A RANDOMIZED CONTROLLED STUDY OF LOW-FAT DIET AND MULTIPLE SCLEROSIS


Background: The role of diet in reducing the severity of multiple sclerosis (MS) has long been of interest. Past observational studies suggest that a diet low in total fat and saturated fat can reduce disease activity and disability progression. However, this study is the first randomized controlled study to examine the potential benefits and safety of a very-low-saturated-fat, plant-based diet in the management of relapsing-remitting MS. Objectives: The primary objective is to compare new T2 lesion formation on brain magnetic resonance imaging (MRI) of the low-fat diet group with that of the control group. The secondary objectives are 1) to assess the effects of the study diet on clinical activity of MS as assessed by relapse rate and disability progression as well as effects on fatigue, depression, and quality of life; 2) to study the effects of the study diet on serum markers of inflammation, soluble intercellular adhesion molecule–1, matrix metalloproteinase–1, tumor necrosis factor, and interferon; and 3) to assess compliance, safety, and tolerability of the study diet for 12 months. Methods: The study is a randomized controlled two-arm trial. Subjects (N = 54) are randomly assigned to the low-fat diet group or the control group, which follows their regular diet. Both groups will be instructed to exercise for 30 minutes a day, 5 days a week. Subjects are followed for 12 months and are evaluated at baseline and at 1, 3, 6, 9, and 12 months. They undergo brain MRI at baseline and at 12 months. Blood samples are collected for safety and immune assays at baseline and at 6 and 12 months. All visits include a physical examination, Expanded Disability Status Scale, Multiple Sclerosis Functional Composite, and self-administered questionnaires to assess MS-related quality of life, fatigue, depression, and level of physical activity. Medications, compliance, and adverse events are monitored by means of monthly follow-up calls. Results: Study is ongoing.

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