



Hormone-balancing Effect of Pre-Gelatinized Organic Maca (*Lepidium peruvianum* Chacon):

(III) Clinical responses of early-postmenopausal women to Maca in double blind, randomized, Placebo-controlled, crossover configuration, outpatient study

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ABSTRACT

Objective: This is the second, conclusive part of the clinical study on responses of early-postmenopausal women to standardized doses of pre-Gelatinized Organic Maca (Maca-GO).

Design: Total of 34 Caucasian women volunteers participated in a double-blind, randomized, four months outpatient crossover configuration Trial. After fulfilling the criteria of being early-postmenopausal: blood Estrogen (E2<40pg/ml) and Follicle Stimulating Hormone (FSH>30IU/ml) at admission, they were randomly allocated to Placebo (P) and Maca-GO (M) treatments (2 groups of 11 participants each). Two 500mg vegetable hard gel capsules with Maca-GO or Placebo powder were self-administered twice daily with meals (total 2g/day).

Methods: At admission and follow-up monthly intervals, body mass index (BMI), blood pressure, levels of gonadal, pituitary, thyroid and adrenal hormones, lipids and key minerals were measured. Bone markers were determined after four months M and P use in 12 participants. Menopausal symptoms were assessed according to Greene's Score (GMS) and Kupperman's Index (KMI). Data were analyzed using multivariate technique on blocs of monthly of results and canonical variate technique was applied to GMS and KMI matrices.

Results: Two mouths application of Maca-GO stimulated ($P<0.05$) production of E2, suppressed ($P<0.05$) blood FSH, Thyroid (T3) and Adrenocorticotrophic hormones, Cortisol, and BMI, increased ($P<0.05$) low density lipoproteins, blood Iron and alleviated ($P<0.001$) menopausal symptoms. Maca-GO noticeably increased bone density markers.

Conclusion: In conclusion, Maca-GO applied to early-postmenopausal women (i) acted as a toner of hormonal processes along the Hypothalamus-Pituitary-Ovarian axis, (ii) balanced hormone levels and (iii) relieved symptoms of menopausal discomfort, (hot flushes and night sweating in particular), thus, (iv) exhibited a distinctive function peculiar to adaptogens, providing an alternative non-hormonal plant option to reduce dependence on hormone therapy programs (HRT).

Short title: Maca in Postmenopausal Women: (III) Clinical Study - Crossover Design

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