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# A Clinical Study on the Effects of a Dietary Supplement on Sleep Quality

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## OBJECTIVE

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The primary objective of this randomized, double-blind, placebo-controlled clinical study was to assess the efficacy of a nutritional supplement containing Saffron Stigma Extract and Magnesium on sleep quality. A secondary objective was to assess the impact of the supplement on facial skin attributes.

## BACKGROUND

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Sleep is essential for health and wellness. Inadequate sleep is linked with negative side effects, including decreased productivity, poor decision making, unstable mood, and a less effective immune response<sup>1</sup>. Conversely, quality sleep has numerous physical and mental health benefits. Because of this, people are always looking for solutions to cultivate improved sleep quality. In addition to practicing good sleep hygiene, there is a need for high-quality dietary supplements that can promote and support healthy, restful sleep without negative side effects. Previous research on dietary supplementation with Saffron Stigma Extract and Magnesium has shown sleep-related benefits, which is why these ingredients were used to form the basis for the supplement blend studied here.<sup>2-4</sup>

## STUDY DESIGN

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Forty healthy adults aged 20–60 years old with significant sleep disturbance (as determined by having a score  $\geq 5$  on the Pittsburgh Sleep Quality Index) were recruited to participate in the study. Subjects were randomly assigned and given either a supplement containing 225 mg of Magnesium and 14 mg Saffron Stigma Extract (n=26) or a placebo (n=14). Each group was instructed to take the supplement or placebo daily, 30–60 minutes before bedtime, for four weeks. Both subjects and researchers were blinded, meaning they did not know who was taking the product and who was taking the placebo.

Subjects filled out a daily sleep diary. Subjects also completed four validated questionnaires: the Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), Perceived Stress Scale (PSS), and Restorative Sleep Questionnaire (RSQ-W) at baseline and weeks 1 and 4.

Lastly, a dermatologist assessed skin attributes of all subjects at baseline, week 1, and week 4.

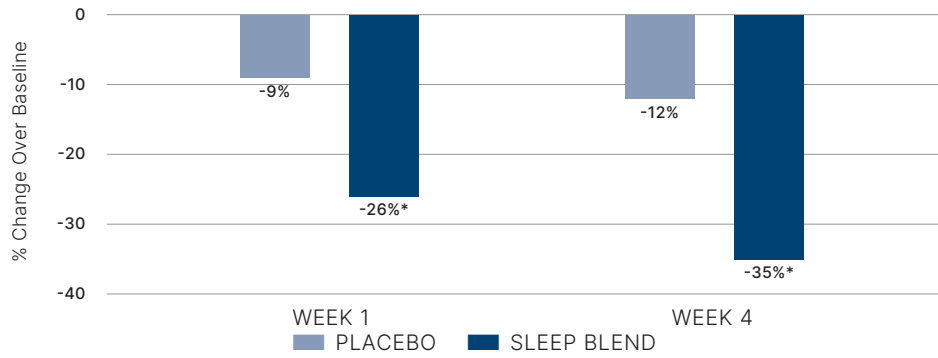
## RESULTS

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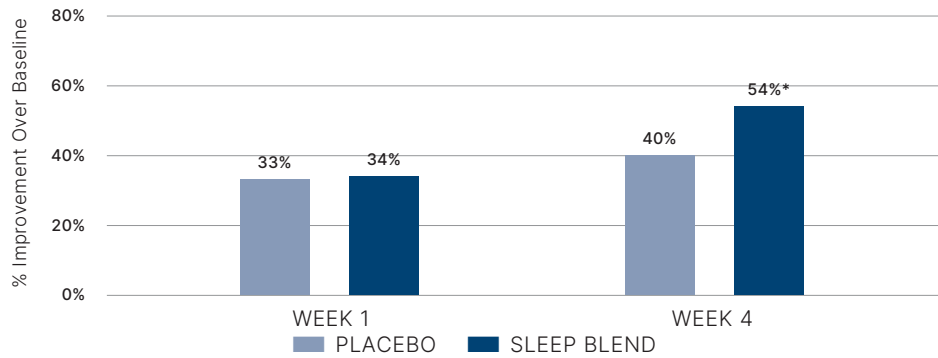
### EFFECTS ON SLEEP QUALITY

The supplement group reported improvement in several measurements related to sleep quality, as derived from the sleep diary. First, after week 1 and week 4, the supplement group had a statistically significant reduction in how drowsy they felt as they woke up ( $*p < 0.05$  vs placebo) (Figure A), with 89% of the supplement group reporting an improvement in feeling less drowsy upon waking. The supplement group also reported a 54% improvement in how refreshed they felt as they woke up after week 4, compared to baseline ( $*p < 0.05$  vs placebo) (Figure B).

**FIGURE A: % REDUCTION IN ANSWERING:  
"HOW DROWSY DO YOU FEEL AS YOU WAKE UP?"**

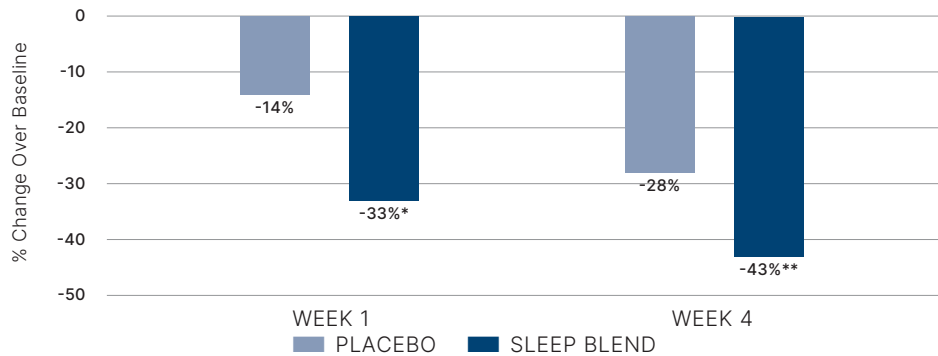


**FIGURE B: % IMPROVEMENT IN ANSWERING:  
"HOW REFRESHED DO YOU FEEL AS YOU WAKE UP?"**



Additionally, after week 1, the supplement group reported an average 33% reduction in how long it took them to fall asleep (\* $p < 0.05$  vs placebo) (Figure C), increasing to 43% after week 4 (\*\* $p < 0.001$  vs baseline). Moreover, 96% of the supplement group reported improvement in sleep quality after 4 weeks.

**FIGURE C: REDUCTION IN ANSWERING:  
"AFTER SETTLING DOWN, HOW LONG DID IT TAKE YOU TO FALL ASLEEP?"**

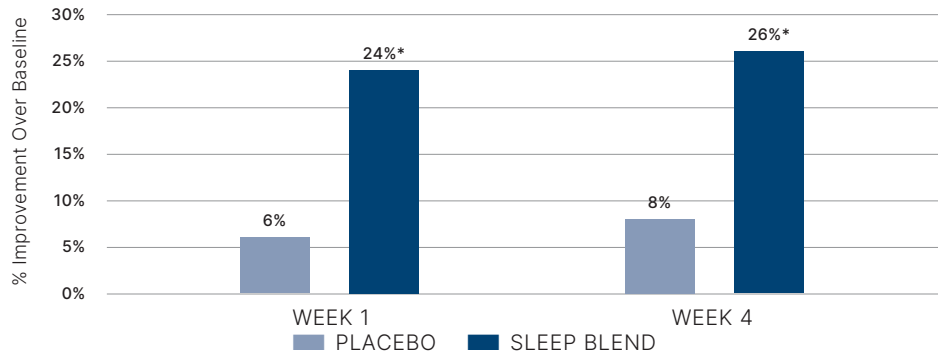


Statistically significant changes in PSQI, ISI, PSS, and RSQ-W between the groups were not detected, likely due to a very strong placebo effect, although both groups improved over baseline after 4 weeks ( $p < 0.05$ ).

### EFFECTS ON SKIN ATTRIBUTES

Subjects were assessed by a trained dermatologist on several skin attributes, including radiance, clarity, luminosity, fine lines, smoothness, softness, firmness, and overall appearance. The dermatologist grading showed statistically significant improvements in skin radiance at both week 1, with a 24% improvement over baseline\*, as well as at week 4, with a 26% improvement over baseline\* (\* $p < 0.05$  vs placebo) (Figure D). No significant changes were observed in other skin attributes.

FIGURE D: DERMATOLOGIST GRADING – SKIN RADIANCE



## CONCLUSIONS

This study showed that supplementing daily with a blend of Saffron Stigma Extract and Magnesium for 4 weeks improved some aspects of sleep quality, including decreased drowsiness upon awakening, feeling more refreshed upon awakening, and falling asleep more quickly, in addition to improvements in skin radiance. Some of these benefits were noted after only 1 week of supplementation, with even better results after 4 weeks. It is plausible that the improved aspects of sleep quality contributed to the skin radiance benefits seen in this study, although more research is needed to confirm this.

Additionally, the supplement was well-received and effective for almost all the subjects who took it, as reflected by 96% of subjects in the supplement group reporting improved sleep quality.

No adverse events related to the supplement were reported in this study, indicating the supplement was well-tolerated. Together, these results indicate the supplement improved sleep quality parameters without negative side effects.

## REFERENCES

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