

# Pilot Randomized Controlled Trial of Melatonin versus Low-Dose Quetiapine for Insomnia in Generalized Anxiety Disorder

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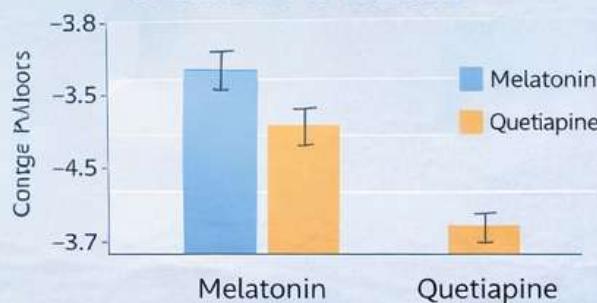
## Background

Insomnia is a persistent clinical issue in patients with generalized anxiety disorder, often resistant to standard anxiolytic interventions. Currently, comparative preliminary data evaluating melatonin and low-dose quetiapine for sleep disturbances in this population are limited, necessitating further investigation to establish evidence-based treatment approaches.

## Methods

- Baseline PSQI values were comparable between groups: melatonin  $12.5 \pm 2.4$  versus quetiapine  $12.3 \pm 2.4$  ( $p = 0.78$ ). At the 12-week assessment, PSQI scores improved to  $6.7 \pm 2.5$  in the melatonin group and  $7.7 \pm 2.0$  in the quetiapine group. Mean reduction in PSQI from baseline to week 12 was  $5.6 \pm 2.0$  points in the melatonin group compared with  $4.6 \pm 1.1$  points in the quetiapine group. This treatment effect favored melatonin, ( $95\% \text{ CI} -0.31$  to  $2.7$  ( $p = 0.11$ ).

Change in PSQI from Baseline to Baseline to Week 12



Incidence of daytime somnolence (10% vs. 0;  $p = 0.09$ ).

No serious adverse events documented in either treatment group.

## Methods

- A single-center, double-blind, parallel-group pilot randomized trial with 20 adults meeting diagnostic criteria for generalized anxiety disorder with clinically significant sleep disturbance.
- Participants were randomly assigned in a 1:1 ratio to receive either melatonin-only or quetiapine 25 mg nightly ( $n=10$ ) for 12 weeks.
- The primary outcome measure was change in Pittsburgh Sleep Quality Index (PSQI) scores from baseline to week 12.
- Secondary outcomes included assessment of daytime somnolence and treatment-related adverse events requiring discontinuation.



No serious adverse events documented in either treatment group.

## Conclusion

- Both melatonin and low-dose quetiapine demonstrated clinically meaningful improvements in sleep quality over the 12-week treatment period, with melatonin showing a modest numerical advantage that did not reach statistical significance. Larger, more powered clinical trials are needed to appropriately detect clinically important differences between interventions.

