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SCIENTIFIC INVESTIGATIONS

A randomized, sham-controlled trial of a novel near-infrared phototherapy device on sleep and daytime function

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Study Objectives: Near-infrared light exhibits several therapeutic properties, but little is known about the benefits to sleep and daytime function. The purpose of this study was to investigate the effects of red and near-infrared exposure before bed on sleep and next-day function.

Methods: Thirty adults (30–60 y) with a self-reported sleep complaint but without a sleep disorder participated in a randomized, sham-controlled study for a duration of 5 weeks. After a 2-week baseline period, participants wore either a cervical red light/near-infrared–emitting collar (combined: 660 nm, 740 nm, 810 nm, and 870 nm) or sham device every other night before bed for 3 weeks. Sleep was measured using actigraphy and sleep diaries. Mood and performance were assessed using weekly self-reported surveys and debrief interviews.

Results: Objective sleep parameters, as measured by actigraphy, did not differ between the active or sham groups, but improved self-reported sleep, as well as perceived improvements in relaxation and mood, were observed among active but not sham users. Both active and sham users improved in Insomnia Severity Index score by the end of the trial.

Conclusions: Red and near-infrared exposure to the head and neck before bed may offer potential therapeutic benefits to sleep and daytime function, but further work needs to be done to determine optimal dose parameters, wavelengths, and milliwatt power level.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Name: Phase II Study—Trial of a Phototherapy Light Device to Improve Sleep Health (PHOTONS); URL: https://clinicaltrials.gov/ct2/show/NCT05116358; Identifier: NCT05116358.

Keywords: sleep, wearables, phototherapy, near infrared, insomnia, actigraphy

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BRIEF SUMMARY

Current Knowledge/Study Rationale: There are few interventions specifically designed to treat subclinical sleep complaints. This study aims to assess the efficacy of a cervical red and near-infrared–emitting device on sleep and daytime function.

Study Impact: In this randomized, sham-controlled study, we show that red and near-infrared phototherapy targeted at the neck before bed improved perceived relaxation, sleep quality, and next-day function.

INTRODUCTION

The population prevalence of suboptimal sleep quality is relatively high, with over 25% of the population sleeping for less than the recommended minimum of 7 hours per night, and approximately 15% regularly reporting trouble falling or staying asleep.[1,2] Although some of these cases may represent sleep disorders, most of the individuals who report some problem with sleep likely do not meet criteria for a sleep disorder. Still, poor sleep quality is associated with poor cardiometabolic health,[3] mental health,[4] and daytime functioning.[5] Despite the high prevalence of these problems and identified associated risks, there are still few interventions that are specifically designed to address subclinical sleep quality.

A wearable device that emits red and near-infrared (NIR) light may be beneficial for sleep and mood. While photobiomodulation, or phototherapy, for sleep typically focuses on the presence or absence of light entering the eye to regulate sleep timing and mood,[6] NIR and red light applied to the skin may create a cascade of effects that improve sleep and daytime function through skin warming and other pathways.[7]

NIR therapy has been shown to improve chronic pain,[8,9] and has been effective and comparable to exercise training in fibromyalgia treatment.[10] It promotes capillary growth in skeletal muscle[11] and exhibits anti-inflammatory effects by attenuating circulating levels of prostaglandin-2.[12]

Some of the observed improvements in pain may also result from the ability of NIR to improve cardiovascular function. This may occur through increased vasodilation via the direct application of heat and upregulation of nitric oxide (NO).[13,14] NIR wavelengths are absorbed by cytochrome c oxidase (CCO), the terminal enzyme of the electron transport chain housed within the mitochondria.[15] This results in an increased rate of respiration and thus increased adenosine triphosphate (ATP) production.[16] In the process of increasing metabolism within the cell, NO photo-dissociates from CCO.[17]

Previous studies have not focused on the benefits of NIR therapy on sleep quality specifically, despite evidence that this

approach may influence related pathways. NIR devices are already commercially available to the general public. Therefore, if these devices do demonstrate benefits for subclinical sleep quality, they may represent a novel approach for improving sleep health.

One way that NIR therapy may also support sleep health is through effects on relaxation. Although relaxation is typically insufficient to treat sleep disorders,[18] other interventions focused on relaxation have been shown to generally improve sleep quality.[19–21] Relaxation from direct heat may help to decrease cortisol levels, thus reducing nocturnal arousals.[22] NIR may also decrease circulating levels of norepinephrine, one of the main neurotransmitters involved in arousal.[23] Last, direct skin warming and NO have both been shown to promote non–rapid eye movement (non-REM) sleep.[24,25]

The objective of the present study was to determine whether an NIR device worn before bed improved sleep quality, reduced sleep onset, increased total sleep time, modified estimated sleep architecture, and/or was associated with improved daytime function following use.

METHODS

Participants

Healthy adults aged 30–60 years (n = 30) were recruited locally from Tucson, Arizona. Recruitment was achieved through flyers and social media advertising. Inclusion criteria were that participants needed to be fluent in English, have access to a mobile device (ie, smartphone) and a residential mailing address, and exhibit a score ≥ 8 on the Insomnia Severity Index (ISI). Individuals were excluded if they had a diagnosed sleep or psychiatric disorder (assessed using self-reported medical history), met apparent criteria for a sleep disorder (assessed using the Sleep Disorder Symptoms Checklist-25 [SDSCL-25][29] administered during the screening interview), took medications that interfered with sleep, or had a medical condition that prevented them from participating in the study. They were also excluded if they were shift workers or had unusual sleep timing, regularly smoked tobacco or cannabis, were pregnant, or were using any other phototherapy devices. Participants were asked to restrict alcohol consumption to no more than 2 drinks within 4 hours of sleep and consume no caffeine after 12 PM while participating in the study.

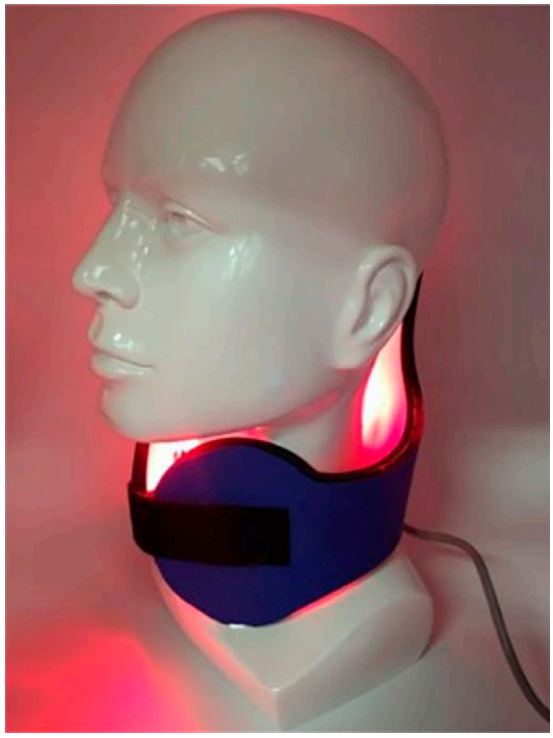
Measures

Phototherapy device

The phototherapy device (CeraZ Technologies LLC, Boca Raton, FL) consisted of a neoprene collar designed to be worn around the neck (**Figure 1** and **Figure 2**), connected to a controller and 36-V power supply. The power supply was connected to a 120/VAC power outlet during use. The collar was fitted with 48 light-emitting diodes that emit 660-nm, 740-nm, 810-nm, and 870-nm wavelengths of red and NIR light at 40 mW each (48 light-emitting diodes × 40 mW each = 1,920 mW total = 192 lumens). This combination of wavelengths was chosen to cover a broad spectrum of potentially therapeutic red and NIR light.

Participants wore the device every other night for 25 minutes' duration in the 1 hour prior to their targeted bedtime. They could watch television, read, listen to music, or pursue other typical prebed relaxation rituals during this time. The activity performed while wearing the device was recorded in the morning sleep diary the next day. The sham devices were identical except that they did not emit any light.

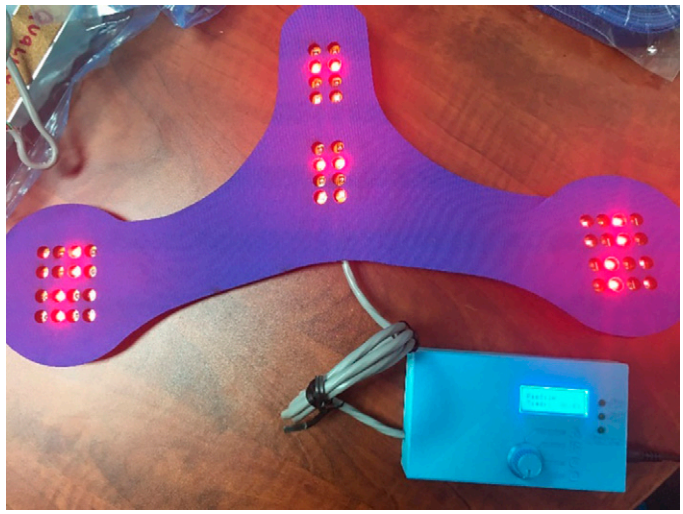
Figure 1—The phototherapy collar.



Oura ring

The Oura Ring Heritage Generation 2 (OURA, Oulu, Finland) measures and approximates sleep vs wake and sleep stages via

Figure 2—The phototherapy device.



accelerometry (for movement) and photoplethysmography (for heart rate).[26] Rings are waterproof, ceramic, and connected to a mobile app that uses a proprietary algorithm to estimate sleep. Previous studies have shown that these devices perform well in capturing sleep vs wake in adults without sleep disorders.[26,27] Data on assessment of sleep stages suggest that these devices roughly approximate polysomnographic sleep stages but are not equivalent to polysomnography.[26] The ring is designed to be worn continuously, apart from during charging. The ring transmits user data to the app at regular intervals throughout the day via Bluetooth, although manual synchronizations can also be triggered by the user through the app. Participants' data were accessed by study personnel via the Oura Teams dashboard.

Sleep diary

The sleep diary[28] was a brief questionnaire designed to be completed within 30 minutes of waking each morning during the study period. It included questions about time to bed and nighttime arousals from the previous night, as well as self-perceived daytime sleepiness and general quality of sleep.

Expectancy questionnaires

Participants were asked about their initial impressions upon their first interaction with the device. They were asked questions about how comfortable the device was, and whether they anticipated that there would be any problems during use. They were also asked about their expectations of how much the device would improve their sleep, ability to relax, daytime mood, energy, and performance on a scale of 0 to 100. They were asked to rate these parameters again upon completion of the study.

Weekly surveys

Surveys were administered the first night of device use and every week thereafter until completion of the study and included demographics items, the SDSCL-25,[29] an instrument that assesses symptoms of common sleep disorders; the Systematic Assessment for Treatment of Emergent Effects (SAFTEE),[30] a survey that is routinely administered during clinical trials to assess for adverse effects; the ISI,[31] a 7-item instrument that assesses for symptoms of insomnia, the Positive and Negative Affect Scale (PANAS);[32] consisting of 2 scales that measure both positive and negative mood; the Perceived Stress Scale (PSS),[33] which assesses perceived stress; the Fatigue Severity Scale (FSS),[34] which asks about current fatigue severity; the Profile of Mood States (POMS),[35] which assesses mood; the Circadian Energy Scale (CIRENS),[36] which assesses chronotype; and the Pittsburgh Sleep Quality Index (PSQI),[37] which assesses recent perceived sleep quality.

Procedure

Baseline period

Participants completed a 2-week baseline period consisting of Oura ring use and sleep diary completion. This established current sleep behavior prior to introducing the intervention.

Intervention period

Following the baseline period, participants continued to use the Oura ring and complete sleep diaries while wearing the phototherapy device every other night for 3 weeks. Weekly surveys were completed during the intervention, and a debrief interview was conducted upon completion.

Statistical analyses

All statistical analyses were completed using STATA SE 17.0 (StataCorp LLC, College Station, TX). Mean weekly sleep diary and Oura data were computed, and the baseline (pre) and intervention (post) averages were compared using paired *t* tests. The first-night survey (prior to device use) and final weekly survey (at the end of the intervention period) were compared using paired *t* tests. The initial expectancy (pre) estimates of improvements in sleep, relaxation, daytime mood, performance, and energy levels were compared to scores provided during the debrief interview (post) using paired *t* tests. All primary outcome data were adjusted using a Holm-Bonferroni correction to account for multiple comparisons.

Exploratory post hoc analyses comparing the baseline period (pre) with the third week of the intervention only (post) were also conducted to detect any potential cumulative effects of device use.

RESULTS

Characteristics of the sample

Characteristics of the sample are reported in **Table 1**. The sample comprised mostly White, middle-class females with a mean age of 51.18 (±10.50) years.

Table 1—Characteristics of the sample.

Demographics	Sham	Active
Age, y	55 ± 7.51	49 ± 11.06
Sex		
Female	80%	90%
Male	20%	10%
Race/ethnicity		
White	90%	85%
Hispanic/Latino	0%	10%
Black (African)	10%	0%
Asian	0%	5%
Financial status		
Lower middle	20%	25%
Middle	40%	35%
Upper middle	40%	40%
Sleep satisfaction		
0–19%	10%	10%
20–39%	50%	5%
40–59%	30%	35%
60–79%	10%	40%
80–100%	0%	10%

Age is reported as mean ± standard deviation.

Table 2—Between-group differences in self-reported perception of the device before and after use.

	Subjective Rating (%)		
Measure	Sham Group	Active Group	*P*
Sleep	−21.5 (30.9)	−3.65 (23.7)	.090
Relax	5.5 (21.7)	17.5 (23.1)	.183
Daytime	−25.0 (23.7)	−10.6 (27.6)	.170
Perform	−26.0 (30.2)	−5.8 (24.4)	.058
Energy	−18.7 (25.7)	−6.8 (25.1)	.233

Data are presented as mean (standard deviation); *t* tests were performed on change scores pre- and postintervention.

Primary outcomes

Subjective ratings

There was a trend toward perceived improvements in daytime performance following participation in the study among active, but not control, participants, but there were no significant differences between groups before or after applying a Holm-Bonferroni correction (Table 2). There were within-group improvements in perceived relaxation and daytime mood among active, but not control, participants (Table 3).

Insomnia severity

There were no between-group differences in ISI score before or after applying a Holm-Bonferroni correction (Table 4). However, as seen in Table 3, there were significant within-group improvements (specifically item 7, which asks, "To what extend do you feel that your current sleep problems interfere with daytime function?") in both the active and control groups.

Objective sleep efficiency

There were no significant differences in sleep efficiency as measured using the Oura ring between active and sham groups before or after applying a Holm-Bonferroni correction (Table 5).

Secondary outcomes

Sleep diary measures

There were no significant between-group differences in sleep diary variables (Table 6). Within-group improvements in perceived sleepiness, as assessed by Karolinska Sleepiness Score, perceived sense of feeling refreshed, and sleep quality were seen in both active and control groups (Table 3). Within-group improvements in perceived sleep-onset latency and sufficient sleep duration were seen in the active, but not control, group.

Table 3—Within-group statistically significant changes across all measures.

	Sham Group		Active Group	
Measure	Mean (SD)	*P*	Mean (SD)	*P*
Survey data				
ISI item 7	−0.75 (0.89)	0.048	−0.70 (1.09)	.009
ISI total	−2.38 (2.20)	0.019	−1.70 (3.39)	.037
SDS insomnia	−1.44 (1.51)	0.021	−1.35 (2.25)	.015
POMS depression	–	–	−0.22 (0.42)	.029
Oura				
REM (%)	–	–	−0.01 (0.02)	.034
Diary				
Karolinska Sleepiness Scale	−0.56 (0.62)	0.019	−0.57 (0.85)	.008
Sleep latency (min)	–	–	−6.33 (7.30)	.001
Sufficient	–	–	0.07 (1.51)	.044
Refreshed	0.35 (0.50)	0.057	0.71 (0.71)	<.0001
Sleep quality	0.37 (0.52)	0.051	0.59 (0.77)	.003
Subjective rating (%)				
Sleep	−21.50 (30.92)	0.055	–	–
Relax	–	–	17.50 (23.14)	.003
Daytime	–	–	17.50 (23.14)	.003
Perform	−18.70 (25.73)	0.047	–	–
Energy	−26.00 (30.17)	0.023	–	–

Data are presented as mean (SD); *t* tests were performed on change scores pre- and postintervention. ISI = Insomnia Severity Index, POMS = Profile of Mood States, REM = rapid eye movement, SD = standard deviation, SDS = Sleep Disorders Symptoms Checklist-25.

Table 4—Between-group differences in survey results.

Survey Data Measure	Sham Group	Active Group	*P*
SAFTEE total score	13.80 (45.18)	−9.40 (11.05)	.036*
SAFTEE (other)	4.10 (8.71)	−2.90 (3.80)	.005*
ISI	−2.38 (2.12)	−1.70 (3.39)	.608
PANAS positive	−1.38 (6.76)	−0.25 (5.41)	.647
PANAS negative	−0.88 (2.78)	−3.00 (4.71)	.246
Perceived Stress Scale	−0.75 (5.90)	−0.40 (6.28)	.893
Fatigue Severity Scale	2.75 (7.32)	−2.10 (6.14)	.085
POMS tension	−0.25 (0.97)	−0.13 (0.57)	.674
POMS depression	−0.17 (0.41)	−0.22 (0.42)	.788
POMS anger	−0.09 (0.89)	−0.16 (0.44)	.787
POMS vigor	0.04 (0.91)	0.11 (0.71)	.838
POMS fatigue	0.03 (1.15)	−0.38 (0.95)	.347
POMS confusion	−0.38 (0.73)	−0.12 (0.42)	.254
Pittsburgh Sleep Quality Index	−0.88 (1.25)	−0.95 (2.61)	.939
SDSCL-25 insomnia	−1.44 (1.51)	−1.35 (2.25)	.910
SDSCL-25 circadian	−0.67 (0.87)	−0.35 (1.18)	.479
SDSCL-25 narcolepsy	0.00 (0.00)	−0.25 (0.72)	.309
SDSCL-25 sleep apnea	−0.89 (1.05)	−0.60 (1.19)	.537
SDSCL-25 RLS	0.00 (0.50)	−0.05 (0.51)	.808
SDSCL-25 parasomnias	−0.22 (0.44)	−0.40 (0.68)	.481
SDSCL-25 grind teeth	0.11 (0.33)	−0.15 (0.67)	0.281

Data are presented as mean (standard deviation); *t* tests were performed on change scores pre- and postintervention. *Statistically significant. ISI = Insomnia Severity Index, PANAS = Positive and Negative Affect Score, POMS = Profile of Mood States, SDSCL-25 = Sleep Disorder Symptoms Checklist-25.

Oura ring data

There were no significant differences in objective sleep measures using the Oura ring between sham and active groups. A spurious decrease in REM sleep among the active group when REM sleep was assessed as a percentage of total sleep minutes (**Table 3** and **Table 5**) was not mirrored when REM sleep was assessed by total minutes.

Survey data

There were statistically significant improvements among users of the active devices, as compared with the control group, in SAFTEE scores pertaining to self-reported problems falling asleep, trouble thinking/concentrating, and anxiety (**Table 4**). There were significant within-group improvements in insomnia symptoms as assessed using the SDSCL-25 insomnia item in both active and control groups. There was a significant within-group improvement in POMS depression subscore among the active, but not control, group.

Exploratory analyses

To account for any potential cumulative effects of device use, change scores were calculated from the baseline period to the third week of the intervention only. There were no significant differences in sleep diary measures or Oura scores.

Table 5—Between-group differences in Oura ring outcomes.

Oura Measure	Group		*P*
	Sham	Active	
Time in bed (min)	3.02 (37.60)	1.71 (37.56)	.929
Total sleep time (min)	7.26 (23.38)	1.52 (21.80)	.512
Sleep efficiency (%)	0.75 (4.12)	−0.24 (2.69)	.541
Light (min)	4.68 (21.03)	0.24 (20.55)	.584
REM (min)	5.30 (14.83)	−3.56 (10.86)	.073
Deep (min)	−2.72 (11.01)	4.84 (11.78)	.102
Light (%)	−0.00 (0.03)	0.00 (0.03)	.912
REM (%)	0.01 (0.03)	−0.01 (0.02)	.047*
Deep (%)	−0.01 (0.04)	0.01 (0.04)	.262
Total wake time (min)	−4.25 (26.90)	0.18 (18.64)	.601
Time to bed (time)	−0.05 (0.28)	−0.06 (0.52)	.960
Time out of bed (time)	0.01 (0.66)	−0.13 (0.60)	.574

Data are presented as mean (standard deviation); *t* tests were performed on change scores pre- and postintervention. *Statistically significant. REM = rapid eye movement.

DISCUSSION

A red and NIR-emitting device worn around the neck before bed may offer some benefits to sleep and next-day function,

Table 6—Between-group sleep diary outcomes.

Diary Measure	Group		*P*
	Sham	Active	
Karolinska Sleepiness Scale	−0.56 (0.62)	0.57 (0.85)	.970
Time to bed (time)	−0.12 (0.05)	0.02 (0.01)	.240
Time to sleep (time)	−0.00 (0.06)	0.03 (0.15)	.583
Sleep latency (min)	−1.50 (6.38)	−6.33 (7.30)	.086
Sleep efficiency (%)	1.64 (3.13)	1.84 (13.67)	.964
Total sleep time (min)	0.00 (0.02)	0.01 (0.03)	.507
Number of awakenings	−0.02 (0.71)	−0.29 (0.77)	.344
Wake after sleep onset (min)	−2.04 (18.71)	0.64 (11.92)	.636
Wake after sleep onset time out of bed (min)	−3.25 (8.44)	0.33 (1.39)	.198
Wake up time (time)	0.01 (0.03)	0.01 (0.03)	.990
Time out of bed (time)	0.00 (0.03)	0.00 (0.02)	.834
Sufficient	0.04 (0.12)	0.07 (1.51)	.594
Refreshed	0.35 (0.50)	0.71 (0.71)	.164
Sleep quality	0.37 (0.52)	0.59 (0.77)	.426

Data are presented as mean (standard deviation); *t* tests were performed on change scores pre- and postintervention.

but further investigation is required. Statistically significant improvements were mostly observed in within-group, self-reported (subjective) data and there were no differences between groups in terms of a priori primary outcomes.

The sham-controlled study design was rigorous in that it assessed the efficacy of the phototherapy device above and beyond other aspects of the protocol that had the potential to improve sleep. The Oura ring is a sleep tracker that can provide regular feedback about sleep quality and duration and may have encouraged some participants to create more sleep opportunity for themselves than they did prior to using the device. Further, the period of mandatory sedentary activity for 25 minutes before bed every other night while wearing the collar (regardless of whether or not it emitted light) may have promoted relaxation for individuals who, prior to the study period, were not allocating sufficient wind-down time before bed. Many participants commented during the debrief interviews that they felt that these 2 activities alone may have improved their sleep. The within-group analyses indicated that both the control and active groups improved in several areas of sleep and mood, which led to fewer statistically significant differences between the 2 groups.

Gamma-amino butyric acid (GABA-ergic) neurons in the preoptic area of the mouse hypothalamus have been shown to respond to changes in ambient temperature.[38] Excitation of these cells through warming of the environment or skin promotes a robust increase in non-REM sleep. Further, although a drop in core body temperature is known to promote sleep onset, Harding and colleagues[38] observed that sleep onset preceded a decrease in core body temperature in these experiments. This points to a unique circuitry that involves skin warming and non-REM onset.[39]

A study by Igaki and colleagues[40] investigated whether sleep was improved after warming the posterior cervical skin—similar to the area warmed in the present study—to approximately 40°C for 30 minutes before habitual bedtime for a period of 6 days. The application of heat to this area improved self-reported feelings of restfulness following subsequent sleep, and delta power, as measured using electroencephalography, increased in the first third of the sleep episodes. The application of heat in both this and the present study may have reduced somatic arousal, promoting parasympathetic nerve activity and perceived relaxation.

The devices used in the present study did not result in any reported adverse effects, although many participants commented that the prototype devices manufactured for this study could become mildly to moderately uncomfortable to wear. This discomfort may have counteracted some of the benefits potentially associated with device use.

Limitations

These findings must be understood within the context of the study limitations. First, this was a small sample of 30 individuals who were mostly White midlife females. As such, the study was underpowered but served as essential exploratory analyses. Second, the use of a commercial multisensory device that provides feedback via the associated app may have served as a sleep intervention that improved sleep in both experimental groups independent of the phototherapy device. The neoprene collar was noted by some participants to be somewhat uncomfortable during use due to rubbing along the jawline and this may have negated some of the potential benefits of phototherapy use. Last, the participants in this study were recruited locally in Tucson, Arizona, where baseline sun exposure is relatively high for residents. Given the importance of daylight exposure for sleep, results obtained in this locale may not necessarily translate to other locations.

CONCLUSIONS

This study used a novel, wearable phototherapy device targeted at improving sleep and next-day function. Usage protocols, including dose parameters, wavelengths, and milliwatt power level, are yet to be refined and were provided by the sponsor based on what was believed to be feasible to ensure adherence. The results of this study suggest that users generally felt that their subjective experience of relaxation and sleep improved, suggesting that cervical warming, or exposure to red and NIR phototherapy, shows promise for improving sleep health in the general population, perhaps through reduced somatic arousal and parasympathetic activation. Whether the effects are mediated by metabolic changes or fluctuations in NO are yet to be determined.

Future studies should explore the optimal frequency and duration of device use as well as modifications to the device structure to improve comfort and fit. Future investigations should also be conducted on larger sample sizes, should consider a crossover design paradigm, and should include a more diverse sample.

ABBREVIATIONS

ISI, Insomnia Severity Index
NIR, near-infrared
PANAS, Positive and Negative Affect Scale
POMS, Profile of Mood States
REM, rapid eye movement
SDSCL-25, Sleep Disorder Symptoms Checklist-25

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