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**File: ■ Lettuce (*Lactuca sativa*) Seed Oil
■ Sleep Disorders**

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RE: Lettuce Seed Oil Supplementation Improves Sleep in Adults in Pilot Study

Yakoot M, Helmy S, Fawal K. Pilot study of the efficacy and safety of lettuce seed oil in patients with sleep disorders. *Int J Gen Med.* 2011;4:451-456.

Although sleep disorders are a common health problem affecting up to one-third of the general population, they are often neglected. Approximately 20-40% of older adults suffer from insomnia at least a few nights per month, which can cause various impairments during the daytime and is associated with various increased health risks that may shorten life span. Pharmaceutical drugs can be prescribed but often result in daytime residual effects, as well as dependency and withdrawal symptoms. Lettuce (*Lactuca sativa*) seed oil has been used in ancient Egyptian medicine as a sleep aid. It has more recently been shown to have significant sedative, analgesic, anticonvulsant, and anti-inflammatory activity in mice. This pilot, prospective, single-blind (patients only), randomized, placebo-controlled study examined the sedative and hypnotic effects of lettuce seed oil in patients complaining of sleeping difficulty with or without anxiety.

The study was carried out in 2 outpatient clinics in Alexandria, Egypt; one at the El Mamorah Psychiatric Hospital and the other at the Green Clinic and Research Centre. Patients over 18 years of age with insomnia complaints who were not using any conventional psychiatric medicines, supplements, or alternative medical therapies were recruited. Alzheimer's-type dementia or other critical diseases were not considered an exclusion factor if there was a supportive caregiver, but neuropsychiatric diseases requiring medication were an exclusion factor.

Patients were randomly assigned to 1 of 2 groups. One group (n=30) received one 1000 mg capsule of Sedan® lettuce seed oil (Pharco Pharmaceuticals; Alexandria, Egypt) and the other group received a matching placebo (n=30). The outcome measure was improvement in the modified State-Trait Anxiety Inventory (STAI) score and a sleeping difficulty score (higher scores indicated a worse condition), which were assessed at baseline and at the end of the 1-week treatment period.

The sleeping difficulty score came from a 10-item questionnaire based on the items of The Leeds Sleep Evaluation Questionnaire and assessed subjective patient estimates of

and satisfaction with sleep quality using a 3-point rating scale (0=rare/nil, 1=sometimes, and 2=often). Both tests had been translated into Arabic and validated previously.

Clinical Global Impression of Change (CGI-C) scores were also recorded at baseline and after 1 week of treatment. CGI-C is a 7-item symptom rating scale (0=not assessed, 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, and 7=very much worse).

Two patients from the treatment group and 1 patient from the placebo group withdrew from the study, 3 patients in each group were lost to follow-up, and 1 patient had recording errors. This left n=25 patients in each group, which were well-matched for age, gender, and baseline sleep scores.

After treatment, there was a statistically significant improvement in mean scores for both the modified STAI and the sleeping difficulty questionnaires for both groups; however, improvements in both tests were significantly greater in the treatment group than in the placebo group ($P<0.05$). In multivariate analysis, treatment and baseline scores statistically significantly affected the outcomes of both the STAI ($P<0.04$) and the sleeping difficulty questionnaires ($P<0.000$).

Patients' rating of their insomnia was "very much or much improved" on the CGI-C scale for 18 out of 25 patients (72%) in the treatment group versus 5 out of 25 patients (20%) in the placebo group (risk ratio: 3.6; 95% confidence interval [CI]: 1.58-8.18).

To the authors' knowledge, this is the first study of the use of lettuce seed oil as a sleep aid. Lettuce seed oil showed statistically significant benefits with no adverse side effects and that it could be especially useful in older adults suffering from mild-to-moderate forms of anxiety and sleeping difficulties. This study has a number of limitations, including a small size, a short follow-up duration, and a single-blind design, but opens up a promising avenue of research.

—*Risa Schulman, PhD*

Referenced article can be found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3119588/pdf/ijgm-4-451.pdf>.

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