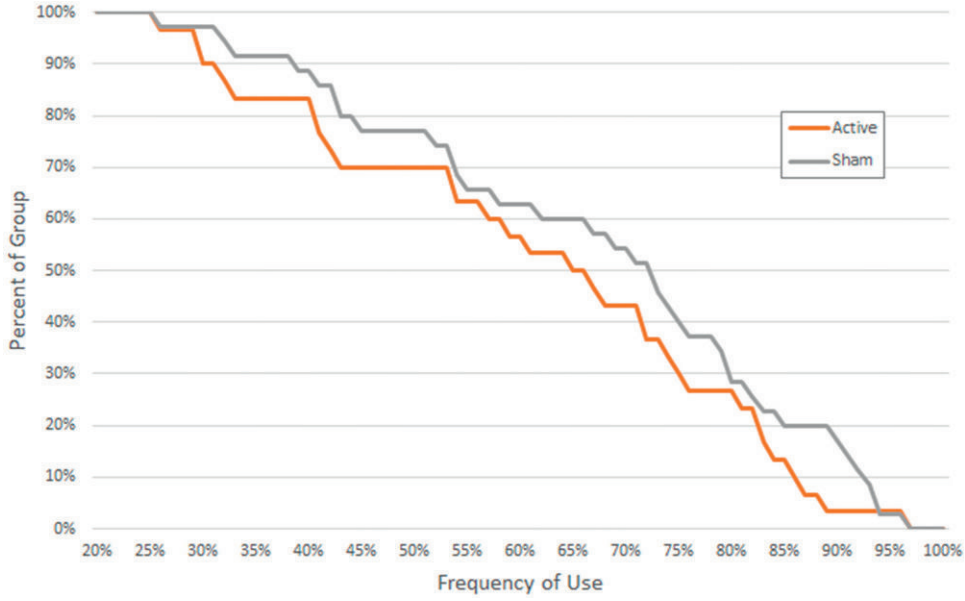


Table 3—Change between baseline and follow-up visit for each outcome measure.

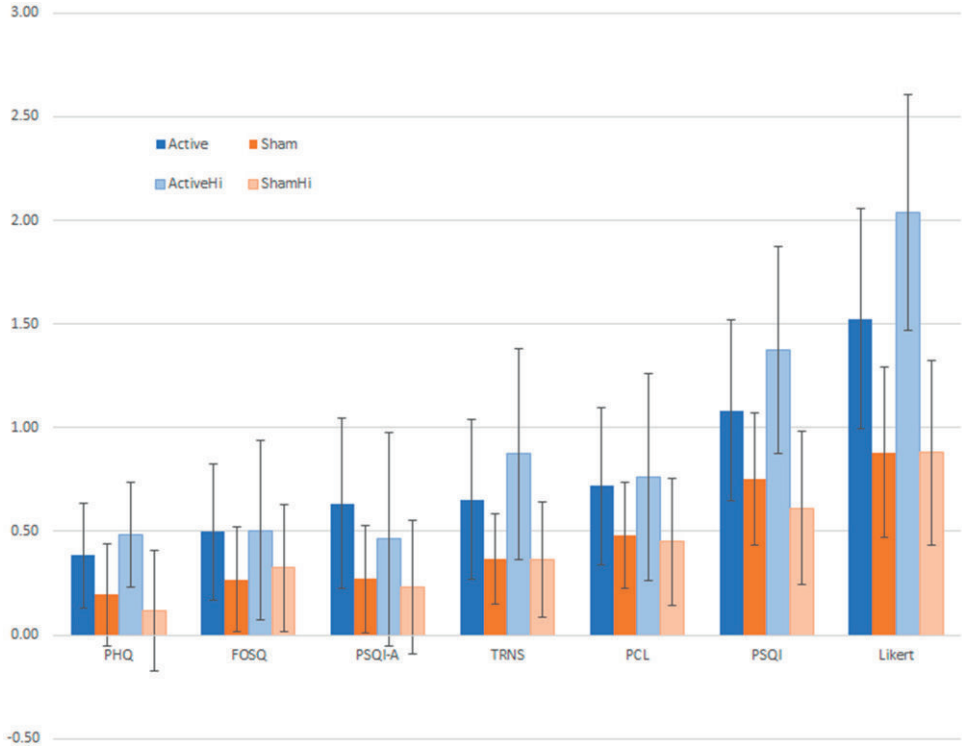
	Full Sample (n = 65)			High Usage (n = 48)		
Outcome Measure	**Active (n = 30)**	**Sham (n = 35)**	***P***	**Active (n = 21)**	**Sham (n = 27)**	***P***
PSQI	−3.3 (3.6)	−2.3 (2.9)	.219	−4.1 (3.4)	−1.9 (2.9)	*.016**
PHQ-9	−2.0 (3.6)	−1.0 (3.8)	.289	−2.5 (3.0)	−0.6 (3.9)	.067
PCL	−9.3 (13.6)	−6.2 (10.0)	.298	−9.9 (14.8)	−5.9 (10.3)	.264
TRNS	−4.6 (7.4)[b]	−2.6 (4.5)	.184	−6.1 (8.1)	−2.5 (5.1)	.063
FOSQ	1.5 (2.7)[a]	0.8 (2.3)[a]	.293	1.5 (3.0)	1.0 (2.4)[c]	.483
PSQI-A	−2.1 (4.6)[b]	−1.1 (2.9)	.298	−1.2 (4.7)	−0.9 (3.1)	.778
NWL	4.6 (4.4)	2.7 (3.7)	.057	6.1 (3.9)	2.7 (3.5)	*.002**

Values in italic represent significance ($P < .05$) after correction for multiple comparisons. Values in sanserif font represent significant changes from baseline (1-sample *t* test, $P < .05$). [a]n = 26 Active, 33 Sham due to missing baseline data. [b]n = 29 Active due to missing follow-up data. [c]n = 26 Sham due to missing baseline data. FOSQ = Functional Outcomes of Sleep Questionnaire, NWL = NightWare Likert, PCL = Posttraumatic Stress Disorder Checklist, PHQ-9 = Patient Health Questionnaire, PSQI = Pittsburgh Sleep Quality Index, PSQI-A = PTSD Addendum to PSQI, TRNS = Trauma-Related Nightmare Scale.

expected to be present in both the Active and Sham conditions. Therefore, significantly greater reductions in both Sleep Latency and Disruptions among regular users provides initial support for a therapeutic effect of haptic stimulation in response to physiological indicators of stress.

Because the NWL has not been used extensively or externally validated, the observed changes in this measure require substantial caution. However, by looking at changes in the individual items separately (**supplemental material**), it is clear that the effect is driven by 2 of the 3 questions. The first

Figure 4—Mean within-person change in measures of interest.



Values are standardized by the baseline whole-sample standard deviation of each measure. Error bars represents 95% confidence intervals. ActiveHi (n = 21) and ShamHi (n = 27) refer to the subset of participants in each study arm with "high" usage, defined as greater than 50% of nights. FOSQ = Functional Outcomes of Sleep Questionnaire, PCL = Posttraumatic Stress Disorder Checklist, PHQ = Patient Health Questionnaire, PSQI = Pittsburgh Sleep Quality Index, PSQI-A = PTSD Addendum to PSQI, TRNS = Trauma-Related Nightmare Scale.

question simply represents the reported duration of sleep in hours, so it is straightforward to infer that the Active condition was associated with approximately 1 additional hour of sleep, on average, while no systematic change in sleep duration was seen in the Sham condition. The second question, which asked participants to rate how "deeply" they had slept over the prior week, did not demonstrate any notable effects relative to baseline or across conditions, potentially suggesting that it was too broad or interpreted differently across participants. The final question, which asked participants how well nightmares were prevented over the prior week, demonstrated a larger difference between conditions in the high usage subsample than in the total sample and contributed to the observation of significant effects of condition on NWL in the post-hoc analysis. However, the face validity of this item is questionable given that the term "prevented" implies an external intervention that would not necessarily be present at baseline. Therefore, while there is no clear interpretation of the item in its current form, it may be capturing valuable information about perceived changes in the occurrence of nightmares that the person attributes to usage of the device. Future studies of nightmare interventions may benefit from exploring self-reported perceptions of efficacy and attributional styles more directly.

Although our results are limited in interpretability, given the nonsignificant primary outcome, multiple factors support further investigation into this novel nightmare treatment modality. First, our post-hoc analysis suggests there may be significant effects in the compliant subpopulation. Second, our study required no utilization of therapists or monitoring, offering an exciting new paradigm in management of nightmare disorder. Third, this approach not only brings forth a new therapy, but also offers potential for the development of promising objective, automatically acquired biomarkers of sleep physiology such as the stress index measures used in the device algorithm responsible for triggering haptic stimuli. These parameters can be used to further develop the treatment algorithm, and they offer clinical utility for tracking patient progress remotely. While some studies testing other therapies for nightmares demonstrated larger effect sizes (d = 1.2,[35] η^2 = .71[36]) than those observed in our post-hoc analysis, they also represent comparisons to baseline or waitlist control. Compared to an active control, the leading treatments, such as imagery rescripting or prazosin, also demonstrated significant effect sizes compared to baseline while failing to differentiate from control.[14,37] It is notable, however, that while more than 70% of participants used the device most of the time, less than half used the device 5 or more days per week—well below the compliance typically achieved in clinical studies of medication or behavioral therapy, but likely more reflective of the real-world scenario.

The approach of utilizing novel DHI to treat nightmares is an exciting positive aspect of this work, and its potential for the future—both in biomarker and therapeutic development—is promising. However, there are several limitations that need to be highlighted from this trial. First, we should note that reliable biomarkers of nightmares have not been established, and thus we cannot prove that this intervention is directly targeting nightmare events; rather, it targets associated physiology (ie, heart rate and movements) calculated as a "stress index." Additional investigation of the associations between these physiological markers and proximal self-reports of nightmares or distressing dreams will be invaluable to developing targeted interventions. Another important limitation is that while changes from baseline were clearly observed, with the intervention trending ahead of placebo, the lack of significance of our prespecified primary outcome must be emphasized to the reader. This may be related to the small sample size and heterogeneous adherence. While usage frequency did not differ across conditions, it may have been related to ease of use, perceived efficacy, life stressors, or personality traits, each of which may plausibly be related to persistence of nightmares and treatment resistance. We did not systematically assess blinding success, so we could not evaluate the possibility that perceived randomization arm, or cues thereof, influenced outcomes. However, the similar usage frequency across conditions suggests that the intervention, haptic stimulation during sleep, did not systematically alter usage. Understanding the determinants of DHI adherence and their influence on outcomes will be critical to the integration of technology into mental health clinical care. A final key limitation is the lack of objective sleep data to more closely examine the effects of the therapeutic. We do not know in which stages of sleep the "stress index" was high and triggered interventions, as we did not capture electroencephalography, nor do we know whether more interventions correlated with more efficacy. These represent important areas for further investigation to better understand the mechanism underlying the observed improvements and to refine the delivery of the intervention.

Other types of physiology, such as sleep stability or heart rate variability remain unknown. While it will be interesting to collect such data in future studies, self-reported improvement in sleep quality remains the primary outcome of interest. Future development of this technology should include analysis of the objective biomarkers from the data recorded by the device to determine if there are potential predictors of treatment response. This will enable more rational design of future trials and validation in larger populations. The observation of differential effects among the subset of participants who used the device on the majority of nights underscores the importance of considering usage patterns in evaluating effectiveness.

In conclusion, the prevalence and chronicity of trauma-related nightmares, especially among servicemembers and veterans, underscores the urgency of effective interventions. While current therapeutic options have reduced morbidity in a subset of patients, their efficacy in controlled studies is generally limited. Here we present evidence of a DHI associated with improved sleep quality, demonstrating that wearable devices could be viable options for treatment of nightmares instead of or alongside medications and behavioral interventions. Further study is required to characterize long-term persistence of benefits, mechanisms of action, and baseline predictors of compliance to identify veterans who may need additional support (eg, smartphone reminders) to achieve sufficient usage for benefits to be attained.

ABBREVIATIONS

DHI, digital health intervention
NWL, NightWare Likert
PSQI, Pittsburgh Sleep Quality Index
PTSD, posttraumatic stress disorder

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ACKNOWLEDGMENTS

The authors would like to thank Dr. Irene Harris for contributions to the initial study design and Mary Evans-Lindquist, Rebecca Hiltner, Chris Prementine, Julia Langlois, and Elayna Waxse for assistance with data collection and input on early drafts of this work. We would also like to thank the veterans who participated for their time and willingness to contribute to veteran research.

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication March 28, 2022
Submitted in final revised form October 5, 2022
Accepted for publication October 6, 2022
Address correspondence to: Nicholas Davenport, PhD, Minneapolis VAHCS, One Veterans Dr., Minneapolis, MN 55417; Email: Nicholas.Davenport@va.gov

DISCLOSURE STATEMENT

All authors have seen and approved the manuscript. All work was performed at the Minneapolis VA Medical Center, Minneapolis, MN. The research reported here was supported with funds provided by NightWare, Inc. This company did not participate in the analysis or reporting of results, and neither author has received direct compensation from NightWare. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the Uniformed Services University, US Government, Department of Defense, or the US Department of Veterans Affairs, and no official endorsement should be inferred. The authors report no conflicts of interest.

Supplemental Material

PSQI:

	Full Sample (n=65)			**High usage (n=48)**		
Outcome Measure	**Active** (n = 30)	**Sham** (n = 35)	**p-value**	**Active** (n = 21)	**Sham** (n = 27)	**p-value**
Subjective Sleep Quality	**0.67 (.84)**	**0.46 (0.69)**	.275	**0.86 (0.85)**	**0.39 (0.74)**	*.048*
Sleep Latency	**0.57 (0.77)**	**0.26 (0.74)**	.105	**0.76 (0.70)**	0.26 (0.71)	*.018*
Sleep Duration	**0.53 (0.86)**	0.20 (0.87)	.126	**0.57 (0.98)**	0.11 (0.85)	.088
Sleep Efficiency	**0.73 (1.26)**	**0.69 (1.41)**	.887	**1.00 (1.38)**	0.48 (1.34)	.196
Sleep Disturbances	**0.27 (0.52)**	0.07 (0.57)	.157	**0.38 (0.50)**	0.02 (0.60)	*.030*
Medications	0.23 (1.22)	0.11 (1.28)	.704	0.29 (1.15)	0.04 (1.34)	.502
Daytime Dysfunction	0.27 (0.78)	**0.49 (0.85)**	.288	0.29 (0.72)	**0.56 (0.89)**	.264

NWL:

	Full Sample (n=65)			**High usage (n=48)**		
Outcome Measure	**Active** (n = 30)	**Sham** (n = 35)	**p-value**	**Active** (n = 21)	**Sham** (n = 27)	**p-value**
How Long (Hrs)	**1.0 (1.1)**	0.0 (1.8)	*.011*	**1.1 (1.1)**	0.2 (1.4)	*.013*
How Deep	0.4 (1.9)	0.1 (1.8)	.491	0.7 (1.9)	0.1 (1.8)	.205
Nightmares Prevented	**3.2 (2.8)**	**2.6 (2.9)**	.371	**4.3 (2.1)**	**2.4 (3.1)**	*.021*

Bold – Within-person change relative to baseline (p<.05)
Italics – Between group difference in change (p<.05)
Not corrected for multiple comparisons