

# Testing ground



## **Pros and cons of participating in clinical trials for MS research.**

by Aviva Patz



**Karen Jackson, diagnosed with MS in 1996, has benefited from medications from clinical trials.**

Photo courtesy of Karen Jackson

Karen Jackson has been happily filling out surveys, giving extra vials of blood and undergoing MRIs and lumbar punctures for clinical trials since 2006. The 58-year-old from Alexandria, Virginia, was diagnosed with relapsing-remitting multiple sclerosis in 1996, then with primary progressive MS in 2003. “For me, it’s a no-brainer,” she says. “There aren’t a lot of treatment options for primary progressive MS. This is a way for me to continue to be part of the solution, part of the answer.”

Clinical trials are at the heart of finding new and better treatments for MS. They help scientists understand how MS develops and whether treatments—from disease-modifying therapies (DMTs) to rehabilitation strategies—are safe and effective. Participating has pros and cons, but one thing is certain: There can be no progress without it. “Everyone owes a debt of thanks to people who have participated in clinical trials, who have helped pushed the field forward, because all trials, even unsuccessful ones, teach us valuable lessons,” says Ari Green, MD, director of the MS Center at the University of California at San Francisco. “Everyone with MS has benefited because of the risk or the inconvenience of the people who came before them.” Read on to learn more about participating in clinical trials for MS and whether they’re right for you.

### **How to find clinical trials**

There are two main sources of MS clinical trial listings: One is the [National Multiple Sclerosis Society website](#), which allows you to search for trials by state, type of MS or keyword. You can also check the website of the [National Institutes of Health](#), where you can search more than 290,000 research studies in all 50 states and in 207 countries. Search by condition to find MS-related trials.

### **Details of trials**

Studies can last from weeks to months to years or even the rest of your life, in the case of long-term research. Timing depends on the phase of the research, what it’s testing and other variables. How you participate will also vary widely—you might be trying an app, modifying your diet, taking vitamins or pills (including disease-modifying therapies), giving extra vials of blood or having extra MRIs, getting your skin biopsied, getting injections or infusions, or testing out different ways of walking, exercising or doing physical therapy.

### **How to enroll**

You can ask your physician to refer you, or you can apply directly by emailing or calling the contact listed in the trial description. The researchers will then determine if you meet the eligibility requirements—for example, you may need to be over 18, live within 150 miles of the research facility and fall within certain levels of disability and duration of disease. Check with your neurologist to ensure it makes sense for you, and put your doctor in touch with the researchers running the study to ensure that it’s a fit. It isn’t always. For example, you might like the idea of testing a DMT, but therapies are sometimes compared to inactive placebos. If

you end up getting a placebo instead of the medication and that could put you at risk, it's not safe for you to participate.

### **Types of studies**

There are two basic types of studies in which people with MS might participate, according to Joan Ohayon, senior nurse consultant with the Neuroimmunology Clinic at the National Institutes of Health.

The first type simply gathers information to understand more about the disease and doesn't involve interventions. For example, the School of Communication Sciences and Disorders at the University of Memphis is studying how different neurological conditions impact speech. Researchers at the University of Illinois in Urbana-Champaign and Carle Hospital are exploring the relationship between nutrition and eye health among people with MS. Then there's a USC Multiple Sclerosis Center study looking to validate a smartphone app called "myMS," which helps track MS at home.



### **Participating in a clinical trial could include commitments and tests, such as getting MRIs.**

For longer-term information gathering, you can get involved in a registry designed to capture the real-life experience of people living with MS. One example is [iConquerMS](#), which involves completing surveys about daily experiences and symptoms, sharing medical records, and suggesting research topics and questions. Another example is [NARCOMS](#), a registry of people willing to participate in MS research that was initiated by the Consortium of MS Centers to facilitate multicenter studies.

The second type of study is an interventional clinical trial that tests new therapies and rehab strategies, whether it's a new treatment or an add-on treatment, or a complementary therapy such as a special diet, yoga or meditation. For example, Dr. Green is studying ways to take advantage of the body's existing capacity for repair. "In MS, primary early damage

occurs to the myelinating cells of the central nervous system,” he explains. “There are cells that are meant to repair that damage, but for some reason in MS they don’t do what they’re supposed to do—we’re looking to help those cells overcome the barriers keeping them from doing their job.” Results of his first trial with a medication, which were promising, were published in *The Lancet* in 2017, and he’s now doing a second trial to evaluate the best timing for that medication.

### **Key factors to consider**

Obviously, you want to consider logistics like the time commitment, scheduling, and whether you can handle what’s involved (like hour-long MRIs every six months) and any risks the study might pose. “It may depend how risk-averse you are,” Ohayon says. Then you’re going to want to start asking questions. You can find a complete list of questions on the website of the [Center for Information and Study on Clinical Research Participation](#), but these are among the most important:

- What are we trying to learn? You might think the answers are in the trial description, but it can be complicated, according to Dr. Green, so ask for a breakdown in simple language.
- What is the background data to support this approach? Ask the investigators to provide evidence of why they believe this therapy will work. Beware of a hard sell, warns Dr. Green. “If you feel like the researchers are making false promises or painting an overly rosy picture of the possible results, that’s a reason to be skeptical,” he says.
- Has the treatment been tested before? If so, on how many people? What are the possible side effects?
- What kinds of tests and treatments are involved? If you’re not comfortable with any of the elements, that’s a deal-breaker. “There’s no reason to feel coerced to participate—it’s your body, it’s your condition,” Dr. Green says.
- What are the possible risks and benefits in the study compared with my current treatment?
- Who will pay for the experimental treatment, or any of the tests, and will I be reimbursed for other expenses such as mileage, parking or meals?
- If the treatment works, can I continue receiving it?

### **Benefits of enrolling**

What’s in it for you? The short answer: You’ll receive regular and careful medical attention from a team of doctors and other health professionals; you’ll possibly have access to new treatments before they’re widely available; and you’ll help others by contributing to understanding of new treatments or procedures. “Sometimes negative studies are just as informative or more informative than positive ones, so it’s good to go into the study thinking, yes, this may benefit me, but more important, I’m benefiting the greater good,” Ohayon says.



**Anita Williams volunteers for clinical trials as a way to contribute to MS research.** Photo courtesy of Anita Williams

Anita Williams, 49, of Aurora, Colorado, has volunteered in clinical trials since 2015 for that very reason. “I said ‘yes’ because I wanted to contribute to MS research, especially as a black woman who would like to see more African Americans represented,” she says. “It’s the MS patients who came before me and participated in clinical trials that gave us the information we have today. The DMTs are all possible because of them, and I want to do the same for others.”

Jackson did benefit from one experimental medication. But more gratifying for Jackson has been having access to top-notch teams of dedicated and passionate clinicians. When she developed a pressure sore on her right hip, it was successfully treated the same day by the study team’s wound department. “Had it not been for my connection to the National Institutes of Health, I wouldn’t have gotten that early intervention and would have suffered so much longer,” she says.

### **Potential downsides of enrolling**

What are the risks? Besides logistical inconveniences—the time, interventions and even costs involved—the experimental treatment you’re getting may not be effective. Or you could be in the control group and not get active medicine. Worse, you could take the active medicine and have unpleasant and even serious side effects. “It could be that you take a medication and suddenly your disease gets worse—it’s definitely a risk,” Ohayon says. “But there are many steps along the way to minimize the risk category.” It’s important to note that participants are monitored closely for side effects and other issues.

## Phases of clinical trials

Every therapy undergoes several phases of testing:

- Phase I is a small study that determines the safe dose range and flags any safety concerns and side effects.
- Phase II starts looking at the effectiveness of the therapy and further evaluates its safety.
- Phase III is a bigger study, sometimes with thousands of people and spanning years, that compares this therapy with standard or similar treatments or no treatment (placebo). To earn FDA approval, the drug must prove to be as good as or better than what already exists.
- Phase IV follows FDA approval and is designed to monitor how the treatment is working. “It’s not just boom, it’s approved, we’re done,” Ohayon says. “We still monitor safety and effectiveness for a long time.”

Ultimately, volunteering for MS research could benefit your disease, but in Dr. Green’s experience, it will definitely benefit your state of mind. “In my years of doing this, I’ve seen that the people who participate in clinical trials are happier because they’re part of the work that’s helping overcome something they’re living with,” he says. “There’s an injustice to MS—it harms people at a crucial time of their lives and robs them of certain opportunities and experiences, so it really helps people psychologically to be fighting back.”

**Aviva Patz is a writer in Montclair, New Jersey.**

Learn more about [enrolling in clinical trials](#).