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The effect of melatonin, magnesium, and zinc on primary insomnia in long-term care facility residents in Italy: a double-blind, placebo-controlled clinical trial

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Abstract

Objectives: To determine whether nightly administration of melatonin, magnesium, and zinc improves primary insomnia in long-term care facility residents.

Design: Double-blind, placebo-controlled clinical trial.

Setting: One long-term care facility in Pavia, Italy.

Participants: Forty-three participants with primary insomnia (22 in the supplemented group, 21 in the placebo group) aged 78.3 ± 3.9 .

Intervention: Participants took a food supplement (5 mg melatonin, 225 mg magnesium, and 11.25 mg zinc, mixed with 100 g of pear pulp) or placebo (100 g pear pulp) every day for 8 weeks, 1 hour before bedtime.

Measurements: The primary goal was to evaluate sleep quality using the Pittsburgh Sleep Quality Index. The Epworth Sleepiness Scale, the Leeds Sleep Evaluation Questionnaire (LSEQ), the Short Insomnia Questionnaire (SDQ), and a validated quality-of-life instrument (Medical Outcomes Study 36-item Short Form Survey (SF-36)) were administered as secondary end points. Total sleep time was evaluated using a wearable armband-shaped sensor. All measures were performed at baseline and after 60 days.

Results: The food supplement resulted in considerably better overall PSQI scores than placebo (difference between groups in change from baseline PSQI score=6.8; 95% confidence interval=5.4-8.3, $P<.001$). Moreover, the significant improvements in all four domains of the LSEQ (ease of getting to sleep, $P<.001$; quality of sleep, $P<.001$; hangover on awakening from sleep, $P=.005$; alertness and behavioral integrity the following morning, $P=.001$), in SDQ score ($P<.001$), in total sleep time ($P<.001$), and in SF-36 physical score ($P=.006$) suggest that treatment had a beneficial effect on the restorative value of sleep.

Conclusion: The administration of nightly melatonin, magnesium, and zinc appears to improve the quality of sleep and the quality of life in long-term care facility residents with primary insomnia.

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