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A randomised, double-blind, placebo-controlled, parallel-group study of the standardised extract shr-5 of the roots of *Rhodiola rosea* in the treatment of subjects with stress-related fatigue.

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Abstract

The aim of the study was to assess the efficacy of the standardised extract SHR-5 of roots of **Rhodiola Rosea** L. in the treatment of individuals suffering from stress-related fatigue. The phase III clinical trial took the form of a randomised, double-blind, placebo-controlled study with parallel groups. Participants, males and females aged between 20 and 55 years, were selected according to the Swedish National Board of Health and Welfare diagnostic criteria for fatigue syndrome. A total of 60 individuals were randomised into two groups, one (N = 30) of which received four tablets daily of SHR-5 extract (576 mg extract/day), while a second (N = 30) received four placebo tablets daily. The effects of the extract with respect to quality of life (SF-36 questionnaire), symptoms of fatigue (Pines' burnout scale), depression (Montgomery - Asberg depression rating scale - MADRS), attention (Conners' computerised continuous performance test II - CCPT II), and saliva cortisol response to awakening were assessed on day 1 and after 28 days of medication. Data were analysed by between-within analyses of variance. No serious side effects that could be attributed to the extract were reported. Significant post-treatment improvements were observed for both groups (placebo effect) in Pines' burnout scale, mental health (SF-36), and MADRS and in several CCPT II indices of attention, namely, omissions, commissions, and Hit RT SE. When the two groups were compared, however, significant effects of the SHR-5 extract in comparison with the placebo were observed in Pines' burnout scale and the CCPT II indices omissions, Hit RT SE, and variability. Pre- VERSUS post-treatment cortisol responses to awakening stress were significantly different in the treatment group compared with the control group. It is concluded that repeated administration of R. **ROSEA** extract SHR-5 exerts an anti-fatigue effect that increases mental performance, particularly the ability to concentrate, and decreases cortisol response to awakening stress in burnout patients with fatigue syndrome.

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