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A Randomized Controlled Trial of a Nutrient Supplement in the Treatment of Fibromyalgia

Category: 11 Soft tissue and regional musculoskeletal disease, fibromyalgia

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Liam Martin, Bonnie Kaplan, Susan Crawford, Rhonda Kennedee
University of Calgary, Calgary, AB, Canada

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The beneficial effects of a nutrient supplement called E.M.Power+ in the management of fibromyalgia (FM) was reported in a recently published case study (Martin & Kaplan, 1999). The supplement contains 36 ingredients: minerals, vitamins, amino acids, and antioxidants. A randomized, double-blind placebo-controlled trial was conducted to evaluate the supplement's efficacy in the treatment of FM.
In total, 99 patients from the area, diagnosed with FM by ACR criteria, participated in this clinical trial (7 males, 92 females; average age=51.5 years, SD=11.3). All patients signed an consent form. Exclusion criteria included any known abnormalities of mineral metabolism, any serious neurological disorders, and involvement in medico-legal

proceedings related to FM. Patient assessments which were completed pre-intervention, at 3 months, at 6 months and at 9 months into the study included the following: the number of tender points and total myalgic score (TM); Fibromyalgia Impact Questionnaire (FIQ), a Self Efficacy Scale (SEF), the CES-D Depression Scale, a Quality of Life (QOL) measure, and the Illness Intrusiveness Response Scale (IIRS). Patients were randomly assigned to receive the active supplement (N=51) or the placebo (N=48). All patients took 24 capsules of the supplements daily for 6 months, and were then invited to participate in an open label extension for 3 more months. Fifty of the patients continued in the open trial.

Results showed no significant group differences on any demographic or illness-related variables at the pre-intervention assessment. There were 34 dropouts due primarily to gastrointestinal complaints such as loose stools and diarrhea. No significant group differences emerged at any time during the study for the FIQ (primary outcome measure), or for the SEF, CES-D, QOL, or IIRS. No significant group differences emerged in the number of tender points and the total myalgic score at pre-intervention, 3 months, 6 months or 9 months: both groups of patients showed improvement over the course of the trial. Despite these results, a significant group difference did emerge for the change in the number of tender points from 6 to 9 months ($t(47)=2.21$, $p<.05$), when both groups were taking the active supplement. The number of tender points for patients in the active group decreased significantly more than the number for those in the placebo group between 6 and 9 months. Similarly, there was a significant group difference for the change in the tender point score from 6 to 9 months ($t(47)=3.13$, $p<.05$), with the tender point score for patients in the active group decreasing significantly more compared to those in the placebo group.

The results of this study argue against nutritional deficiencies being a primary or important cause of FM.

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