

Clinical Trials Receiving Funding from the National MS Society

The MS movement has achieved more breakthroughs for MS than the world has seen for any other neurological disease. All of that progress has brought us to a profound new moment: The next chapter in our story could be the last chapter for MS. We have never been closer to an MS cure: to understanding how to prevent the disease and reverse its course; to finding treatments for progressive MS as effective as those we've discovered for relapsing-remitting MS; to bringing life-changing solutions and treatments to everyone with MS.

The National MS Society champions the most promising pathways to cures:

- Stop MS in its tracks by ending disease activity, ensuring no change in disease manifestations, and preventing further progression for those who already have MS. This includes everyday solutions such as diet, exercise, and other lifestyle factors.
- Restore what's been lost by repairing the nervous system, reversing symptoms and disabilities, and boosting rehabilitative approaches to restore function.
- End the disease forever by preventing clinical onset, finding the cause of MS, understanding what triggers it, and implementing prevention strategies against it.

Clinical trials are critical to finding solutions for people living with MS. Below are clinical trials currently receiving funding from the National MS Society. <u>Click here for information on trials and other studies that are currently recruiting participants</u>.

Approach: Stop/Progression

Title: Bile acid supplementation for Multiple Sclerosis

Primary Investigator: Pavan Bhargava, MBBS, MD, Johns Hopkins University

Amount Awarded: \$355,455

Trial Objective: Johns Hopkins researchers are investigating whether a dietary supplement can be beneficial for the immune system, gut bacteria and MS disease activity.

Title: Lipoic acid for the treatment of progressive multiple sclerosis Primary Investigator: Rebecca Spain, MD, MSPH, Oregon Health & Science University Amount Awarded: \$1,180,578 Trial Objective: Investigators are conducting a clinical trial to determine if the oral supplement, lipoic acid, is an effective treatment for progressive forms of multiple sclerosis.

Title: Multiple Sclerosis-Simvastatin Trial 2 (MS-STAT2) Primary Investigator: Jeremy Chataway MA, PhD, FRCP, MS Society UK Amount Awarded: \$1,333,572

Trial Objective: Researchers are leading a multicenter trial in the UK to test whether a repurposed cholesterol-lowering therapy can slow the course of secondary progressive MS.





Approach: Stop/Disease Activity

Title: Assessment of the Clinical Importance of Insulin Resistance & Steroid-Associated Hyperglycemia in Relapsing Multiple Sclerosis

Primary Investigator: Myla Goldman, MD, Virginia Commonwealth University

Amount Awarded: \$329,238

Trial Objective: A team from the University of Virginia School of Medicine is exploring whether controlling blood sugar can decrease the severity and/or improve recovery from MS relapse.

Title: CharriotMS Trial: Cladribine to halt deterioration in people with advanced MS Primary Investigator: Klaus Schmierer, MD, PhD, Queen Mary University of London Amount Awarded: \$313,000 to MS Society UK Trial Objective: A team of UK researchers are testing the effects of Cladribine on upper limb function in people with advanced MS.

Title: Discontinuation of Disease Modifying Therapies (DMTs) in Multiple Sclerosis (MS) – co-funding with Patient Centered Outcome Research Institute (PCORI) Primary Investigator: John Corboy, MD, University of Colorado Denver Amount Awarded: \$326,463 Trial Objective: A trial to determine if and when MS therapies should be discontinued.

Title: Evaluating the effects of short-term B-cell depletion on long-term disease activity and immune tolerance in relapsing multiple sclerosis

Primary Investigator: Bardia Nourbakhsh, MD, Johns Hopkins University

Amount Awarded: \$397,248

Trial Objective: Johns Hopkins researchers are exploring the longer-term impacts of short-term use of B-cell depleting therapy on the immune system and MS disease activity.

Title: A randomized controlled trial of vitamin D supplementation in multiple sclerosis **Primary Investigator:** Ellen Mowry, MD, MPH, Johns Hopkins University **Amount Awarded:** \$1,728,702

Trial Objective: Investigators are conducting a clinical trial to compare the effectiveness of vitamin D supplementation (standard versus high dose) at reducing MS disease activity, when added to standard therapy with glatiramer acetate.

Title: Development of a telehealth obesity intervention for patients with MS **Primary Investigator:** Jared Bruce, PhD, University of Missouri - Kansas City **Amount Awarded:** \$756,058.60

Trial Objective: A University of Missouri team is testing the effectiveness of an MS-specific weigh loss/healthy living program delivered by phone, since obesity can worsen MS severity.





Approach: Stop/Delivery of Care

Title: Electronic Pill Bottle Monitoring to Promote Medication Adherence for People with MS **Primary Investigator:** Farrah Mateen, MD, PhD, Massachusetts General Hospital **Amount Awarded:** \$55,000

Trial Objective: Researchers at Massachusetts General Hospital are testing if an electronic pill bottle cap can monitor and remind people with MS about taking their medications.

Title: Pilot Feasibility Study of Out-of-Pocket Cost Communication and Supportive Financial Services for Reducing Financial Toxicity Among Multiple Sclerosis Patients
Primary Investigator: Gelareh Sadigh, MD, Emory University
Amount Awarded: \$55,000
Trial Objective: Emory investigators are exploring whether a cost information program can decrease financial burden and increase compliance with care in people with MS.

Approach: Restore/Repair Damage

Title: Trials for remyelination in MS: from bench to bedside to home **Primary Investigator:** Riley Bove, MD, University of California, San Francisco **Amount Awarded:** \$708,972

Trial Objective: Researchers are testing a novel molecule that may repair myelin in women with MS ages 45-60, using a home-based trial that employs digital tools to measure improvements.

Title: Phase 2, Randomized, Double Blind, Placebo Controlled Study of Intrathecal autologous MSC-NP Cells in Patients With MS

Primary Investigator: Saud Sadiq, MD, Tisch MS Research Center of New York

Amount Awarded: \$1,000,000

Trial Objective: A phase II clinical trial to see whether stem cells derived from individuals' own bone marrow can inhibit immune mechanisms and augment tissue repair in progressive MS.

Approach: Restore/Functional Recovery

Title: A physical activity-based tracking intervention to enhance cognitive and neural plasticity **Primary Investigator:** Ruchika Prakash, PhD, Ohio State University

Amount Awarded: \$631,261

Trial Objective: Researchers are testing whether increasing physical activity through the use of simple accelerometers can improve cognitive functioning in MS.

Title: Lifestyle physical activity intervention for improving cardiorespiratory fitness and vascular comorbidity risk in multiple sclerosis

Primary Investigator: Lara Pilutti, PhD, University of Ottawa

Amount Awarded: \$351,620

Trial Objective: University of Ottawa researchers are testing an intervention to increase physical activity to determine if it can improve fitness and reduce vascular disease risk in MS.





Title: Neurologic Music Therapy to Improve Gait Dysfunction in Multiple Sclerosis Primary Investigator: Eric Klawiter, MD, Massachusetts General Hospital Amount Awarded: \$55,000 Trial Objective: Massachusetts General researchers are testing a method of walking to a beat or music to see if it improves walking in people with MS.

Title: Does melatonin improve insomnia in patients with MS? Primary Investigator: Riley Bove, MD, University of California, San Francisco Amount Awarded: \$55,000 Trial Objective: Researchers at UCSF are testing whether sleep problems improve in people with MS with the use of melatonin.

Title: Interval vs. continuous walking training for people with multiple sclerosis: a comparison of effectiveness

Primary Investigator: Evan Cohen, PT, PhD, Rutgers, The State University of New Jersey **Amount Awarded:** \$52,100

Trial Objective: Rutgers researchers are testing whether providing rest intervals throughout walking rehabilitation efforts improves their effectiveness.

Title: Tai Chi and Mindfulness Training to Improve Postural Control and Quality of Life in People with Multiple Sclerosis: A Community-Based Intervention Study

Primary Investigator: Richard Van Emmerik, PhD, University of Massachusetts **Amount Awarded:** \$54,972

Trial Objective: UMass researchers are testing Tai Chi and Mindfulness Meditation training for their ability to improve balance in people with MS.

Title: Waking hypnosis in the treatment of MS-related fatigue: pilot and feasibility study **Primary Investigator:** Maria Mendoza, PhD, University of Washington **Amount Awarded:** \$54,997

Trial Objective: University of Washington are testing two hypnosis techniques for their ability to reduce fatigue in people with MS, including Spanish speakers.

Title: Reducing depression and anxiety in individuals with MS and their caregivers: An emotion regulation skills training intervention

Primary Investigator: Abbey Hughes, PhD, Johns Hopkins University **Amount Awarded:** \$54,972

Trial Objective: Testing the efficacy of a unique group-based therapy for improving emotion regulation in people with MS and their carepartners.





Title: Developing A Person-centered Internet-based Health Action Process Approach to Promoting Physical Activity in People with Multiple Sclerosis

Primary Investigator: Chung-Yi Chiu, PhD, University of Illinois at Urbana-Champaign **Amount Awarded:** \$548,359

Trial Objective: Researchers at the University of Illinois are testing a program aimed at increasing physical activity among people with MS to promote healthier lifestyles.

Title: Gaze and postural stability in persons with MS at risk for falls: Characterizing deficits and response to treatment

Primary Investigator: Lee Dibble, PT, PhD, University of Utah

Amount Awarded: \$436,219

Trial Objective: Researchers are investigating whether exercises specifically designed to improve inner ear function can improve balance and vision stability in people with MS.

Title: Online program to reduce depression in MS – a phase III international multicenter randomized controlled trial

Primary Investigator: Stefan Gold, PhD, Charité - Universitätsmedizin Berlin Amount Awarded: \$1,397,712

Trial Objective: Researchers at Berlin, Germany's Charité University Medical Center are testing the effectiveness of a computer program for overcoming MS-related depression.

Title: Virtual Reality-treadmill combined intervention for enhancing mobility and cognitive function in patients with Relapsing-Remitting Multiple Sclerosis

Primary Investigator: Jeffrey Hausdorff, PhD, Tel Aviv Sourasky Medical Center

Amount Awarded: \$938,522

Trial Objective: Researchers in Tel Aviv and the University of Illinois at Urbana-Champaign are testing a rehabilitation strategy that addresses walking and thinking in an integrated approach.

Title: The Effects of Working Memory Training on Brain Function, Structure, and Cognition in MS **Primary Investigator:** Janet Shucard, PhD, The State University of New York at Buffalo **Amount Awarded:** \$608,859

Trial Objective: Investigators are testing two training programs for improving cognitive function in people with MS.

Title: A randomized trial of positive airway pressure therapy to treat cognitive dysfunction in MS patients with obstructive sleep apnea

Primary Investigator: Tiffany Braley, MD, Regents of the University of Michigan

Amount Awarded: \$827,966

Trial Objective: University of Michigan researchers will determine whether a commonly used treatment for sleep apnea could improve cognitive performance in people with MS.





Title: A Randomized Controlled Trial of Telephone-Delivered Cognitive Behavioral Therapy, Modafinil, and Combination Therapy of Both Interventions for Fatigue in Multiple Sclerosis
Primary Investigator: Dawn Ehde, PhD, University of Washington
Amount Awarded: \$83,450
Trial Objective: Supplemental funding to a PCORI-funded trial testing interventions for improving fatigue.

Title: Open-Label Placebos to Treat Fatigue in Multiple Sclerosis Primary Investigator: Tapan Mehta, PhD, University of Alabama at Birmingham Amount Awarded: \$54,953 Trial Objective: Researchers are testing the ability of the placebo effect to reduce MS-related fatigue.

Title: Interacting with Nature using virtual reality: A pilot intervention to restore cognitive fatigue in MS Primary Investigator: Hala Darwish, PhD, American University of Beirut Amount Awarded: \$49,900 Trial Objective: A team in Beirut is testing whether interacting with nature via virtual reality can decrease

cognitive fatigue in people with MS.

Title: Dietary Approaches to Treating Multiple Sclerosis Related Fatigue **Primary Investigator:** Terry Wahls, MD, The University of Iowa **Amount Awarded:** \$1,098,981

Trial Objective: A team at the University of Iowa is comparing two dietary approaches to determine their effectiveness for treating MS-related fatigue.

Title: Project BIPAMS: Behavioral Intervention for increasing Physical Activity in MS **Primary Investigator:** Robert Motl, PhD, University of Alabama at Birmingham **Amount Awarded:** \$813,305

Trial Objective: Researchers are testing an internet-based behavioral intervention with people with MS to increase their physical activity and alleviate symptoms.

Title: MOVE MS: Group Exercise Program

Primary Investigator: Brynn Adamson, PhD, University of Illinois at Urbana-Champaign **Amount Awarded:** \$36,974

Trial Objective: Researchers at the University of Illinois-Urbana Champaign are testing a novel communitybased exercise program that may help to increase physical activity in people who have MS.

Title: Feasibility and efficacy of a high-intensity interval training program in persons with MS **Primary Investigator:** Elizabeth Hubbard, PhD, Berry College **Amount Awarded:** \$54,995

Trial Objective: Researchers are looking at the impact of individualized arm and leg exercise regimens on movement, fatigue, depression and other symptoms in people with mobility impairments.





Title: Characterizing the Acute Response to Adapted Exercise in Non-ambulatory People with MS **Primary Investigator:** Lara Pilutti, PhD, University of Ottawa

Amount Awarded: \$44,821

Trial Objective: University of Ottawa researchers are studying the impacts and enjoyment of adapted exercise in people with MS who use wheelchairs.

Title: Adaptive motor learning of fall resistance skills through slip exposure in multiple sclerosis **Primary Investigator:** Feng Yang, PhD, Georgia State University **Amount Awarded:** \$54,483

Trial Objective: Researchers are testing whether training people with MS with controlled falling experiences can build skills around how to react against fall situations to prevent them.

Title: A randomized controlled trial of remotely-supervised transcranial direct current stimulation (RS-tDCS) for the treatment of fatigue in multiple sclerosis

Primary Investigator: Leigh Charvet, PhD, New York University Langone Medical Center **Amount Awarded:** \$532,862

Trial Objective: New York University researchers are conducting a small clinical trial of transcranial direct current stimulation to assess its effectiveness for treating MS-related fatigue.

Title: Validation of a Fall Prevention Program Among Non-Ambulatory Wheeled Mobility Device Users with Multiple Sclerosis

Primary Investigator: Laura Rice, PT, PhD, University of Illinois at Urbana-Champaign **Amount Awarded:** \$570,217

Trial Objective: Researchers at the University of Illinois at Urbana-Champaign are developing a program designed to help prevent falling for people with MS who are wheelchair users.

Title: Comparative Effectiveness of an Exercise Intervention Delivered via Telerehabilitation and Conventional Mode of Delivery

Primary Investigator: Deborah Backus, PT, PhD, Shepherd Center

Amount Awarded: \$137,500

Trial Objective: The Society is supporting an extension of a clinical trial, funded by PCORI, to compare the effectiveness of a supervised exercise program done at home or in person in MS.

Title: Mindfulness based Cognitive Therapy and Cognitive Behavioral Therapy for Chronic Pain in MS **Primary Investigator:** Dawn Ehde, PhD, University of Washington **Amount Awarded:** \$879,991

Trial Objective: University of Washington researchers are conducting a clinical trial testing two non-pharmacological approaches to managing pain in people with MS.





Title: A Randomized Controlled Trial of a Multicomponent Walking Aid Program for People with MS **Primary Investigator:** Michelle Cameron, PT, MD, Oregon Health & Science University **Amount Awarded:** \$534,358

Trial Objective: Researchers are testing whether a standardized program provided by physical therapists, that helps to select, fit, and train in using walking aids, can prevent falls in MS.

Title: Physical Activity, Quality of Life and Disease Outcomes in Youth with Multiple Sclerosis: the ATOMIC (Active Teens Multiple Sclerosis) Physical Activity Research Program
Primary Investigator: E. Yeh, MD, The Hospital for Sick Children
Amount Awarded: \$665,469
Trial Objective: A team is testing if a smartphone app that provides tailored physical activity info/coaching can increase physical activity in pediatric MS.

Title: Efficacy of a psychological intervention to improve ability to cope with uncertainty in MS **Primary Investigator:** Ivan Molton, PhD, University of Washington

Amount Awarded: \$1,029,346

Trial Objective: Researchers are comparing traditional behavioral therapy with briefer counseling to determine how to better help people newly diagnosed with MS to cope with the uncertainty of the disease.

Title: Effects of non-invasive brain stimulation on cognitive function in patients with MS **Primary Investigator:** Wan-Yu Hsu, OTR, PhD, University of California, San Francisco **Amount Awarded:** \$209,702

Trial Objective: UCSF researchers are investigating the potential benefits of non-invasive brain stimulation, called transcranial alternating current stimulation, to treat cognitive deficits in people with MS.

Title: Hypnosis and Mindfulness Meditation for Fatigue Management in MS **Primary Investigator:** Mark Jenssen, PhD, University of Washington **Amount Awarded:** \$611,701

Trial Objective: A team is evaluating two ways for individauls with MS to mange fatigue on their own, without needing to work with a trained clinician: self-hypnosis or mindfulness.

Title: Split-belt treadmill training in the lab and sensory cueing in the real world to reduce limb asymmetries and improve gait

Primary Investigator: Brett Fling, PhD, Colorado State University Amount Awarded: \$752,709

Trial Objective: Colorado State specialists are studying whether a rehabilitation program that specifically addresses asymmetries that may exist between legs can improve walking in people with MS.

