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File: ■ Ashwagandha (*Withania somnifera*, Solanaceae)
■ Weight Management
■ Chronic Stress

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RE: Ashwagandha Useful for Weight Management in Adults under Chronic Stress

Choudhary D, Bhattacharyya S, Joshi K. Body weight management in adults under chronic stress through treatment with ashwagandha root extract: A double-blind, randomized, placebo-controlled trial. *J Evid Based Complementary Altern Med*. April 6, 2016; [epub ahead of print]. doi: 10.1177/2156587216641830.

Stress causes elevation of the hormone cortisol, which can lead to weight gain; in part, because it increases hunger. Chronic stress is also correlated with an increase in food intake and reduced physical activity. Moreover, stress elicits cravings for high-calorie foods via an activation of the hypothalamic-pituitary-adrenal axis. Clinical trials have shown that ashwagandha (*Withania somnifera*, Solanaceae) root extract reduces stress as measured by psychological instruments and physiological markers such as cortisol. The purpose of this randomized, double-blind, placebo-controlled study was to assess the efficacy of ashwagandha root extract in improving general well-being, reducing markers of stress, and controlling weight gain in adults with chronic stress.

Subjects (n = 52, aged 18-60 years) with symptoms of chronic, routine work stress and a body mass index (BMI) between 25 and 39.9 kg/m^2 were recruited from outpatient clinics in Pune, India. Included subjects had a Perceived Stress Scale (PSS) score ≥ 20. Excluded subjects met any of the following criteria: diagnosable eating disorder, participation in a weight-loss program in the past 3 months, predisposition to weight gain due to genetic or endocrine conditions, diagnosed neurologic disorder, unstable medical condition, known allergy/side effects to ashwagandha, pregnant or lactating, taking medications known to affect weight (e.g., corticosteroids, antidepressants, antipsychotics, mood stabilizers, and antiepileptic drugs), history of alcohol abuse or smoking, and clinically significant acute unstable hepatic, renal, cardiovascular, or respiratory disease.

Subjects received either placebo (inert filler) or 300 mg ashwagandha root extract (KSM-66 Ashwagandha; supplied by Ixoreal Biomed; Los Angeles, California) standardized to 5% withanolides, 2x/day for 8 weeks. To aid in blinding, placebo capsules were stored with a cloth envelope containing ashwagandha root extract for a few days, so that the smell of the ashwagandha extract permeated the placebo capsules. The primary

outcome measures were the PSS and the Food Cravings Questionnaire-Trait (FCQ-T). Secondary outcome measures were the Oxford Happiness Questionnaire (OHQ), the Three-Factor Eating Questionnaire (TFEQ, which measures eating behavior), serum cortisol levels, body weight, and BMI. Assessments were made at baseline, 4 weeks, and 8 weeks. Safety was assessed with the Patients' Global Assessment of Tolerability to Therapy (PGATT) scale at 8 weeks.

At baseline, there were no significant differences between groups in occupational status, symptoms of stress, PSS scores, or cortisol levels. One subject in each group was not compliant with the treatment; therefore, the per-protocol dataset (n = 50) was used for the efficacy analysis. The intent-to-treat dataset (n = 52) was used for the safety analysis.

Primary outcomes
The ashwagandha group had a significant decrease in mean PSS score compared with the placebo group at 4 weeks and 8 weeks (P = 0.05 and P = 0.0015, respectively). Also, the ashwagandha group had a significantly greater degree of reduction (percent mean change from baseline) in PSS score compared with placebo (P = 0.0025 and P < 0.0001, respectively).

The FCQ-T consists of 9 components. At 8 weeks, the mean score for the FCQ Planning component for the ashwagandha group was significantly lower than the placebo group (P = 0.0406), and the percent change from baseline was significantly greater (P = 0.0087). The mean score for the FCQ Positive Reinforcement component for the ashwagandha group was significantly lower than the placebo group at 4 weeks (P = 0.0589) and 8 weeks (P = 0.0287), and the percent change from baseline was significantly greater for the ashwagandha group at 4 weeks (P = 0.0067) and 8 weeks (P < 0.0001). For the ashwagandha group, there were no significant differences in the mean scores for the FCQ Negative Reinforcement, Lack of Control, or Emotion components compared to placebo; however, the percent change from baseline for these components was significant at both 4 and 8 weeks as follows: Negative Reinforcement (P = 0.008 and P = 0.0083, respectively), Lack of Control (P = 0.0443 and P = 0.047, respectively), and Emotion (P = 0.0352 and P = 0.068, respectively). The percent change from baseline for the FCQ Environment component was significantly greater for the ashwagandha group at 8 weeks (P = 0.039). There were no significant differences between treatment groups for the FCQ Thoughts about Food, Physiological, or Guilt components.

Secondary outcomes
The mean OHQ score was significantly improved in the ashwagandha group compared with the placebo group (P = 0.0087) at 8 weeks, and the percent change from baseline was significantly greater for the ashwagandha group at both 4 weeks (P = 0.0342) and 8 weeks (P < 0.0001). Mean serum cortisol levels were significantly lower in the ashwagandha group compared with the placebo group at 8 weeks (P = 0.0132), and the percent reduction in cortisol was significantly greater for the ashwagandha group at both 4 weeks (P = 0.0328) and 8 weeks (P = 0.0019). Both groups had a mean reduction in weight over time and the difference between groups was not significant. However, the ashwagandha group had a significantly greater percent decrease in weight from baseline compared with the placebo group at 4 weeks (P = 0.0503) and at 8 weeks (P = 0.0148). BMI did not significantly differ between groups; however, the percent mean reduction

from baseline BMI was significantly greater for the ashwagandha group at 4 weeks (P = 0.0429) and at 8 weeks (P = 0.0096).

There were no significant differences between treatment groups for the mean scores of the 3 TFEQ components; however, the percent change from baseline was significantly greater for the ashwagandha group at both 4 and 8 weeks in the "Uncontrolled Eating" (P = 0.0542 and P = 0.0247, respectively) and "Emotional Eating" (P = 0.0207 and P = 0.0135, respectively) components.

There were no significant differences between groups in any vital sign. A total of 96% of the subjects in both groups reported excellent tolerability to treatment on the PGATT. Two subjects reported adverse events of giddiness, heaviness of head, blurring of vision, and/or hyperacidity. However, the authors do not report which treatment groups these subjects were in or whether the events were considered related to treatment.

Overall, in this population, ashwagandha significantly improved psychological stress (PSS score) and physiological stress (serum cortisol levels), as well as well-being and happiness (OHQ). These data support other clinical research that shows that ashwagandha improves stress and anxiety. Ashwagandha significantly improved several components of food cravings (FCQ-T) and eating behavior (TFEQ). The mean percent reductions in body weight and BMI were significantly greater in the ashwagandha group. These data support the hypothesis that the antistress activity of ashwagandha results in reduced food cravings, better eating behaviors, and weight loss. The authors conclude that ashwagandha "can be useful for body-weight management in patients experiencing chronic stress. However, further studies are required to bolster the potential of ashwagandha to prevent weight gain caused by long-term chronic stress." The authors recommend that future studies also measure serum levels of hormones involved in appetite regulation such as leptin and ghrelin.

The authors acknowledge that the data are preliminary because of the short study duration and small sample size; otherwise, the study was generally well designed and executed. This article fulfilled most of the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Deficiencies included sample size calculations, baseline data for body weight and BMI, recruitment dates, assessment of blinding, and discussion of potential sources of bias. The authors declare no conflict of interest.

—Heather S. Oliff, PhD

The American Botanical Council has chosen not to include the original article.