



Early Intervention Clinical Trials Description

Scientists are planning to conduct [therapeutic studies](#)¹ to explore the ability of [experimental \(new\) treatments](#)² to slow or stop the onset and progression of Parkinson's disease (PD). These [early intervention trials](#)³ will recruit people with [biological and clinical risk factors](#)⁴ for the possible development of PD. **Participants will not have a diagnosis of PD at the time of study enrollment. They will have some biological and clinical signs that put them at higher risk for Parkinson's disease.**

Study drugs will be selected based on safety and scientific evidence that they could benefit people with early signs of Parkinson's. These drugs may include medications taken by mouth, intravenous (IV) infusions, and/or self-injection. Potential therapies will have been previously tested in other groups of people, including those with PD and without PD.

To speed scientific breakthroughs, some new therapies may be tested in a platform trial. This means two or more investigational drugs can be tested at the same time (in different groups of participants). Each study drug will have a matching [placebo](#)⁵. Participants will first be randomly assigned to a study treatment group, if there are multiple available (e.g., treatment A, treatment B). They will then be randomly assigned to receive either the active experimental drug or matching placebo in that study treatment group (e.g., drug A or placebo A). Depending on the number of treatment groups, the chances of receiving placebo may range from 25% to 50%.

Early intervention trials may ask participants to enroll for at least two years and maybe longer. They may ask participants to visit a clinical site often, at least four times a year. Additional (potentially monthly) visits may also be required to receive study medications.

The risks and potential side effects will depend on the specific study treatment. Generally, side effects will be mild to moderate and temporary. As is the case with all experimental treatments, new and unexpected side effects could be discovered with further study. Participants will be closely monitored for any side effects or negative reactions. Volunteers may withdraw from the study at any time.

Studies will test for any long-term benefits to disease progression. There is no guaranteed benefit to joining an early intervention trial.

¹ Therapeutic studies: types of clinical studies that test how treatments work in people

² Experimental treatments (also known as investigational treatments or interventions): treatments that are being tested in clinical trials for a specific disease or condition but are not yet approved for use by regulatory bodies

³ Early intervention trials: trials testing treatments (interventions) to slow or stop disease progression in people at risk of developing Parkinson's

⁴ Parkinson's risk factors include certain genetic mutations, dopamine loss, abnormal alpha-synuclein, ongoing smell loss, family history of disease

⁵ Placebo: an inactive version of the study drug that looks similar to and is given the same way as the active experimental treatment being tested