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File: ■ Ashwagandha (*Withania somnifera*, Solanaceae)

■ Sleep

■ Quality of Life

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RE: Safety and Efficacy of Ashwagandha Extract on Sleep and Well-being in Elderly Adults

Kelgane SB, Salve J, Sampara P, Debnath K. Efficacy and tolerability of ashwagandha root extract in the elderly for improvement of general well-being and sleep: A prospective, randomized, double-blind, placebo-controlled study. *Cureus*. February 2020;12(2): e7083. DOI: 10.7759/cureus.7083.

Adequate sleep is important for successful aging and quality of life (QOL). However, many elderly people suffer from insomnia and other sleep-related issues. Ashwagandha (*Withania somnifera*, Solanaceae) root extract is used in Ayurveda to reduce stress and anxiety and improve sleep. Its effects on cognitive function, sleep, and other therapeutic applications have shown promise in preliminary preclinical and clinical studies. The purpose of this randomized, double-blind, placebo-controlled study was to assess the effect of ashwagandha on QOL and sleep parameters in the elderly.

Healthy adults (n = 50, aged 60-85 years) were recruited from outpatient clinics in Thane, India. Included participants had an Eastern Cooperation Oncology Group (ECOG) score of 0 to 1, body mass index (BMI) of 22-32 kg/m², and body weight ≥ 50 kg. Excluded participants had known renal insufficiency; history of renal failure; used hormone replacement therapy; had unmanaged diabetes mellitus or hypertension; had a past/present chronic inflammatory condition; or had blood coagulation issues within 90 days prior to the screening. Participants were treated with placebo (starch) or 300 mg ashwagandha (KSM-66®; Ixoreal Biomed Inc.; Los Angeles, California) two times per day for 12 weeks. The placebo capsules were initially stored with the ashwagandha capsules to absorb the scent. The primary outcome measure was the change in QOL as assessed with the World Health Organization Quality of Life (WHOQOL-BREF) questionnaire. The secondary outcome measures were the Sleepiness Scale, Mental Alertness on the Rise Scale, and Sleep Quality Likert Scale. Safety was assessed with the Patient's Global Assessment of Tolerability to Therapy (PGATT) and efficacy was assessed using Physician's Global Assessment of Efficacy to Therapy (PGAET). Assessments were made at Week 4, 8, and 12.

Thirty-nine participants completed the study. Six participants dropped out of the ashwagandha group, and five participants dropped out of the placebo group due to noncompliance. No one dropped out due to adverse events. Baseline demographics were similar between groups. Both groups had a similar total WHOQOL-BREF score at baseline. At 12 weeks, both groups improved on the WHOQOL-BREF score; however, the change from baseline was significantly greater for the ashwagandha group compared with the placebo group on the Total Score ($P < 0.001$), Global Domain ($P < 0.001$), Psychological Domain ($P < 0.001$), Physical Domain ($P < 0.001$), and Environment Domain ($P < 0.05$). Changes on the Sleepiness Scale were not significantly different from baseline or between groups. At 12 weeks, both groups improved on the Mental Alertness on Rising Scale and Sleep Quality Likert Scale; however, the change from baseline was significantly greater for the ashwagandha group compared with the placebo group ($P < 0.05$ and $P < 0.0001$, respectively). Ashwagandha was well-tolerated. PGAET was rated good to excellent for 100% of participants in the ashwagandha group compared with 60% of the placebo group. PGATT was rated good to excellent for 100% of participants in the ashwagandha group and 100% of the placebo group.

The authors conclude ashwagandha significantly improved sleep, mental alertness, and QOL in elderly people. The KSM-66 was well-tolerated. Limitations of this study are that it was conducted at a single site, the population was small, the sleep measures may not have been validated questionnaires, and adequate blinding was not confirmed.

The authors declare no conflicts of interest.

—*Heather S. Oliff, PhD*

Referenced article can be accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7096075/>.

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