

Joint Event on

PEDIATRICS, NUTRITION & PRIMARY HEALTHCARE NURSING

July 16-18, 2018 Dubai, UAE

A prospective, interventional, randomized, parallel, double blind and placebo controlled clinical trial to evaluate the efficacy and safety of low dose fine mist sublingual melatonin (Instavit®, London, UK) in the treatment of occasional sleeplessness

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Introduction: Sleep disorders affect over 70 million people in the USA representing 20% of the population. The problem has been deemed a public health epidemic by the Center for Disease Control and Prevention (CDC) contributing to a host of medical conditions including cancer, obesity, diabetes, depression and hypertension.

Objective: To review the effectiveness and safety of low dose (0.8 mg) fine mist sublingual Melatonin for the treatment of occasional sleeplessness.

Method: 50 subjects were selected for a single center, prospective; double blind randomized controlled trial assessing the safety and efficacy of low dose, fine mist sublingual melatonin spray versus placebo. Subjects were randomly allocated to one of two arms and sleep quality was assessed over a 28-day period using sleep logs, sleep diaries and the Insomnia Severity Index.

Result: All 50 participants completed the trial and varying degrees of sleeplessness was noted at baseline. Low dose fine mist sublingual Melatonin spray had a significant effect on time taken to fall asleep within 30 minutes; 92% low dose, fine mist melatonin, 23% placebo ($p < 0.001$); sleep duration of more than 7 hours; 96% low dose, fine mist melatonin, 32% placebo ($p < 0.001$) and good/excellent sleep quality; 92% low dose, fine mist melatonin, 24% placebo ($p < 0.001$). No adverse effects were noted.

Conclusion: The results show that low dose, fine mist sublingual melatonin spray is very effective in the treatment of occasional sleeplessness and results in less time taken to fall asleep, increased sleep duration and sleep quality versus placebo.

Biography

Jatin R Joshi has completed his Medical Training at University College, London followed by General Surgical and Plastic Surgical Training at renowned centers in London and Oxford. He is the Founder of Instavit Ltd, a leading Spray Supplement Manufacturer. He has published several papers and written textbooks on General and Plastic Surgery as well as Nutritional Supplementation.

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