

## Understanding Inclusion and Exclusion Criteria

Inclusion and exclusion criteria help researchers find the most suitable candidates to participate in clinical trials. It is important when running a clinical trial to try and find a group of people with as similar symptoms as possible. This enables researchers running the trial to compare the results and enables them to draw conclusions.

For each clinical trial the lead researcher or Principal Investigator will identify the group of people that will best help them answer their research question. First of all they will look at how long someone has had Parkinson's, their primary symptoms, whether they are taking treatment and what that treatment is.

Then the Principal Investigator will identify a list of other things that a potential participant must have if they can be included in the study – and a list of things that would exclude a potential participant for safety reasons. These are called the inclusion and exclusion criteria and will change for each trial being designed.

An example follows:

<b>Inclusion Criteria</b>	<b>Exclusion criteria</b>
Male and female patients age 40 to 80 years old	Female patients trying to conceive
A confirmed diagnosis of Parkinson's (by DAT Scan or similar)	Other significant diseases or co-morbidities e.g. cardiac failure, renal failure, hepatic failure
Hoehn & Yahr stage I to III (the clinical measure of severity of disease)	Allergies to certain medications
Willingness to provide DNA data	Use of investigational drugs within one year prior to the start of the study
Willing and able to comply with scheduled visits and planned procedures of the trial	
Willing and able to provide informed consent	

Participants cannot join a clinical study without satisfying a study's inclusion and exclusion criteria first. The complete list of inclusion and exclusion criteria varies from study to study. To protect patient safety and yield accurate results, establishing a thorough set of inclusion and exclusion criteria allows researchers to conduct studies safely and effectively.