Medical Research Archives

European Society of Medicine

OPEN ACCESS

Published: April 30, 2024

Citation: Hausenblas HA, Lynch T, et al., 2024. Effectiveness of a proprietary *Dichrostachys glomerata* extract (DYG-400®) on Adult's Sleep Quality and Activity: A Pilot Trial Medical Research Archives, [online] 12(4). https://doi.org/10.18103/mra.v12i4.5268

DOI
https://doi.org/10.18103/mra.v12i4.5268

ISSN: 2375-1924

RESEARCH ARTICLE

Effectiveness of a proprietary *Dichrostachys glomerata* extract (DYG-400®) on Adult's Sleep Quality and Activity: A Pilot Trial

Heather A. Hausenblas[1]*, PhD, Tarah Lynch[1], MS, Shaylee Beefus[3], Tiffany Braverman[3], Stephanie Hooper[2], MPH

[1]. Jacksonville University
[2]. University of North Florida
[3]. Wellness Discovery Labs

***Corresponding author:** hhausen@ju.edu

ABSTRACT

Objectives: The purpose of this study was to examine the effectiveness of *Dichrostachys glomerata* (Dyglomera®) supplementation on adults' sleep quality and daytime activity.

Methods: Using a double-blind placebo-controlled pilot trial, 56 adults with nonclinical poor sleep (M age = 44.50) were randomized to either the *Dichrostachys glomerata* Group (300 mg/d) or Placebo Group for 60 days. Outcomes were the self-reported Insomnia Severity Index and objective sleep and daytime activity via the Oura Ring. Analysis was undertaken at Day 0 (Baseline), Day 30, and Day 60.

Results: The *Dichrostachys glomerata* Group had improved Insomnia Severity Index symptoms, with significant improvements from Day 0 to Day 60. Objective sleep measures indicated that the *Dichrostachys glomerata* Group had significantly improved sleep score and deep sleep duration, while the Placebo Group declined in these parameters. The *Dichrostachys glomerata* Group also improved on sleep latency and time awake, contrasting with worsened of these sleep metrics in the Placebo Group, p's < .05. No group differences were found for REM. The *Dichrostachys glomerata* Group improved significantly on the activity outcomes.

Conclusion: These results provide preliminary support for the potential of *Dichrostachys glomerata* supplementation to enhance both sleep and daytime activity. Further research is warranted to validate these findings in diverse populations. Clinical trial registry = ISRCTN10099861.

Keywords: Sleep quality, activity, intervention

Introduction

Sleep is essential for maintaining physical, social, and psychological well-being.[1-3] Insufficient and poor quality sleep are associated with adverse health outcomes including reduced productivity, impaired work performance, and lower levels of physical activity.[4,5] Despite the well-established importance of sleep, sleep dissatisfaction is prevalent among the general population, with up to 41.7% of adults reporting insufficient sleep and 48% reporting difficulties with sleep initiation or maintenance.[6] Although medication may be effective for treating sleep disorders, there is still an unmet need for safe and accessible sleep aids for individuals with suboptimal nonclinical sleep issues.[7]

Furthermore, traditional interventions involving over-the-counter and prescription medications often come with undesirable side effects, limited efficacy, and the potential for dependency.[7] Therefore, research exploring alternative interventions that can enhance sleep quality and daytime functioning in those with poor sleep habits is warranted.

Despite the widespread use of herbal plants for addressing various health concerns, there are limited randomized controlled trials evaluating their effectiveness for improving sleep quality.[8] Within this context, *Dichrostachys glomerata*, a plant known for its safety profile and potential lipid-lowering properties, has garnered attention for its potential health effects. In regions like western Cameroon, the fruit and seeds of *Dichrostachys glomerata* are commonly employed as a spice, reflecting its cultural relevance and accessibility.[9]

Dichrostachys glomerata boasts a rich chemical composition, featuring flavonoids, phenolic compounds, alkaloids, tannins, saponins, and terpenoids.[10] Existing *in vitro* and *in vivo* research has found its antioxidant properties, along with its ability to reduce fasting serum glucose levels and glycated hemoglobin.[11-13] Moreover, *Dichrostachys glomerata* has demonstrated effectiveness in ameliorating oxidative stress.[14,15] Given the association between poor sleep and oxidative stress, interventions targeting oxidative stress may enhance sleep quality.[16]

Therefore, the purpose of this pilot study was to investigate the effectiveness of a standardized powder derived from *Dichrostachys glomerata* fruit pods (DYG-400) on sleep quality in adults with nonclinical poor sleep quality using a randomized double-blind placebo-controlled trial design. The primary outcomes were self-reported and objective sleep quality/quantity. The secondary outcomes were daytime activity and safety/adverse events.

Methods

Participants: Participants were 56 adults (*M* age = 44.50, age range = 25 to 60 years, *n* = 43 women).

Exclusion Criteria: Individuals meeting any of the following criteria were excluded from participation: (1) any metabolic or endocrine related dysregulation including but not limited to: diagnosis of type I or type II diabetes, liver, kidney, or pancreatic dysfunction; (2) history of sleep-affecting disorders; (3) highly stressful events within 4 weeks of baseline; (4) use of weight-influencing medications within 1 month of baseline; (5) use of Ca channel blockers, anxiolytics or SSRIs, no more than 5 times per month, and not within seven days of baseline; (6) unstable use of other medication; (7) current hormone therapy; (8) excessive alcohol consumption; (9) smoking; (10) elevated caffeine intake; (11) irregular sleep-inducing work schedules; (12) inability to engage in spontaneous physical activity; (13) metabolic disorder, a sleep disorder, or a psychiatric condition; (14) pregnancy, attempts at conception, or breastfeeding; (15) use of sleep/weight supplements or medications; (16) actively intermittent fasting, actively trying to lose weight, or have lost more than ± 3kg in previous 3 months; (17) moderate or severe obesity (BMI ≥ 35), (18) clinical insomnia as determined by the Insomnia Severity Index, and (18) individuals deemed incompatible with the study protocol.

Study design: This study was approval by Sterling Institutional Review Board (10504) in compliance with the Declaration of Helsinki standards for ethical principles regarding human participant research and registered with ISRCTN registry (ISRCTN10099861).

This study was conducted in a double-blind, parallel treatment, stratified random, placebo-controlled manner. The independent variable was the *Dichrostachys glomerata* (DYG-400®) nutritional supplement. The dependent variables were sleep quality (primary outcomes) and daytime activity and adverse events (secondary outcomes). Sample size power calculation indicated that 30 participants were needed in each group to achieve a power of 80% and alpha < .05 (https://clincalc.com/stats/samplesize.aspx).

Procedures: Following preliminary screening, eligible participants provided Institutional Review Board approved informed consent prior to enrolment. Participants completed the Insomnia Severity Index on Day 0, Day 30, and Day 60. In addition, participants maintained a daily diary to document adherence and adverse events. Participants completed the self-report surveys via a SurveyMonkey link that was sent via email or text.

Participants were instructed to maintain their habitual lifestyle patterns and refrain from introducing new exercise, diet, or health interventions during the study. Data were collected from March 2023 to June 2023 and were stored electronically.

Intervention: A randomized double-blind placebo-controlled pilot trial design was employed, with participants randomly assigned to either the *Dichrostachys glomerata* group (DYG-400®) or Placebo Control group (PG) for the duration of the two-month trial. A computer-based randomization via SPSS to automate the random assignment process was used. Participants were directed to consume 300 mg, 1 x per day of the allocated substance. DYG-400®, an aqueous ethanol extract of *Dichrostachys glomerata* fruit pods (standardized to Myricetin 1.6% and Luteolin 1.0%), that was supplied by Gateway Health Alliances, Inc (https://www.ghainc.com/; Fairfield, CA, USA). The manufacturing process was as follows: *Dichrostachys glomerata* fruit pods were extracted using aqueous ethanol. The resulting solution was concentrated and dried to yield DYG-400®. The placebo was rice protein.

Trial Reporting: The Consolidated Standards of Reporting Trials (CONSORT, including reporting of harms) was used to report this trial.

Blinding: To ensure that all participants and researchers were unaware of the treatment assignments, Gateway Health Alliances provided the supplement/placebo labelled as either A or B. The supplement/placebo pills were identical in color, odor, and size. At the conclusion of the study, immediately following the last assessment, the research team was unblinded. The participants were then unblinded and informed of their assigned condition.

Adherence: $N = 61$ participants enrolled and consented and 56 completed the trial, representing an adherence rate of 92%. Two participants from the placebo group (PG) dropped out due to reasons unrelated to the study, and 3 participants ($n = 2$ from the PG and $n = 1$ from the *Dichrostachys glomerata* group (DG) withdrew due to nonserious self-reported adverse events.

Statistical analysis: Data were analyzed for normality by examining skewness and kurtosis scores and using Shapiro-Wilk test and Q-Q plot. Outliers were characterized as data points that exceeded three interquartile ranges beyond 25th and 75th percentiles. However, no extreme outliers were observed. Continuous data were presented as Mean (SD) and analyzed using linear mixed model with Condition, and Time as fixed factors and subject as random factor. Statistical analyses were performed using Excel and Statistical Product and Service Solutions (SPSS) [version 28].

Measures

Insomnia Severity Index: The Insomnia Severity Index is a 7-item self-report measure assessing symptoms of poor sleep. This index assesses sleep onset, sleep maintenance, early morning awakening problems; sleep dissatisfaction; interference of sleep difficulties with daytime functioning; whether sleep problems are noticed by others; and distress caused by sleep difficulties. The Insomnia Severity Index has excellent internal consistency (Cronbach alpha = .91).[17]

Oura Ring. The Oura Ring is a novel, multisensory device that quantifies daily physical activity, night-time sleep duration, and estimates sleep stages, including REM (https://ouraring.com/). The ring also measures motion and body temperature. The Oura Ring uses physiological signals (a combination of motion, heart rate, heart rate variability, and pulse wave variability amplitude) in combination with sophisticated machine learning based methods to calculate deep, light and rapid-eye-movement (REM) sleep in addition to sleep/wake states. Rings are waterproof, made in ceramic, and come with a dedicated mobile App. They come in different sizes (US standard ring sizes 6–13) and weigh about 15 g with a battery life of about 3 days. The ring automatically connects via Bluetooth and transfers data to a mobile platform via the dedicated App. The Oura Ring has high validity in the assessment of nocturnal heart rate, heart rate variability, movement and sleep outcomes in healthy adults in their natural environment.[18-20]

Daily Diary: The Daily Diary assessed supplement adherence and adverse events.

Results

Sleep Outcomes

For the Insomnia Severity Index, a significant main effect for Condition, $F(1,54) = 535.09$, $p < .001$, and Time, $F(2,108) = 3.51$, $p = .03$, and a nonsignificant interaction was evidenced, $F(2,108) = 0.53$, $p = .59$. Post hoc analyses revealed that the DG had nonsignificant improvements in insomnia symptoms from Baseline to Day 30, and significant improvements from Baseline to Day 60. The PG had a significant improvement from Baseline to Day 30, $p < .05$, and a nonsignificant worsening of insomnia symptoms from Day 30 to Day 60 (see table 1).

For Overall Sleep Score, significant main effects for Condition, $F(1,290) = 174559.68$, $p < .001$, Time, $F(8,2320) = 0.52$, $p = .84$, and Interaction, $F(8,2320) = 1.84$, $p = .05$, were evidenced. Post hoc analyses indicated significant improvements in the Sleep Score from Baseline to Day 60 for the DG, $p < .05$. In comparison, the PG had a significant decrease in the Sleep Score from Baseline to Day 60, $p < .05$.

For Deep Sleep, significant main effect for Condition, $F(1,290) = 68050.88$, $p < .001$, and Time, $F(8,2280) = 3.11$, $p = .002$, and a nonsignificant interaction, $F(8,2280) = 1.67$, $p = .10$, were evidenced. Both the DG and PG's deep sleep improved significantly more from Baseline to Day 30 and Baseline to Day 60. Although the DG time in deep sleep improved more than the PG by Day 60, it was a nonsignificant interaction.

Sleep Efficiency represents the percentage of time spent asleep. Significant main effects for Condition, $F(1,290) = 109467.72$, $p < .001$, and Time, $F(8,2288) = 1.83$, $p = .05$, were evidenced. The interaction was nonsignificant, $F(8,2288) = 1.63$, $p = .11$. Post hoc analysis indicated a significant improvement from Baseline to Day 60 for the DG.

Sleep Latency is the amount of time that it takes to fall asleep at night. Significant main effects for Condition, $F(1,290) = 109467.72$, $p < .001$, and Interaction were found, $F(8,1824) = 2.11$, $p = .04$. The main effect for Time was nonsignificant, $F(8,1824) = 0.90$, $p = .52$. The DG sleep latency improved, while the PG worsened.

For REM sleep a significant main effect for Condition, $F(1,290) = 109467.72$, $p < .001$, was evidenced. The main effect for Time, $F(8,2128) = 0.88$, $p = .54$, and the Interaction, $F(8,2128) = 1.65$, $p = .11$, were nonsignificant. REM sleep decreased for both the DG and PG from Baseline to Day 60.

For Sleep Duration a higher score indicated a longer sleep duration. A significant main effect for Condition, $F(1,290) = 51457.47$, $p < .001$, was evidenced. The main effect for Time, $F(8,2322) = 0.38$, $p = .93$, and the Interaction, $F(8,2322) = 1.07$, $p = .54$, were nonsignificant. Post hoc analysis revealed a significant improvement in sleep duration from Baseline to Day 30 and Baseline to Day 60 for the DG. In comparison, the PG had a significant decrease in sleep duration from Baseline to Day 60.

Awake Time is the time spent awake in bed before and after falling asleep. Lower scores indicate less time awake during the night. A significant main effect for Condition, $F(1,290) = 5841.75$, $p < .001$, was evidenced. The main effect for Time, $F(8,2320) = 1.13$, $p = .34$, and the Interaction, $F(8,2320) = 1.16$, $p = .32$, were nonsignificant. The DG had a significant improvement in Time Awake from Baseline to Day 60, $p < .05$, while the PG had a nonsignificant worsening of time awake at night at Day 30 and Day 60.

For Time in Light Sleep, significant main effect for Condition, $F(1,290) = 5841.75$, $p < .001$, was evidence. However, a nonsignificant main effect for Time, $F(8,2320) = 1.13$, $p = .34$, and Interaction, $F(8,2320) = 1.16$, $p = .32$, were found. The DG had a significant improvement in light sleep from Baseline to Day 30. And the PG had a significant improvement from Baseline to Day 60.

Total sleep (minutes) reflects the amount of time spent in light, REM, and deep sleep. Significant main effects for Condition, $F(1,290) = 54033.81$, $p < .001$, and Interaction, $F(8,2320) = 1.42$, $p = .05$, were evidenced. The main effect for Time, $F(8,2320) = 0.28$, $p = .97$, was nonsignificant. The DG significantly improved in total sleep from Baseline to Day 60, while the PG significantly decreased in sleep from Baseline to Day 60, $p < .05$.

For Sleep Readiness Balance, significant main effects for Condition, $F(1,290) = 87727.57$, $p < .001$, and the Interaction, $F(8,2320) = 4.62$, $p < .001$, were evidenced. The main effect for Time, $F(8,2320) = 1.58$, $p = .13$, was nonsignificant. Sleep readiness balanced improved significantly from Baseline to Day 60 for the DG, compared to a worsening for the PG.

Activity Outcomes

For the Activity Score, a significant main effect for Condition, $F(1,305) = 40366.02$, $p < .001$, and interaction, $F(8,2440) = 2.83$, $p = .004$, were evidenced. The main effect for Time, $F(8,2440) = 0.49$, $p = .86$, was nonsignificant. The DG activity improved from Baseline to Day 60, and it decreased from Baseline to Day for the PG.

For Stay Active, significant main effect for Condition, $F(1,305) = 33756.39$, $p < .001$, was found. The main effect for Time, $F(8,2440) = 0.21$, $p = .99$, and the Interaction, $F(8,2440) = 0,65$, $p = .74$, were nonsignificant. The Stay Active scores improved over time for the DG and decreased for the PG.

For Activity Balance, significant main effects for Condition, $F(1,290) = 153581.94$, $p < .001$, and Time, $F(8,2320) = 3.23$, $p < .001$, were evidenced. The interaction was nonsignificant, $F(8,2320) = 1.65$, $p = .10$. Post hoc analyses revealed that Activity Balance improved significantly from Day 0 to Day

60 for the DG, and worsened for the PG. Moderator analysis by gender revealed no gender effects, p's > .05.

Adverse Events

The supplement was well-tolerated and only one adverse event was reported for the DG compared to two adverse events reported for the PG. For the DG, the adverse event reported was gastrointestinal symptoms after taking the supplement. For the PG, the two adverse events reported were heart palpitations and a liver concern.

Conclusion

The purpose of this pilot study was to investigate the effectiveness of a standardized powder DYG-400® derived from *Dichrostachys glomerata* fruit pods on sleep quality for adults with nonclinical poor sleep quality using a randomized double-blind placebo-controlled design. Our findings provide preliminary evidence that *Dichrostachys glomerata* (DYG-400®) supplementation led to improved sleep quality and daytime activity compared to the placebo. Interpretation of the results, study limitations and implications, and future research directions are discussed below.

The DYG-400® displayed a notable trend toward improved self-reported Insomnia Severity Index scores, which reached significance by Day 60. In contrast, the PG had an initial significant improvement within the first 30 days, followed by a nonsignificant decrease in symptoms from Day 30 to Day 60. The Insomnia Severity Index encompasses various dimensions of sleep health, including sleep initiation and maintenance difficulties, early morning awakenings, satisfaction with sleep, impact on daily functioning, perception of sleep issues by others, and the distress associated with these difficulties.

Improvements in self-reported sleep for the DYG-400® were verified by the objective outcomes. The Oura Ring sleep parameters, including deep sleep, sleep latency, REM sleep, sleep efficiency, and light sleep provide a comprehensive understanding of sleep patterns and quality. The *Dichrostachys glomerata DYG-400®* supplementation demonstrated significant effects on various aspects of sleep and activity, highlighting its potential in promoting both improved sleep quality and daytime activity.

For example, the Overall Sleep Score, which measures overall objective sleep quality, the DG exhibited enhanced sleep quality over the 60-day study. Conversely, the PG experienced a decline in sleep quality. These findings underscore the divergent impact of this intervention on sleep quality, emphasizing the effectiveness of *Dichrostachys glomerata* DYG-400® supplementation in enhancing sleep outcomes within the DG. Importantly, the DG Overall Sleep Score of 82 fell within the range indicating good overall sleep quality.

Although the DYG-400® time in deep sleep improved more than the placebo group by Day 60, it was a nonsignificant interaction. Deep sleep refers to the physically restorative slow-wave sleep stage where bodily repair processes occur. The DYG-400® also improved in Time Awake from Baseline to Day 60, while the PG had a nonsignificant worsening of time awake at night at Day 30 and Day 60. Sleep efficiency, which represents the percentage of time spent asleep, improved for the DG from Baseline to Day 60. A sleep efficiency of 85% is a sign of peaceful and uninterrupted sleep.

From Day 0 to Day 60 the PG light sleepdecreased, while the DYG-400® light sleep increased. Light sleep should account for between 45-55% of a healthy and natural sleep cycle. The DYG-400®significantly improved in Total Sleep from Baseline to Day 60, while the PG significantly decreased in sleep from Baseline to Day 60. Total Sleep reflects the amount of time spent in light, REM, and deep sleep. Finally, no improvements for the DYG-400® and PG were found for REM sleep which is associated with dreaming, memory consolidation, and creativity.

For daytime activity, the Stay Active scores improved over time for the DYG-400® and decreased for the PG. Stay Active measures how well the participant managed to avoid inactivity (sitting or standing still). For the Activity Score, the DYG-400® activity improved from Baseline to Day 60, and it decreased from Baseline to Day 60 for the PG. Activity is the time spent sitting, standing, or otherwise inactive. Inactive time doesn't include resting or sleep. Having five to eight hours or less of inactive time a day has a positive effect on the Activity Score. Moving regularly and avoiding long periods of inactivity helps adults stay healthy.

Similarly, Activity Balance improved significantly from Day 0 to Day 60 for the DYG-400®, and worsened for the PG. The Readiness Activity Balance scores measures how the activity level is affecting adult's readiness to perform. When the activity balance is optimal, it reflects adequate (and not excessive) activity. This boosts recovery and energy levels.

Finally, the Stay Active scores improved over time for the DYG-400®and decreased for the PG. Stay Active estimates the total daily inactive time while

adults are awake. This contributor excludes when adults are naturally sedentary (e.g., asleep). To improve Stay Active contributor, adults should aim to keep inactive time under 8 hours each day.

The supplement was well-tolerated with only 1 mild adverse event reported in the DYG-400®. This finding expands genotoxicity results that found DYG-400® was safe in an animal model.[21]

Different dietary supplements aimed at improving sleep quality are available on the market, and most have limited research supporting their efficacy. Research has found that amino acids, vitamin D, and melatonin supplements improve sleep quality.[22] However, high heterogeneity and wide confidence levels plague this research, calling for a need for further clinical trials examining the effectiveness of dietary supplements. The results of this study provide preliminary data highlighting the effectiveness of DYG-400® for improving aspects of sleep and daytime activity. Further research is needed with larger and more diverse samples over longer durations to validate these early findings. Additional mechanistic research is also warranted to better understand how *Dichrostachys glomerata, DYG-400®,* supplementation may impact sleep regulatory processes.

Availability of data and materials: Data and/or statistical analyses are available upon request on a case-by-case basis for noncommercial scientific inquiry and/or educational use as long as Institutional Review Board restrictions and research agreement terms are not violated.

Acknowledgments: The authors thank Gateway Health Alliances, Inc. Fairfield, CA, USA, for providing support to complete this study.

Disclosure statement: The authors report there are no competing interests to declare.

Table 1: Mean (M) and Standard Deviation (SD) Scores for the Insomnia Severity Index and Oura Ring Sleep and Activity Data for the *Dichrostachys glomerata* Group and Placebo Group by Time

	***Dichrostachys glomerata* Group**			**Placebo Group**		
	Baseline M (SD)	**Day 30 M (SD)**	**Day 60 M (SD)**	**Baseline M (SD)**	**Day 30 M (SD)**	**Day 60 M (SD)**
Insomnia Severity Index	7.93 (4.24)	6.61 (3.91)	5.90 (3.08)†	8.63 (3.64)	6.57 (3.95)†	7.36 (4.58)
Overall Sleep Score‡	80.62 (9.40)	81.34 (9.49)	82.73 (8.49)†	82.93 (9.63)	83.21 (8.23)	81.92 (9.09)†
Deep Sleep (min)‡	112.22 (49.60)	118.22 (45.85)†	121.90 (48.42)†	90.44 (38.37)	99.94 (34.13)†	98.76 (41.73)†
Sleep Efficiency Score	86.68 (13.93)	85.46 (13.57)	91.49 (10.76)†	91.22 (10.58)	90.33 (10.49)	90.32 (9.54)
Sleep Latency (min)‡	13.07 (15.53)	12.13 (13.54)†	10.50 (9.15)†	10.50 (9.15)	11.33 (11.3)	11.46 (10.32)†
REM Score	86.29 (17.12)	84.96 (17.3)	83.73 (18.67†	87.70 (18.17)	87.96 (16.91)	83.74 (20.73) †
Sleep Duration (min)	483.49 (90.78)	488.88† (99.74)	488.37† (88.78)	493.80 (87.62)	492.26 (88.27)	486.70† (104.51)
Time Awake (min)	63.02 (38.95)	64.89 (49.69)	51.47† (35.96)	54.35 (35.72)	57.32 (36.12)	55.94 (30.67)
Time in Light Sleep (min)	196.30 (65.5)	194.95 (62.37)†	198.27 (61.50)	229.03 (58.72)	230.22 (59.85)	220.85 (67.82)†
Total Sleep Time‡	420.43 (79.27)	422.45 (87.12)	426.80 (77.04)†	439.38 (77.94)	437.53 (80.63)	430.76† (89.24)
Activity Score‡	80.96 (13.18)	83.47 (13.69)	84.86 (12.03)†	80.47 (17.24)	79.69 (17.41)	77.73 (17.86)†
Stay Active Score	76.32 (15.29)	79.25 (15.74)	79.41 (14.82)†	78.79 (16.18)	77.58 (16.27)	77.92 (17.05)
Readiness Score Activity Balance Score‡	77.95 (9.65)	80.66 (11.76)†	79.06 (9.65)†	79.70 (9.14)	80.1 (7.38)	78.00 (9.54)
Readiness Sleep Balance Score‡	80.65 (11.99)	80.77 (12.15)	82.69 (11.71)†	79.07 (13.02)	80.73 (7.34)	77.76 (11.63)†

Note: Lower scores indicate an improvement for Insomnia Severity Index, Time Awake, and Sleep Latency. Higher scores indicate an improvement for Overall Sleep Score, Sleep Duration, Total Sleep Time, Activity Score, Stay Active Score, Readiness Sleep Balance Score, and Sleep Efficiency, and REM. Min = minutes.

† = significant improvement from Baseline.

‡ = significant interaction.

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