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A RANDOMIZED, TRIPLE-BLIND, PLACEBO CONTROLLED TRIAL INVESTIGATING A STANDARDIZED CORN LEAF EXTRACT ON SLEEP IN HEALTHY ADULTS WITH SLEEP DIFFICULTIES

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Introduction: Difficulties falling and/or staying asleep affects over one quarter of American adults. Current management strategies include prescription sleep aids; however, long-term use is associated with adverse effects and natural alternatives may provide safer and more effective relief. UP165, a standardized corn leaf extract (CLE), has shown to bind melatonin receptors, increase melatonin synthesis and increase total sleep time (TST) and deep sleep in rodents and in a pilot clinical trial. Therefore, this study investigated the safety and efficacy of CLE on sleep quality in a healthy population.

Methods: This clinical trial enrolled 80 healthy adults (18-65 years; n=40/group) with difficulties falling and/or staying asleep. Participants were assigned to CLE or placebo for 28 days. Following a 7-day run-in period, objective (actigraphy with electroencephalogram) and subjective (Pittsburgh Sleep Quality Index; PSQI) sleep measures, were assessed at baseline (Day 0), and Days 14 and 28, with safety assessed at screening and Day 28.

Results: At Day 14, there was an increase in rapid eye movement (REM) (6.4 vs. -3.2 min; p=0.042) and decrease in awake duration (-17.9 vs. 17.0 min; p=0.021) for participants supplemented with CLE compared to those on placebo. At Day 28, there were increases in TST (35.2 vs. -16.9 min), REM (8.3 vs. -4.4 min) and light sleep time (30.8 vs. -12.4 min) for the CLE group compared to the placebo group ($p < 0.05$). Compared to placebo, participants supplemented with CLE demonstrated significantly shorter sleep onset latency and less sleep fragmentation by Day 14. CLE improved sleep efficiency and increased sleep maintenance on both Days 14 and 28. The PSQI sleep latency score decreased from baseline at Days 14 and 28 for the CLE group whereas the Placebo group decreased at Day 28 only ($p < 0.05$). Post-hoc analysis supported these findings with a significant increase of 35.7 min in non-REM sleep at Day 28 for participants supplemented with CLE compared to a decrease of 10.6 min for those on placebo. Supplementation with CLE was safe and well tolerated.

Conclusion: The current study suggests supplementation with CLE may improve sleep parameters in a healthy population with sleep difficulties.

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