

# Effects of a Supplement System on Objectively Measured and Perceived Sleep: A Randomized Controlled Study

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## Abstract

**Objective:** The aim of this study was to evaluate effects of a supplement system on objective and perceived sleep outcomes in a non-clinical adult sample.

**Methods:** Adults (55% female, mean age=51) who reported being in good health and were screened for physical and lifestyle factors that could affect sleep participated in a controlled 12-week field study. During the 4-week baseline period, participants slept at home in their usual environment without use of a supplement. Following a 4-week baseline period, participants were randomly assigned to use either supplement or control for 4 weeks. Then they crossed over to use the other product (either supplement or control) for 4 weeks. The supplement period used Rebalance Health Anxiety System, a three-part supplement system containing multiple vitamins and dietary nutrients with enhanced absorption. Sleep was measured objectively, using a polysomnography-validated noncontact monitoring device, and by self-report each morning. Compared to the control supplement, controlling for baseline sleep, using Rebalance resulted in multiple objective sleep improvements including: falling asleep faster (18% difference;  $p=0.003$ ), decreased number of nighttime awakenings (6% difference;  $p=0.044$ ), fewer minutes awake after initial sleep onset (13% difference;  $p=0.001$ ), smaller proportion of the night spent awake after initial sleep onset ( $p<0.001$ ), improved sleep efficiency ( $p<0.001$ ), and improved sleep maintenance ( $p<0.001$ ). Daily questionnaire assessment did not show a significant increase in perceived sleep quality, but the perception of feeling more well-rested upon waking increased ( $p=0.043$ ).

**Conclusion:** Compared to a control, the supplement system was associated with falling asleep faster, waking up less often, spending less time awake during the night, and better sleep efficiency and sleep maintenance. In addition to these objectively measured outcomes, participants reported feeling more well-rested in the mornings. This research indicates that the three-part supplement system can be a useful tool for supporting sleep.

## Introduction

Studies have consistently shown that poor sleep is associated with worse physical health and mental health outcomes [1-3]. Supplements including particular ingredients have been shown to improve sleep; for example, recent meta-analyses have shown that melatonin improves objective sleep outcomes and self-reported sleep quality, including increases above placebo conditions [4-6]. Other types of dietary supplements have also been found to improve sleep, including, for instance, zinc and vitamin B6 [7,8]. The current study examines the Rebalance Health Anxiety System, which is a three-part supplement system that contains multiple vitamins and dietary nutrients. The supplements are taken three times a day to enhance absorption and to ensure the correct dosage of ingredients.

## Materials and Methods

### Participants

Participants were recruited *via* an eligibility questionnaire sent to a large database of people who have indicated interest in engaging in sleep research. To be included, participants had to be adults living in the United States, with difficulty falling asleep or staying asleep but no clinical sleep disorders or other medical conditions affecting sleep, no autoimmune disease or history of low cortisol levels, no abnormalities with the buccal mucosa, no use of medications or substances affecting sleep, no children currently under the age of three living in the home, no lifestyle factors that would affect sleep (such as shiftwork or travel), not pregnant or planning to become pregnant, and not having any allergy or adverse reaction to any of the supplement ingredients. Sterling Institutional Review Board (IRB) approved this study (protocol number 11706). Participants ( $n=35$ ) were 55% female, aged 23-72 (Mean=51, SD=13.4), and the majority identified as white/Caucasian (73%).

### Design and procedures

This study was designed as a within-person comparison between an active treatment (Rebalance Health Anxiety System supplement) and a control supplement. Rebalance Health

System supplements have been reported on previously and have been associated with alleviated vasomotor symptoms in menopausal women [9]. Rebalance Health Anxiety System supplements are taken three times a day to ensure absorption and proper dosage of the ingredients. The morning lozenge included vitamin B6 and Ashwagandha root; the afternoon lozenge included magnesium biglycinate, zinc citrate, and Ashwagandha root; and the bedtime lozenge included melatonin, L-Theanine, L-Tryptophan, and Ashwagandha root. We have highlighted some of the relevant ingredients for sleep here, but for a full list of supplement ingredients, see Supplementary Table 2. A control was created, also taken three times a day, that only contained vitamin B2 as an active ingredient. For both the active and control conditions, two morning lozenges were taken within 1 h after waking, two afternoon lozenges were taken between 4:00 p.m-7:00 p.m., and one bedtime lozenge was taken approximately 30 min before falling asleep.

The study used a 4 × 4 × 4 crossover design, with 4 weeks of baseline, 4 weeks of supplement use, and 4 weeks using the control. Half the participants were randomly assigned to receive the control first and Rebalance second, while the other half received the opposite order. Participants were not aware which supplement they were taking.

Participants filled out online questionnaires each morning to report on perceived sleep and compliance with taking the supplement three times per day, as instructed. Only nights where participants took the supplements all three times as instructed were included in the analyses.

## Measurement

SleepScore Max is a non-contact monitoring device which monitors respiratory signal and motion using ultra-low power radiofrequency waves to measure objective sleep (wake, light, deep, REM [Rapid Eye Movement]). The sensor is placed next to the bed and turned on prior to going to sleep *via* a companion app. The magnitude and duration of gross movements and micro-movements, as well as full breathing cycles, are captured by SleepScore Max and transformed into 30-sec epoch sleep data using proprietary algorithms. SleepScore Max has shown good agreement with gold-standard polysomnography, exceeding the agreement typically reported for actigraphy-based devices

[10-12]. Standard sleep metrics are calculated using the 30-sec epoch data.

In addition to the aforementioned objective assessment, participants completed daily questionnaires in the mornings. These included 100-point visual analog scales on perceived sleep quality and feeling well-rested, along with three questions asking participants if they took all three doses of the supplement, as instructed, the previous day.

## Statistical analyses

Objective sleep data from each night and daily questionnaires from each morning were analyzed using multilevel regression analyses with a random intercept to account for nights nested within participants. Using the multilevel regression, we analyzed nights using the supplements compared to nights using control, controlling for baseline nights (when neither the control nor the supplements were used). The model used was:  $\text{Sleep measure}_{ij} = \text{Const}_{0ij} + B^* \text{Test period}_{ij} + \text{baseline}_{ij}$ . Test period was coded as 0 for observations during the control period and 1 for nights during the active supplement period. Baseline was coded as 1 for baseline nights and 0 for both control and supplement periods.

## Results

### Objective sleep

Nightly objective sleep analyses (number of nights=1987 nested within 35 participants), showed that using the active supplement resulted in significant sleep improvements compared to nights when using control supplement, controlling for baseline sleep. Participants experienced shorter sleep onset latency (average of 4 min faster, 18% difference,  $p=0.003$ ), decreased number of awakenings during the night after initially falling asleep (6% difference,  $p=0.044$ ), reduced wake after sleep onset (average of 6 fewer minutes awake, 13% difference,  $p=0.001$ ), lower proportion of the night spent awake after initially falling asleep (1% relative decrease,  $p<0.001$ ) improved sleep efficiency, with participants asleep for a larger proportion of their time in bed (change from 85% to 86%,  $p<0.001$ ), and improved sleep maintenance with participants experiencing more consistent sleep (change from 90% to 91%,  $p<0.001$ ) (Table 1).

**Table 1:** Objective sleep and multilevel regression results comparing nights while using Rebalance to nights while using control, controlling for baseline sleep, for  $n = 35$  ( $n = 1987$  nights).

	Observed		Estimated		
	Control	Rebalance	Intercept	$\beta$	p-value
SleepScore (0-100)	81.17	81.32	80.7	0.37	0.528
BodyScore (0-100)	82.16	82.55	81.54	0.47	0.437
MindScore (0-100)	77.73	77.34	77.02	0.13	0.865

Total Sleep Time (min)	397.24	396.22	394.07	1.65	0.662
Sleep Onset Latency (min)	21.92	18.25	24.86	-3.34	0.003
Number of Awakenings	5.09	4.78	5.36	-0.26	0.044
Wake After Sleep Onset (min)	44.92	39.3	50.04	-5.22	0.001
Time in Bed (min)	468.15	459.16	471.72	-5.63	0.159
Sleep Efficiency	0.85	0.86	0.84	0.01	<0.001
Sleep Maintenance	0.90	0.91	0.89	0.01	<0.001
Light (min)	249.02	245.97	247.45	-0.02	0.996
Deep (min)	76.17	77.82	75.05	1.2	0.428
REM (min)	71.9	72.43	71.52	0.52	0.745
% Light Sleep	56%	56%	55.57	0.32	0.431
% Deep Sleep	18%	19%	17.15	0.57	0.120
% REM Sleep	16%	16%	16.01	0.27	0.408
% Wake After Sleep Onset	10%	9%	11.10	-1.14	<0.001

**Note:** For the supplement and control periods, each average was calculated by averaging nights across participants, and then averaging those participants' averages to a single simple average, listed under Observed in the table. Listed under Estimated are the outcomes of the multilevel regression analyses. Constant represents the estimated value of the sleep metric during the supplement period. The beta coefficient can be interpreted as the increase or decrease in sleep outcome in the metric of that outcome (e.g., minutes) when comparing the supplement period to the control period. P-value represents statistical significance. A mixed-effects model with random intercept was used. Regression model was as follows:  $SleepMeasure_{ij} = \beta_0 + \beta_1 * BaselineSleepMeasure_{ij} + \beta_2 * TestPeriod_{ij} + u_{0j} + e_{ij}$ . TestPeriod was coded as 0 for nights during the baseline period when participants did not use any product, 1 for nights when participants used the control, and 2 for nights when participants used the supplement.

### Self-reported daily sleep

Multilevel regression analyses were used to analyze daily questionnaire data in which participants reported on the previous night's sleep each morning (2361 nights nested in n=35 participants). Results showed that participants reported feeling more well-rested, rated on a 0-100 scale, on nights they used the active supplement compared to nights they used the control supplement, controlling for baseline sleep ( $\beta = 1.92$ ,  $p=0.043$ ). However, there was no significant change in perceived sleep quality ( $\beta = 1.07$ ,  $p= 0.263$ ).

### Discussion

Sleep is extremely important for overall health and well-being [1-3]. According to the U.S Centers for Disease Control and Prevention (CDC), 37% of American adults reported not getting

enough sleep in 2022 [13]. Thus, interventions to improve sleep are needed. The current study aimed to test a supplement intervention on sleep. The study found that Rebalance Health System supplements significantly improved multiple objective sleep measures compared to the control condition on a non-clinical sample of adults without sleep disorders.

When using the supplement system, compared to nights using the control, objectively measured sleep improved in a variety of ways. Specifically, the supplements were associated with shorter sleep onset latency, meaning that participants fell asleep significantly faster compared to the control condition. Participants using the supplement system also woke up significantly fewer times during the night and spent less time awake during the night after initially falling asleep, both in duration and proportion of the night, compared to the control condition. Furthermore, they had better sleep efficiency

(sleeping for a longer proportion of the time they were in bed) and sleep maintenance (more consistent sleep). When using the supplement system, participants also reported feeling significantly more well-rested compared to when using the control. Rebalance Health System supplements, therefore, significantly improved both objective and self-reported measures of sleep.

Although there are numerous strengths to this study, there are some limitations that need to be acknowledged with the current results. There may have been some self-selection bias in the sample, as participants had previously indicated they were interested in sleep research and agreed specifically to engage in a supplement study. In addition, participants were limited to the United States, and future research should examine supplement systems in other countries.

## Conclusion

To conclude, this study found that Rebalance Health System supplement was associated with improvements in objective and perceived sleep compared to a control condition. The supplements, which include vitamin B6, zinc, Ashwagandha, and melatonin, helped the research participants fall asleep faster and reduced their time awake at night. The supplements also resulted in increased sleep efficiency and maintenance, meaning participants spent more of their time in bed asleep and experienced more consistent sleep. In addition to these objectively measured findings, daily questionnaire data revealed that participants woke up feeling more well-rested when using the supplements compared to the control.

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