

Deep Brain Stimulation (DBS) in Early Stage Parkinson's Disease

Thank you for taking part in this survey. The purpose of this survey is to understand what factors people with early stage Parkinson's disease (PD) and their loved ones would consider to be important when participating in a trial like the one described on the following pages. **This survey refers to a hypothetical/pretend research study, not an actual study.**

Please read the following description of a hypothetical/pretend clinical trial testing deep brain stimulation (DBS) for patients with early stage Parkinson's disease.

What scientists know:

For patients with advanced stage Parkinson's disease (PD), deep brain stimulation (DBS) improves motor function, increases the amount of "on" time per day, and lessens the daily amount of Parkinson's medications needed.

Over 100,000 people with PD have been treated with DBS therapy, and safety is well-established. DBS surgery involves placing two thin electrodes in the brain that are connected to a device similar to a heart pacemaker, which is placed under the skin just below the collarbone. Once the surgery is complete, all components of the DBS system are inside the body, so there are no restrictions on activities such as bathing or swimming.

What scientists are hoping to test in a new clinical study:

Researchers at Vanderbilt University Medical Center plan to conduct an FDA-approved, multicenter clinical trial of DBS in early stage PD. No Parkinson's therapy has been proven to slow disease progression. However, results from a pilot study found that DBS may decrease the risk of disease progression, reduce the number of medications needed, and slow the progression of rest tremor when applied early in the course of the disease. A 2023 study suggests that refining the location where DBS is given will slow PD motor symptom progression, and the study below is designed to test this question.

In this study, each participant will be closely followed for 2 years by neurologists at academic medical centers who are experts in PD and DBS. All participants will receive a DBS implant soon after enrolling in the trial and continue PD medications throughout the study. For the 2 year study, half of the participants will have their DBS device turned on and half will have their DBS device kept off, and participants will not know if their DBS is on or off during that 2 year period. During key study visits at 3, 12, and 24 months after DBS implant, participants will stay at a hotel near the medical center and temporarily stop their PD treatment for 1 week so that careful measurements of untreated PD symptoms can be made. These visits are important to understand how PD progresses after DBS is provided. Participants will be compensated for their time throughout the study, and at the conclusion of the study, all participants will have their DBS device turned on.

Please complete the following brief survey to help us better understand how **a person with Parkinson's disease or their loved one** feels about a PD patient's participation in a study of this nature.

1. Do you currently have a diagnosis of Parkinson's disease by a physician or other health care professional?
 - a. Yes
 - b. No

Skip Logic: If (b. No) is selected, skip to "Do you identify yourself as a care partner for someone with Parkinson's disease?"

PD section

[PD inclusion (DBS=no, ≤4 years meds, dysk=no)]

2. Have you had deep brain stimulation (DBS)?
 - a. Yes
 - b. No
 - c. Not sure

Skip Logic: If (a. Yes) is selected, skip to End of Survey Thank you 1

3. Are you currently taking prescription medications for Parkinson's disease?
 - a. Yes
 - b. No
 - c. Not sure

Skip Logic: If (b. No or c. Not sure) is selected, skip to "Would you consider becoming a participant in a trial like this?"

4. How long have you been taking prescription medications for Parkinson's disease?
 - a. Less than or equal to 4 years
 - b. Greater than 4 years
 - c. Not sure

Skip Logic: If (b. Greater than 4 years) is selected, skip to End of Survey Thank you 1.

5. Do you ever have abnormal movements of your body that you can't control such as twisting, writhing, or jerking that you think are caused by your medication? You may have heard your doctor call these movements dyskinesia. (This is not referring to typical rest tremor that is often present when medications wear off.)
 - a. Yes
 - b. No
 - c. Not sure

Skip Logic: If (a. Yes) is selected, skip to End of Survey Thank you 1.

6. ***Below is an excerpt from the hypothetical/pretend clinical trial description shown in the beginning of this survey.***

What scientists are hoping to test in a new clinical study:

In this study, each participant will be closely followed for 2 years by neurologists at academic medical centers who are experts in PD and DBS. All participants will receive a DBS implant soon after enrolling in the trial and continue PD medications throughout the study. For the 2 year study, half of the participants will have their DBS device turned on and half will have their DBS device kept off, and participants will not know if their DBS is on or off during that 2 year period.

During key study visits at 3, 12, and 24 months after DBS implant, participants will stay at a hotel near the medical center and temporarily stop their PD treatment for 1 week so that careful measurements of untreated PD symptoms can be made. These visits are important to understand how PD progresses after DBS is provided. Participants will be compensated for their time throughout the study, and at the conclusion of the study, all participants will have their DBS device turned on.

Would you consider learning more about becoming a participant in a trial like this? *Please refer to the trial description above.*

- a. Yes
- b. No
- c. Not Sure

Skip Logic: If (b. No) is selected, skip to End of Survey Thank you 2.

7. Do any of the following motivations influence your interest in learning more about participating in a clinical trial like this? Please select all that apply.
- a. Progression of my PD motor symptoms may be slowed
 - b. I may be able to reduce my PD medication(s)
 - c. My PD symptoms are not adequately controlled
 - d. None of the above

Non-PD section

8. Do you identify yourself as a care partner for someone with Parkinson's disease?

A care partner is someone who regularly provides support to a person with a health condition so that they can meet their day-to-day care needs, such as through physical, emotional, or social support.

- a. Yes
- b. No
- c. Not sure

Skip Logic: If (b. No) is selected, skip to end of survey thank you 1.

9. Does the person with Parkinson's disease for whom you are a care partner meet all of the following criteria?

- Has never had deep brain stimulation (DBS) **AND**
- Is not taking PD meds or has not taken PD medications longer than four years **AND**
- Does not experience abnormal movements that they cannot control such as twisting, writhing, or jerking that are caused by their medication. You may have heard their doctor call these movements dyskinesia. (This is not referring to typical rest tremor that is often present when medications wear off.)

- a. Yes, the person with PD meets all of the above criteria
- b. No
- c. Not sure

Skip Logic: If (b. No) is selected, skip to end of survey thank you 1.

10. ***Below is an excerpt from the hypothetical/pretend clinical trial description shown in the beginning of this survey.***

What scientists are hoping to test in a new clinical study:

In this study, each participant will be closely followed for 2 years by neurologists at academic medical centers who are experts in PD and DBS. All participants will receive a DBS implant soon after enrolling in the trial and continue PD medications throughout the study. For the 2 year study, half of the participants will have their DBS device turned on and half will have their DBS device kept off, and participants will not know if their DBS is on or off during that 2 year period. During key study visits at 3, 12, and 24 months after DBS implant, participants will stay at a hotel near the medical center and temporarily stop their PD treatment for 1 week so that careful measurements of untreated PD symptoms can be made. These visits are important to understand how PD progresses after DBS is provided. Participants will be compensated for their time throughout the study, and at the conclusion of the study, all participants will have their DBS device turned on.

Would you consider supporting the person with Parkinson's in learning more about becoming a participant in a trial like this? *Please refer to the trial description above.*

- a. Yes
- b. No
- c. Not Sure

Skip Logic: If (b. No) is selected, skip to End of Survey Thank you 2.

11. Do any of the following motivations influence your support of the person with Parkinson's learning more about participating in a clinical trial like this? Please select all that apply.
- a. The progression of their PD symptoms may be slowed
 - b. They may be able to reduce their PD medication(s)
 - c. Their PD symptoms are not adequately controlled
 - d. None of the above

End of Survey thank you 1:

Thank you for participating in Fox Insight. We appreciate your interest in sharing your experiences.

Please click on the next arrow below (>>) to submit your responses and be redirected to the Fox Insight website.

End of Survey thank you 2:

Thank you for participating in Fox Insight. Your answers will help us learn more about PD research participation. **Please click on the next arrow below (>>) to submit your responses and be redirected to the Fox Insight website.**