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[Lancet](#). 1995 Aug 26;346(8974):541-4.

### Improvement of sleep quality in elderly people by controlled-release melatonin.

[Garfinkel D](#), [Laudon M](#), [Nof D](#), [Zisapel N](#).

#### Source

Day Care Unit, E Wolfson Medical Center, Holon, Israel.

#### Abstract

Melatonin, produced by the pineal gland at night, has a role in regulation of the sleep-wake cycle. Among elderly people, even those who are healthy, the frequency of sleep disorders is high and there is an association with impairment of melatonin production. We investigated the effect of a controlled-release formulation of melatonin on sleep quality in 12 elderly subjects (aged 76 [SD 8] years) who were receiving various medications for chronic illnesses and who complained of insomnia. In all 12 subjects the peak excretion of the main melatonin metabolite 6-sulphatoxymelatonin during the night was lower than normal and/or delayed in comparison with non-insomniac elderly people. In a randomised, double-blind, crossover study the subjects were treated for 3 weeks with 2 mg per night of controlled-release melatonin and for 3 weeks with placebo, with a week's washout period. Sleep quality was objectively monitored by wrist actigraphy. Sleep efficiency was significantly greater after melatonin than after placebo (83 [SE 4] vs 75 [3]%,  $p < 0.001$ ) and wake time after sleep onset was significantly shorter (49 [14] vs 73 [13] min,  $p < 0.001$ ). Sleep latency decreased, but not significantly (19 [5] vs 33 [7] min,  $p = 0.088$ ). Total sleep time was not affected. The only adverse effects reported were two cases of pruritus, one during melatonin and one during placebo treatment; both resolved spontaneously. Melatonin deficiency may have an important role in the high frequency of insomnia among elderly people. Controlled-release melatonin replacement therapy effectively improves sleep quality in this population.

#### Comment in

[Improvement of sleep quality by melatonin](#). [Lancet. 1995]

PMID: 7658780 [PubMed - indexed for MEDLINE]

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[Nord J Psychiatry. 2005]

[Efficacy of prolonged release melatonin in insomnia patients aged 55-80 years: quality of sleep and next-day alertness outcomes.](#) [Curr Med Res Opin. 2007]

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[Efficacy and safety of prolonged-release melatonin in insomnia patients with diabetes: a randomized, double-blind, crossover study.](#) [Diabetes Metab Syndr Obes. 2011]

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[Arch Gerontol Geriatr.](#) 1997 Mar-Apr;24(2):223-31.

## **Improvement of sleep quality by controlled-release melatonin in benzodiazepine-treated elderly insomniacs.**

[Garfinkel D](#), [Laudon M](#), [Zisapel N](#).

### **Source**

Aging Research, Day Care Unit, The E. Wolfson Medical Center, Holon 58100 and Meonot Maccabi, 7 Hanna Senech St., Bat-Yam 59303, Israel.

### **Abstract**

Benzodiazepines are widely used in the elderly population for the initiation of sleep. However, very frequently, complaints about poor sleep maintenance persist despite benzodiazepine treatment. Melatonin, a hormone produced by the pineal gland at night, is involved in the regulation of the sleep/wake cycle. Melatonin production decreases with age and can also be inhibited by benzodiazepines. We have recently reported on the association between insomnia and impaired melatonin output in the elderly. In the present study we have investigated the efficacy of melatonin replacement therapy in improving sleep in 21 elderly subjects who have been taking benzodiazepines and had low melatonin output. In a randomized, double-blind, crossover designed study the subjects were treated for three weeks with 2 mg per night of controlled-release melatonin and for 3 weeks with placebo, 2 h before desired bedtime with a 1-week washout period between treatment periods. Subjects' sleep was assessed by wrist actigraphy. Melatonin treatment significantly increased sleep efficiency and total sleep time and decreased wake after sleep onset, sleep latency, number of awakenings and fragmental index, as compared to placebo. The results of our study indicate that melatonin replacement therapy can improve sleep quality in the elderly and that the beneficial effects are augmented in the presence of benzodiazepines.

PMID: 15374128 [PubMed]

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[Melatonin, a promising role in taxane-related neuropathy.](#) [Clin Med Insights Oncol. 2010]

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[J Clin Endocrinol Metab](#). 2001 Oct;86(10):4727-30.

## **Melatonin treatment for age-related insomnia.**

[Zhdanova IV](#), [Wurtman RJ](#), [Regan MM](#), [Taylor JA](#), [Shi JP](#), [Leclair OU](#).

### **Source**

Department of Brain and Cognitive Sciences, Clinical Research Center, Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, MA 02139, USA.

### **Abstract**

Older people typically exhibit poor sleep efficiency and reduced nocturnal plasma melatonin levels. The daytime administration of oral melatonin to younger people, in doses that raise their plasma melatonin levels to the nocturnal range, can accelerate sleep onset. We examined the ability of similar, physiological doses to restore nighttime melatonin levels and sleep efficiency in insomniac subjects over 50 yr old. In a double-blind, placebo-controlled study, subjects who slept normally (n = 15) or exhibited actigraphically confirmed decreases in sleep efficiency (n = 15) received, in randomized order, a placebo and three melatonin doses (0.1, 0.3, and 3.0 mg) orally 30 min before bedtime for a week. Treatments were separated by 1-wk washout periods. Sleep data were obtained by polysomnography on the last three nights of each treatment period. The physiologic melatonin dose (0.3 mg) restored sleep efficiency (P < 0.0001), acting principally in the midthird of the night; it also elevated plasma melatonin levels (P < 0.0008) to normal. The pharmacologic dose (3.0 mg), like the lowest dose (0.1 mg), also improved sleep; however, it induced hypothermia and caused plasma melatonin to remain elevated into the daylight hours. Although control subjects, like insomniacs, had low melatonin levels, their sleep was unaffected by any melatonin dose.

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