

Long-term Effects of Bio-electromagnetic-energy-regulation Therapy on Fatigue in Patients With Multiple Sclerosis

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Abstract

Background • Electromagnetic-field therapy has beneficial short-term effects in multiple sclerosis (MS) patients with major fatigue, but long-term data are lacking.

Primary Study Objectives • To evaluate the long-term effects of a specific electromagnetic therapy device (Bio-Electromagnetic-Energy-Regulation [BEMER]) on MS-related fatigue, we designed a crossover control of a previously performed randomized controlled trial and a long-term open-label follow-up trial.

Design and Setting: Crossover and open-label follow-up trials at a single neurological outpatient center.

Participants • Patients with relapsing-remitting MS who had major fatigue (N = 37 patients).

Intervention • After a previous randomized controlled trial (exposure to low-frequency pulsed magnetic fields for 8 min twice daily or to placebo treatment for 12 wk), a crossover from control to treatment for another 12 weeks, followed by an open-label follow-up trial to 3 years, were done.

Primary Outcome Measures • The outcome criteria were the Modified Fatigue Impact Scale (MFIS), Fatigue Severity Scale (FSS), German long version of the Center for Epidemiologic Studies Depression Scale (CES-D), Multiple Sclerosis Functional Scale (MSFC), and Expanded Disability Status Scale (EDSS).

Results • Patients previously on placebo during the randomized controlled trial experienced significant reductions in fatigue after crossing over to treatment. The MFIS and FSS scores were significantly lower in the open-label group than in the control subjects after follow-up. Participation in the open-label treatment was the strongest predictor of low fatigue outcome after follow-up. Electromagnetic-field therapy was well tolerated.

Conclusions • In this long-term study, a beneficial effect of long-term BEMER therapy on MS fatigue was demonstrated. Electromagnetic-field therapy may be a useful therapeutic modality in MS patients with severe fatigue. (*Altern Ther Health Med.* 2011;17(6):22-28.)

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Fatigue is a common symptom of multiple sclerosis (MS), affecting >75% patients.¹ For most patients, fatigue constitutes one of the worst and most distressing symptoms of the disorder.² Fatigue may occur in all clinical phenotypes of MS and affects patients of all ages.³ This symptom is an integral part of the disease process, usually is present at the time of diagnosis, and may be a primary presenting complaint.

Fatigue is not closely related to physical signs of disability or magnetic resonance imaging markers of disease activity, but it may increase when the patient experiences a relapse.^{2,4} The etiology and pathophysiology of MS-related fatigue are

unknown. Studies have not demonstrated an association between MS-related fatigue and the level of disability, clinical disease subtype, or sex.⁵

Management strategies include medication, exercise, and behavioral therapy.⁶ There have been reports of beneficial effects of immunomodulatory drugs on fatigue⁷; however, the efficacy of treatment remains disappointing.⁶

The potential benefits of nonpharmacologic magnetic-field therapy, as reported in a recent meta-analysis,⁸ warranted further investigation, even though the mechanism of modulating MS-related fatigue is unknown.⁸ Therefore, we previously performed a randomized, double-blind controlled trial⁹ on the effect of a specific electromagnetic-therapy device (Bio-Electro-Magnetic-Energy-Regulation [BEMER], Innomed International AG, Triesen, Liechtenstein), which uses broadband, extremely weak, low-frequency pulsed electromagnetic fields (EMF),¹⁰ on patients with relapsing-remitting MS with major fatigue in an outpatient setting. The previous study showed that the level of fatigue, as measured by different fatigue scales, was significantly lower in the treatment than the placebo group after 12 weeks of treatment.⁹