



# eLITERATURE REVIEW

## eMultipleSclerosis Review

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## eMultipleSclerosis Review VOLUME 1, ISSUE 3

### *New Insights into Lifestyle Modification*

#### In this Issue...

Historically, lifestyle choices and health-related quality of life have been underappreciated as relevant to people with MS. However, it is becoming increasingly evident that modifiable aspects of lifestyle, particularly environmental exposures, diet, and exercise, may play important roles in the risk or prognosis of MS.

In this issue, we review key publications providing new information about:

- Obesity as a risk factor for MS
- The potential effects of higher sodium intake as a risk and prognostic factor;
- Vitamin D status and MS risk
- The results of interventions to improve balance and reduce falls
- The impact of exercise on MS symptoms
- Improving urinary incontinence through non-surgical/nonpharmaceutical interventions



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**Length of Activity**  
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## LEARNING OBJECTIVES

After participating in this activity, the participant will demonstrate the ability to:

- Discuss the role of obesity, vitamin D status, and sodium intake in multiple sclerosis, and to consider possible mechanisms by which diet could impact the disease.
- Evaluate the impact of pilot trials of rehabilitative and physical activity enhancement on neurologic function and aspects of wellness in people with multiple sclerosis.
- Describe the impact of treating urinary dysfunction on the health-related quality of life in people with MS.

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## GUEST AUTHOR OF THE MONTH



Commentary & Reviews  
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#### **Guest Faculty Disclosure**

Dr. Mowry has indicated that she has received research grant support from Biogen and free medication for clinical trials from Teva.

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## Unlabeled/Unapproved uses

Dr. Mowry has indicated that she will not reference unlabeled/unapproved uses of drugs or products.

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## COMMENTARY

There has been renewed focus on the influence of modifiable lifestyle factors on multiple sclerosis risk and prognosis in the past few years. Several studies have evaluated the role of obesity in MS, particularly since the rise in MS incidence reported in several locations throughout the world interestingly parallels the obesity epidemic as well. In Langer-Gould et al., reviewed in this issue, adolescent obesity in girls does appear to influence the odds of MS. Although these results are similar to those of other large case-control studies that have evaluated body size in adolescence as a risk factor for MS,<sup>1,2</sup> the other studies typically evaluated self-reported body size retrospectively, while the Langer-Gould paper captured height and weight as reported in the clinical record. A more recent, population-based study in Denmark, which also evaluated actual recorded height and weight prior to MS onset, reported similar findings, including the discrepancy between girls and boys.<sup>3</sup>

It still remains unclear whether the lack of association of BMI and pediatric-onset MS in boys is actually true; certainly it may be the case, but since the number of males is smaller, the confidence intervals surrounding the estimated effect are too wide to be conclusive. In fact, other studies reported an association or trend for an association of BMI and greater odds of MS in males as well as females.<sup>1,2</sup> It is also unclear from these

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association studies whether reducing BMI could reduce the risk of MS or if obesity and MS are both related to a different, unidentified risk factor. Further, whether obesity is a risk factor for a worse prognosis in people with established MS remains to be determined.

Related to obesity, diet itself has continued to be a source of interest as potentially influencing MS risk or prognosis. Recent studies of the mouse model of MS showed a possible role for excess salt/sodium as a risk factor for the disease.<sup>4,5</sup> Farez et al, as discussed in the review, demonstrated that people with MS who consumed more sodium were more likely to develop relapses or new/active brain lesions on neuroimaging.

Notably, this study did not use the gold standard - the 24-hour urine sodium — to measure sodium; instead, the first morning urine was used, along with an estimating equation, to predict 24-hour urine sodium levels. Further, the analyses were not adjusted for other dietary habits that might instead be responsible for the apparent relationship (such as macronutrient content or overall calories consumed). The interpretability of the cross-sectional portion of the study is difficult, since reverse causality is a larger concern with such a study design. Nonetheless, the emerging data about a potential role for diet as a modifier of MS risk or prognosis are exciting. Diet could potentially influence MS through several mechanisms, including direct modulation of the immune system, altering the gut microbiota, or affecting metabolism (including mitochondrial function or oxidative stress). However, no data from randomized, controlled trials are available at this time to support specific dietary recommendations to either prevent MS or improve the prognosis for those who have the diagnosis already.

There are numerous papers that show an inverse association between 25-hydroxyvitamin D levels and more inflammatory activity, as well as possibly neurodegeneration and disability in people who already have MS. The paper by Mokry et al is very interesting: using a unique method called Mendelian randomization (which helps minimize concerns about unmeasured confounding), lower predicted levels of 25-hydroxyvitamin D caused by the four genetic variants related to vitamin D metabolism were found to be associated with substantially increased odds of having MS. It strongly corroborates a previous study that showed an inverse association between vitamin D levels and the odds of MS; in particular, people with 25-hydroxyvitamin D levels above approximately 100 nmol/L (40 ng/mL) demonstrated a marked reduction in the odds of subsequently developing the disease.<sup>6</sup> Both studies focused on people of European or Caucasian ancestry, so whether vitamin D status is as meaningful for people of different racial backgrounds is not known. Further, the optimal dosage or target 25-hydroxyvitamin D levels are not known, nor is it clear if there is a critical age window in which vitamin D status is important or if vitamin D levels should be maintained in a specific range for the entire lifespan.

There continues to be an increase in research focusing on the impact of exercise and physical activity on MS. In the reviewed study by Gunn et al, a systematic review was undertaken to evaluate whether the published literature generally supports rehabilitation/exercise for the reduction of imbalance and falls. While the associated meta-analysis showed a benefit for balance, the confidence intervals surrounding the estimates for falls were wide. However, it's important to note that the studies included in this review were heterogeneous in many ways, and only two studies were included in the meta-analysis for the impact of such interventions on falls. Further, other potentially meaningful measures of physical activity were not explored as outcomes.

In contrast, data continue to support the role of exercise or physical activity as modifiers of MS-related symptoms and quality of life. The (reviewed) pilot, randomized, controlled trial by Pilutti and colleagues used a web-based behavioral intervention designed to increase physical activity. In addition to successfully affecting activity, they also showed those assigned to the intervention had improvements in several symptoms that often plague people with MS, such as depression, anxiety, and fatigue. In another analysis of this study reported by this group, those in the intervention group who were less disabled also showed improvements in cognition, as well as other improvements that correlated with increased physical activity (measured by questionnaires or by a pedometer).<sup>7</sup> These results, while preliminary, are exciting in that they suggest that exercise, a modifiable lifestyle factor widely known to be good for the promotion of overall health, may also improve not only aspects of physical functioning, but also psychological functioning and perhaps health-related quality of life in people with MS.

Urinary dysfunction is common in people with MS and causes a great deal of stress and

embarrassment, as well as an overall reduction in health-related quality of life. The reviewed meta-analysis by Block and colleagues evaluated studies that attempted using varied nonsurgical, nonpharmaceutical interventions, guided by physical therapists, to

control bladder symptoms. Challenges included the limited number or size of the available studies, as well as differing specific interventions between the studies. Nonetheless, there appears to be a strong suggestion for a benefit of physical therapy interventions on quality of life and the degree of urinary incontinence. In addition to a benefit from physical therapy and other behavioral modifications to improve voiding control (as well as typical medical or catheterization-type approaches), newer treatment options with varying levels of evidence for ameliorating bladder dysfunction in patients with MS include percutaneous tibial nerve stimulation, sacral neuromodulation, and botulinum toxin injections.<sup>8</sup>

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8. Panicker JN, Fowler CJ, Kessler TM. [Lower urinary tract dysfunction in the neurological patient: clinical assessment and management](#). *Lancet Neurol*. 2015;14:720-732.

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## OBESITY AS A RISK FACTOR FOR MS

Langer-Gould A, Brara SM, Beaver BE, Koebnick C. Childhood obesity and risk of pediatric multiple sclerosis and clinically isolated syndrome. *Neurology*. 2013;80:548-552.



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This study used the large clinical database of Kaiser Permanente Southern California (KPSC) to evaluate a role for childhood obesity as a risk factor for pediatric-onset multiple sclerosis (MS). The strengths of this study include the somewhat population-based nature of KPSC; further, actual height and weight data were recorded as part of routine care and were calculated prior to symptom onset.

In the study, body mass index (BMI) was classified as under/normal weight (the reference BMI; BMI for age < 85th percentile), overweight (BMI for age ≥ 85th percentile or BMI ≤ 25 kg/m<sup>2</sup>), moderate obesity (BMI for age ≤ 95th percentile or BMI ≤ 30 kg/m<sup>2</sup>), or extreme obesity (BMI for age ≥ 1.2 x 95th percentile, or ≤ 35 kg/m<sup>2</sup>). The influence of BMI on the odds of MS was evaluated with adjustments for sex, age at onset (2-11 years or 12-18 years), and race/ethnicity.

Seventy-five children with MS and 913,097 controls were included in the study. Overall, increasing BMI category was associated with increased odds of MS (P value for trend = .05; odds ratio for extreme obesity = 2.10, 95% CI 1.00, 4.41), but this effect was driven by a rather strong association with higher BMI and MS in girls than in boys. The odds of having MS or the first episode consistent with MS (clinically isolated syndrome), adjusted for age at onset and race ethnicity, increased with increasing BMI category in girls (P <

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.005) but not in boys ( $P = .93$ ). In particular, girls who were extremely obese had a nearly four-fold greater odds of developing MS compared to those who were under/normal weight ( $OR = 3.76$ , 95% CI 1.54, 9.16). The association appeared to be stronger for adolescent-onset than for early-onset pediatric MS.

The presented data raise questions regarding the variety of mechanisms by which obesity might influence the risk of MS. Further, the lack of an association in boys needs to be clarified. If it is true that obesity is an etiologic factor for MS, it may be that reducing obesity could reduce the risk of MS, at least for some people.

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## HIGHER SODIUM INTAKE AND INCREASED DISEASE ACTIVITY

Farez MF, Fiol MP, Gaitan MI, Quintana FJ, Correale J. Sodium intake is associated with increased disease activity in multiple sclerosis. *J Neurol. Neurosurg Psychiatry*. 2015;86:26-31.



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This study, conducted in Argentina, evaluated whether dietary sodium intake is associated with the risk of relapses or changes in brain MRI in people who already had a diagnosis of relapsing-remitting MS. The investigators evaluated a longitudinal cohort of 70 subjects for two years, although a second group of 50 subjects was evaluated cross-sectionally. In the longitudinal group - accounting for age, sex, disease duration, MS treatment, 25-hydroxyvitamin D levels, BMI, and smoking status - taking in more than 4.8 gm of sodium per day, measured by estimated sodium excretion, was associated with a substantially greater risk of relapse (incidence rate ratio 3.95, 95% confidence interval 1.4, 11.2,  $P = .01$ ) compared to those taking in less than 2 gm of sodium per day. Higher amounts of sodium intake were also longitudinally associated with increased risk of developing new or gadolinium-enhancing lesions on brain MRI (incidence rate ratio 3.42, 95% CI 1.37, 8.55,  $P = .008$ ).

This study had some design limitations, most notably that the way sodium intake was measured may have had flaws. Nonetheless, if the results are confirmed, a clinical trial of low-sodium diet could ascertain whether such a dietary intervention has meaningful impact on disease activity.

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## VITAMIN D AND MS RISK

Mokry LE, Ross S, Ahmad OS, et al. Vitamin D and risk of multiple sclerosis: a Mendelian randomization study. *PLoS Medicine*. 2015;12:e1001866.



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The authors performed a MS case-control study to calculate whether each individual had variants in four genes. Each genetic variant had previously been linked to lower levels of 25-hydroxyvitamin D (one variant is in vitamin D-binding protein; the others are involved in the conversion of 7-dehydrocholesterol to cholesterol, synthesis of 25-hydroxyvitamin D, or inactivation of 1,25-dihydroxyvitamin D).

The authors then estimated how much lower the vitamin D level would be in each case or control, depending on which variants they possessed. Finally, they assessed whether this estimated vitamin D level (presented as log-transformed 25-hydroxyvitamin D) was linked with MS status. Of note, only people of European ancestry were included in the study.

Lower estimated vitamin D levels, as predicted by these genetic variants, were associated with greater odds of being having MS. Specifically, each one standard deviation lower log-transformed 25-hydroxyvitamin D level was associated with a twofold greater odds of MS ( $OR=2.0$ , 95% CI [1.7, 2.5],  $P = 7.7 \times 10^{-12}$ ). Sensitivity analyses removing the two genetic

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variants that have been associated with mechanisms of action other than vitamin D metabolism led to mild attenuations in the strength of the association, thereby eliminating concerns that the association seen was due to actions unrelated to the effects of vitamin D.

This study provided confirmatory evidence that vitamin D status is associated with MS risk. It remains unclear whether increasing vitamin D levels through oral supplementation lowers MS risk and, if so, what the optimal levels of vitamin D might be.

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## REHABILITATION TO REDUCE FALLS AND IMPROVE BALANCE IN MS

Gunn H, Markevics S, Haas B, Marsden J, Freeman J. Systematic review: the effectiveness of interventions to reduce falls and improve balance in adults with multiple sclerosis. *Arch Phys Med Rehabil*. 2015 Jun 10. pii: S0003-9993(15)00455-4



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In this manuscript, the authors sought to evaluate whether there was sufficient evidence in the published literature to support rehabilitation interventions to reduce falls or to reduce imbalance (a risk factor for falls). The authors also sought to evaluate if specific types or amounts of rehabilitation were of particular help. A systematic review/meta-analysis was undertaken, including published (in English) literature up to late 2014 and the past five years of conference abstracts. Articles were required to be randomized or quasi-randomized, controlled trials evaluating rehabilitation interventions (vs no intervention or placebo) for the impact on falls and/or balance. Exercise types were categorized into strength training; endurance training; training in gait, balance, and function; and general exercise programs, along with "active console games" (eg, electronic game-based training).

After screening 529 potential studies, a total of 97 abstracts were reviewed; 16 papers, representing 15 studies, were included in the final review. Five of the studies evaluated falls as an outcome, only two of which could be assessed in a meta-analysis; in these, the exercise interventions did not appear to meaningfully reduce falls (pooled risk ratio 0.74, 95% confidence interval 0.12, 4.38,  $P = .74$ ). The pooled standardized mean difference for balance was 0.55 (95% confidence interval 0.35, 0.74,  $P < .001$  for test of overall effect). Gait, balance, and functional training interventions appeared to have the greatest impact on effect size; there was a positive correlation of benefit with the number of minutes per week of the intervention, while a negative correlation existed between benefit and the duration of the overall program (in weeks). The authors comment that there was a high concern for bias in 30% of the included papers and that the wide confidence intervals may denote that a type II error (falsely accepting the null hypothesis) occurred.

Several small studies have evaluated the role of rehabilitation on outcomes for people with MS, so the approach of a systematic review/meta-analysis provides for pooling some of the results, allowing for inferences from the combined analysis. Unfortunately, only two studies could be evaluated in a pooled analysis with respect to an outcome of falls, so the confidence intervals surrounding the estimate were large. However, rehabilitation was found useful in improving balance.

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## EXERCISE AND ITS IMPACT ON MS SYMPTOMS

Pilutti LA, Dlugonski D, Sandroff BM, Klaren R, Motl R. Randomized controlled trial of a behavioral intervention targeting symptoms and physical activity in multiple sclerosis. *Mult Scler*. 2014;20:594-601.



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In this study, the authors performed a randomized, controlled trial of a physical activity behavioral intervention in people with MS to determine whether the intervention improved fatigue, depression, anxiety, sleep quality, pain, and health-related quality of life. The trial included 82 participants with MS (ages 18 to 64) who were still able to walk but who were

doing less than 60 minutes of physical activity per week. Participants were randomized to a wait list or to access a web-based physical activity intervention that used social cognitive theory designed to motivate increased physical activity, specifically walking, for a six-month period. In addition, subjects in the intervention arm had one-on-one web-based coaching sessions from members of the study team.

In addition to improving physical activity, the intervention also led to statistically significant improvements in the Fatigue Severity Scale ( $p = 0.001$ ) as well as in measures of depression ( $P = .006$ ) and anxiety ( $P = .006$ ) based on the Hospital Anxiety and Depression Scale; there were trends for improvements in pain, sleep quality, and physical health-related quality of life as well. The authors cite as limitations that the study mainly included women with relapsing-remitting MS who could still walk, so whether the results may be broadly generalizable to men, those who are nonambulatory, or those with progressive MS remains unknown.

While the study was small and had some limitations, the results are still intriguing. Regular exercise is recommended for the broader population, but people with MS may derive particular benefit if it is confirmed that exercise modifies some of the more disabling symptoms associated with MS, such as fatigue, depression, and anxiety. It may be particularly exciting in that MS patients are often prescribed multiple medications for disease modification and symptomatic purposes; if exercise has a meaningful impact on some of these outcomes, it may be prescribed in lieu of a pharmaceutical product, reducing concerns about polypharmacy.

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## IMPACT OF PHYSICAL THERAPY ON QUALITY OF LIFE AND URINARY INCONTINENCE

Block V, Rivera M, Melnick M, Allen DD. Do physical therapy interventions affect urinary incontinence and quality of life in people with multiple sclerosis? *Int J MS Care*. 2015;17:172-180.



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In this systematic review/meta-analysis, the authors sought to evaluate if physical therapy improves urinary incontinence and quality of life in people with MS. To be eligible, studies had to include patients with MS patients who had overactive bladder, urgency, or urinary incontinence and underwent physical therapy focused on these bladder symptoms. Further, urinary incontinence and/or quality of life had to be measured before and after the intervention. The authors used two scales to select only studies that met certain levels of evidence and excluded those that focused on bowel dysfunction, included medication or surgical interventions, or were not focused on interventions performed by physical therapists.

After reviewing 42 full-text articles, seven met the criteria for inclusion, although an additional article was removed from the meta-analysis since no quantitative data were available. Three of the six were randomized, controlled trials; the others included one random pilot study; one observational cohort; and one open, controlled, randomized study. The interventions themselves were varied but included transcutaneous posterior tibial nerve stimulation; pelvic floor muscle training with perineometry assistance; individualized bladder rehabilitation programs; combined electromyography, neuromuscular electrical stimulation, and advice about pelvic floor muscle control; and stimulation of the pelvic floor muscles. Control groups typically were treated by a wait list, placebo, or sham intervention, although the neuromuscular electrical stimulation trials used other active control interventions.

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The analyses support that the various therapy interventions have a statistically significant impact in terms of improving the quality of life of MS patients with respect to how urinary leakage impacts their external social activities (-0.62, 95% CI [-1.03, -0.21]) or activities of daily living (-0.76, 95% CI [-1.10, -0.42]). Further, episodes of leakage were also significantly reduced by the interventions (effect size -0.93, 95% CI [-1.32, -0.54]).

This article demonstrates that physical therapy can be used to improve urinary incontinence for people with MS, with a concomitant improvement in related quality of life. This represents just one of many newer strategies available to people with MS to combat urinary dysfunction.

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## KEY TAKEAWAYS

- Dietary and related factors are emerging as important risk or prognostic factors in people with MS.
- Exercise has multiple beneficial effects for relieving symptoms of MS, including both physical functioning as well as mental well-being and fatigue.
- Many new options are emerging for treating urinary dysfunction in people with MS, some of which have been associated with improved health-related quality of life.

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