

CLINICAL PROTOCOL TO SUPPORT PATIENTS WITH MULTIPLE SCLEROSIS*

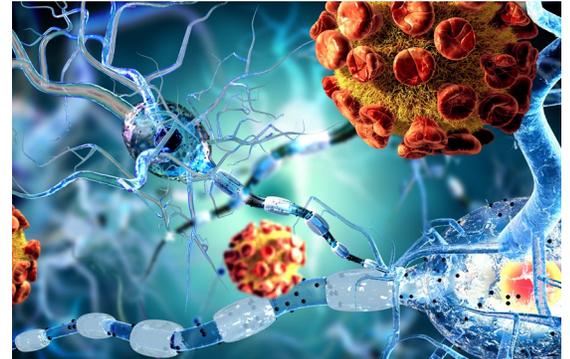
The Pathophysiology of Multiple Sclerosis

Multiple sclerosis (MS) is an autoimmune disease affecting the brain, spinal cord, and optic nerves. It is characterized by neurodegeneration, inflammation, and demyelination, which is damage to the protective coating of some nerves.¹⁻³ Clinical presentations of MS vary widely and can involve any part of the central nervous system (CNS). Symptoms may include limb weakness, abnormal feelings of touch or skin sensations, impaired vision, poor coordination, vertigo, tremors, gait impairment, cognitive dysfunction, depression, seizures, fatigue, impaired speech, and changes in urination and bowel movements.¹

Diagnosis generally occurs between the ages of 20 and 50 and is more prevalent in northern latitudes. Incidence is almost three times higher in women. Risk factors include family history, certain genetic polymorphisms, history of Epstein-Barr virus infection, exposure to tobacco smoke and organic solvents, and insufficient exposure to ultraviolet light.^{1,4}

Clinical diagnosis is based on the 2017 revised McDonald criteria. A definitive diagnosis should be conducted by a neurologist. Management and prognosis vary based on disease severity and symptom profile.¹

This clinical protocol is designed to support patients with multiple sclerosis and includes evidence-based lifestyle and dietary interventions known to support neurological health and a healthy response to inflammation.*



Diagnostic Biomarkers and Clinical Indicators of MS

Tests^{1,5}

- Imaging
 - MRI is used to support MS diagnosis
- Initial blood tests to exclude alternative diagnoses
 - Complete blood count
 - Inflammatory markers
 - > Erythrocyte sedimentation rate
 - Female: 0 to 20 mm/hr
 - Male: 0 to 15 mm/hr
 - > C-reactive protein
 - ≤ 0.8 mg/dL
 - Liver function tests
 - Renal function tests
 - Calcium
 - Glucose
 - Thyroid function tests
 - Vitamin B12
 - 200 to 800 pg/mL
 - HIV serology

Therapeutic Diet and Nutritional Considerations

- Address nutritional deficiencies, particularly vitamins B12 and D. The maintenance of normal serum vitamin D levels may aid in the prevention and/or slowing of disease progression. Vitamin B12 deficiency has been associated with MS due to its role in supporting myelination.^{2,6-8}
- Advise consumption of a diet rich in fruits, vegetables, and omega-3 fatty acids, and low in sugar and hydrogenated fat, which has been shown to have a protective role in MS. The consumption of omega-3 fatty acids may support a healthy response to inflammation²
- Advise intake of nutrients rich in polyphenols, such as curcumin, which has been shown to significantly improve inflammatory markers in individuals with MS.⁶
- Recommend intake of probiotic-rich foods and supplements. Alterations to the gut microbiome have been observed in individuals with MS, and probiotic use has been shown to improve certain MS-related symptoms. Some examples of probiotic-rich foods are sauerkraut, kimchi, kefir, and grass-fed yogurt.^{6,7}

Lifestyle Intervention

- Recommend aerobic and strength-supportive exercise programs that have been shown to improve cardiovascular fitness, muscle strength, quality of life, stability, tiredness, and cognition.³
- Promote techniques that support a healthy mood, such as counseling, restful sleep, and supplementation. Fatigue and depression are common MS-related symptoms that have been shown to improve after nutraceutical interventions. Sleep disturbances may exacerbate symptoms in those with MS.^{1,6,9}
- Provide resources for smoking cessation due to a positive association between smoking and MS, likely due to an increase in inflammation and oxidative stress.⁴
- Recommend stress management techniques such as meditation or similar mindfulness practices, as stress has been associated with increased risk of MS exacerbations.¹



Supplement Protocol

Primary Support:



ImmunoMod-A™

Dose	4 capsules per day with meals
Duration	Ongoing as needed
Formula Highlights	ImmunoMod-A™ has been formulated to help balance a healthy inflammatory response, which is necessary to help maintain optimal immune function in the body.* It features ParActin®, an extract of the herb <i>Andrographis paniculata</i> , which has been shown to help modulate immune, inflammatory, and oxidative pathways.* This product also contains the monosaccharide N-acetyl-D-glucosamine, along with curcumin, a polyphenolic compound extract from the turmeric spice. Both of these compounds help to support a healthy inflammatory response.* Together, the ingredients in ImmunoMod-A™ work to support the proper expression of nuclear factor kappa B (NF-κB) and its related downstream cytokines to help maintain a healthy, balanced immune response.*

OmegaAvail™ Hi-Po

Dose	1-2 softgels per day with food
Duration	Ongoing
Formula Highlights	OmegaAvail™ Hi-Po is our highest potency omega-3 product, providing 1,600 mg of eicosapentaenoic acid (EPA)/docosahexapentaenoic acid (DHA) per 2-softgel serving

Warning: Consult your health-care practitioner before use if you are taking blood thinner medication or if you are planning to have surgery.

D-Evail™ 10K

Dose	1 softgel per day
Duration	Ongoing
Formula Highlights	D-Evail™ 10K is our highest potency vitamin D product, providing a clinically relevant serving of 10,000 IU (250 mcg) of vitamin D in a highly absorbable form alongside vitamins K1 (as phytonadione) and K2 (as MK-4), and geranylgeraniol (GG) to support bone, immune, and cardiovascular health.* Research suggests that combined supplementation of both vitamins D and K may be more supportive than either vitamin alone for both bone and cardiovascular health.* This product uses the Designs for Health Evail™ technology that combines quillaja extract with medium-chain triglycerides (MCTs) for improved nutrient bioavailability.*

Warning: Due to the inclusion of vitamin K in this product, use caution when prescribing D Evail™ products for patients who are taking Coumadin, warfarin, or other anticoagulant medications.

ProbioMed™ 100

Dose	1 capsule per day with a meal
Duration	Ongoing as needed
Formula Highlights	ProbioMed™ 100 is a highly potent, shelf-stable, dairy-free probiotic formulation containing 100 billion CFU per serving. It consists of 10 of the most highly researched probiotic strains, with each strain and specific CFU count being fully disclosed. These are robust strains that are capable of surviving the harsh journey to the intestines and are able to attach to the intestinal walls, where they can grow and function effectively to support gastrointestinal health.* The survivability of the strains is further assisted by delayed-release technology and unique moisture-resistant, desiccant-lined packaging. This novel packaging removes the need for refrigeration, making ProbioMed™ 100 convenient for travelers and anyone on the go.

Adjunct Support:

Vitamin B12

Dose	1 lozenge per day
Duration	Ongoing
Formula Highlights	Vitamin B12 lozenges offer high-dose vitamin B12 in a delicious, berry-flavored lozenge. Each lozenge contains 5,000 mcg of methylcobalamin, which is the activated form of vitamin B12, for enhanced bioavailability.* The easy-to-dissolve lozenge delivery format was designed to support superior nutrient absorption and individuals who may have trouble swallowing capsules or softgels.

For a list of references cited in this document, please visit:
<https://www.designsforhealth.com/protocol-references/ms-references.pdf>

Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health-care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations regarding herb-drug and nutrient-drug interactions, please refer to reliable, evidence-based resources such as the Natural Medicine Database or Stargrove MB, Treasure J, McKee DL. *Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategies*. St. Louis, MO: Mosby-Elsevier; 2008.

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*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.