

A Randomized-Controlled Study of Diet & Multiple Sclerosis

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Background

Emerging evidence suggests diet and vascular risk factors including obesity and hyperlipidemia may influence MS disease progression

This study is the first randomized-controlled trial to examine the potential benefits and safety of a low fat, plant-based diet in the management of relapsing-remitting MS. This is also the first study to explore the effects of a low fat diet on MS using brain MRI

Objective

To determine the compliance and safety of a plant-based low-fat diet and obtain preliminary data on its effects on brain magnetic resonance imaging (MRI), clinical outcomes, lipids, insulin and body weight in relapsing remitting MS patients

Design/Methods

A prospective, RC, rater-blinded 1-year study with subjects assigned to a low-fat diet (diet) or wait-listed (control) group. Study outcomes: changes over one year in: brain MRI new T2 lesion count and other MRI disease activity and atrophy parameters; safety, changes in: relapse rate, disability [expanded disability status score (EDSS)], Timed 25-foot walk (T25W), Fatigue Severity Score (FSS), blood lipids, body weight and compliance

Diet

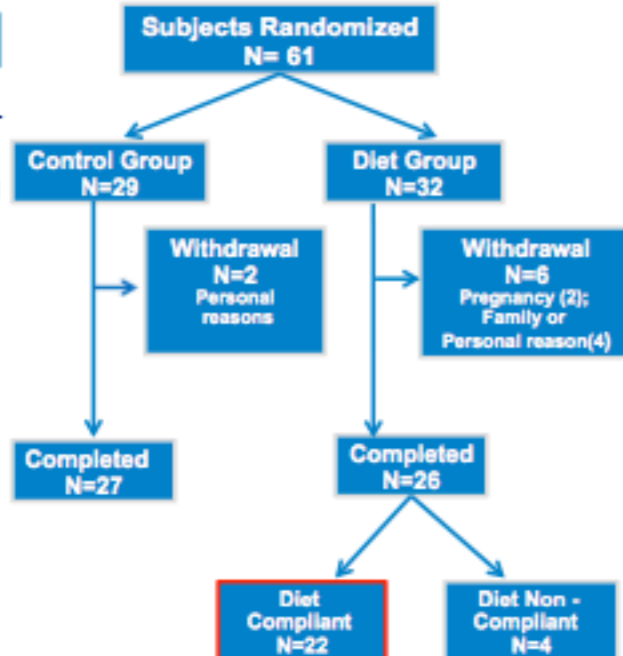
THE DIET (Devised by Dr. John McDougall) is plant based and very low in saturated fat. The daily caloric breakdown is estimated to be as follows: 10% fat, 14% protein, and 76% carbohydrate. Diet is focused on starches, such as potatoes, corn, rice, beans, pasta, oats, and fruits/vegetables. No meat, fish, or dairy intake is recommended

- During the study, subjects were allowed only those over the counter supplements that they were found to be deficient of

DIET TRAINING: Done at the beginning of the study. 10 day residential training program located in Santa Rosa, CA. Included cooking demonstrations, lectures, and outings to local restaurants/grocery stores

DIET COMPLIANCE: Measured by the fat as percent of calories found on food frequency questionnaires (NutriQuest), completed monthly. Subjects with difficulty with diet compliance were counseled by the project dietitian

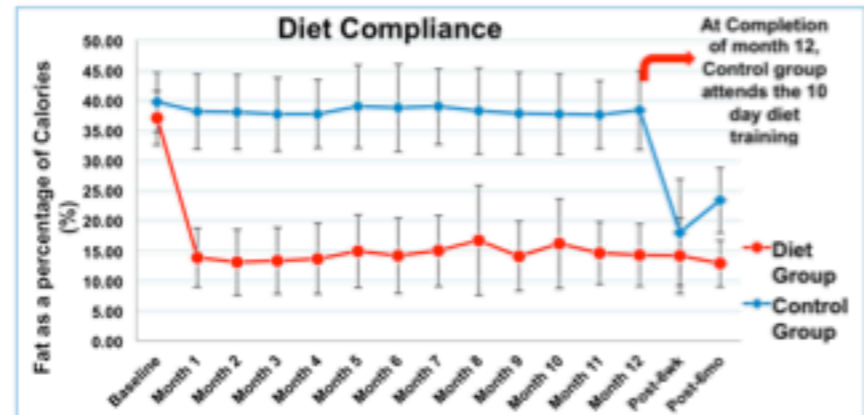
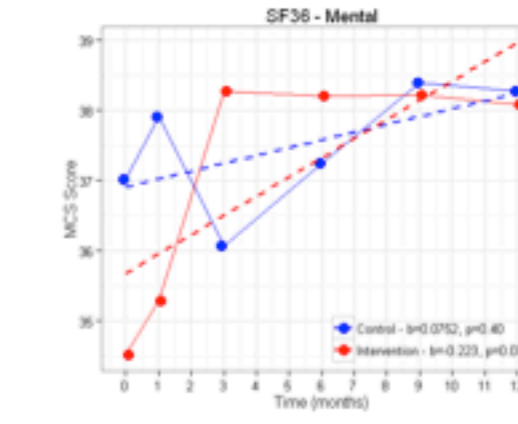
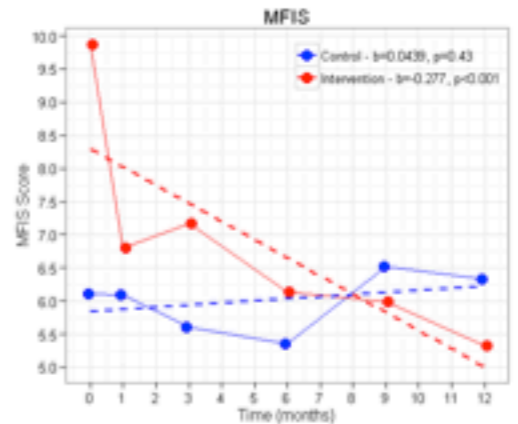
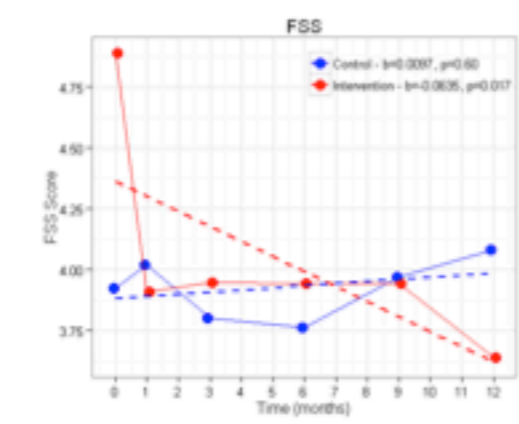
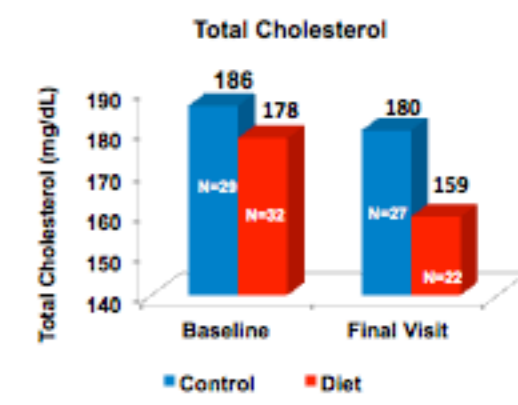
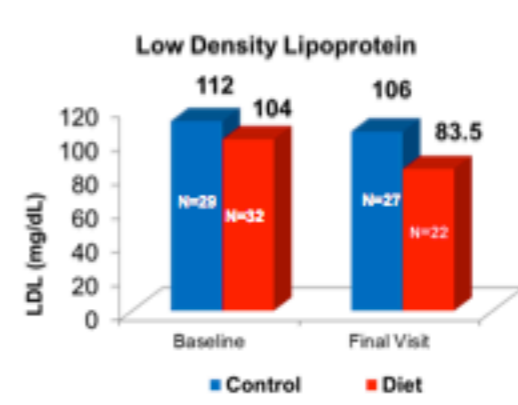
Subject Disposition



Baseline Data

Variables	Control N=29	Diet N=32
Age (years)	40.9 ± 8.48	40.8 ± 8.86
% Female:	89.7%	96.9%
% Male:	10.3%	3.10%
Race		
White -- no. (%)	25 (86.2%)	26 (81.25%)
AA.-- no. (%)	4 (13.8%)	2 (6.25%)
His/Lat. -- no.(%)	-	2 (6.25%)
Other -- no. (%)	-	2 (6.25%)
Disability (EDSS) Score	2.22 ± 0.90	2.72 ± 1.05
Disease Duration -- yrs	5.30 ± 3.86	5.33 ± 3.63
# Relapses in prev. 2 yrs	1.38 ± 0.73	1.69 ± 1.33
Last Relapse (mo)	11.7 ± 5.82	12.0 ± 6.92
Burden of Disease MRI brain	2643.26	4959.97
Newly Enhancing Lesions (MRI)	0.11 ± 0.42	0.78 ± 2.22
Brain Volume (MRI) mm ³	0.82 ± 0.04	0.83 ± 0.03

Results



MRI and clinical outcomes: After baseline difference adjustment, the groups showed no significant changes in the number of active lesions or other MR parameters, relapse rate, EDSS and Timed 25 ft walk.

Conclusions

This study demonstrated safety and achievable compliance for the McDougall diet. Improved lipid profile and weight may yield longer term vascular health and quality of life benefits. Small sample size, use of disease modifying therapies by many subjects, and one year follow up likely contributed to the reduced power to detect changes on MRI and clinical outcomes. Significant improvements in the fatigue measures is worth exploring further. Longer future studies with larger sample size are needed.

Sponsors

McDougall Research & Education Foundation, OHSU Foundation, Department of Veterans Affairs.