A Randomized-Controlled Study of Diet & Multiple Sclerosis

Vijaysriy 1, 2 Gall Marracci, 1, 2 Edward Kim, 1, 2 Rebecca Spain, 1, 2 Michelle Cameron, 1, 2 Shannon Overs, 1, 2 John McDougall, 1
Jesus Lovera, 3, 2 Donnie Burdette, 1, 2

1 Department of Neurology, Oregon Health & Science University; 2 Department of Veterans Affairs MS Center of Excellence-West, Portland, OR, USA; 3 Novant Medical Group, Charlotte, NC, USA; 4 The McDougall Research and Education Foundation, Santa Rosa, CA, USA

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, cross-blinded, 1-year study with subjects assigned to a low-fat diet (control), or well-balanced (centralized), subject-controlled diet. Study outcomes: changes over one year in brain MRI new T2 lesion count and abnormal MRI activity, atrophy, and functional MRI brain activity. Subjects with difficulty with diet compliance were counseled by the project dietician.

Results

- **Baseline Data**
  - **Variables**
    - Control: N=29
    - Diet: N=32
  - **Age** (years)
    - Control: 40.9 ± 8.48
    - Diet: 40.8 ± 8.85
  - **Female (%)**
    - Control: 60.7%
    - Diet: 60.3%
  - **Race**
    - Control: 12.3%
    - Diet: 31.0%
  - **White**
    - Control: 26 (89.6%)
    - Diet: 26 (81.3%)
  - **AA**
    - Control: 4 (13.8%)
    - Diet: 2 (6.25%)
  - **Hispanic**
    - Control: 2 (6.9%)
    - Diet: 2 (6.25%)
  - **Other**
    - Control: 2 (6.9%)
    - Diet: 2 (6.25%)
  - **Disability (EDSS)**
    - Control: 2.22 ± 0.90
    - Diet: 2.72 ± 1.05
  - **BMI**
    - Control: 30.3 ± 3.00
    - Diet: 33 ± 3.03
  - **# Relapses in prev. 2 yrs**
    - Control: 1.30 ± 0.70
    - Diet: 1.69 ± 1.33
  - **Last Relapse (mo)**
    - Control: 11.7 ± 5.65
    - Diet: 12.3 ± 6.22
  - **Burden of Disease**
    - Control: 24.3 ± 20
    - Diet: 46.6 ± 27
  - **Newly Enhancing Lesions (MRI)**
    - Control: 0.11 ± 0.42
    - Diet: 0.78 ± 2.22
  - **Lesions (MRI)**
    - Control: 0.82 ± 0.04
    - Diet: 0.83 ± 0.03

- **MRI and clinical outcomes**
  - **Diet Compliance**
    - Control: Completed N=27
    - Diet: Completed N=32
  - **Major Changes from Baseline**
    - Control: 3 (11.1%)
    - Diet: 5 (15.6%)
  - **Major Changes from Baseline**
    - Control: 3 (11.1%)
    - Diet: 5 (15.6%)
  - **Fat and protein percentage**
    - Control: 2.72 ± 1.05
    - Diet: 2.72 ± 1.05

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.