Adaptive Neurostimulation to Restore Sleep in Parkinson's Disease (Aim 2)

NCT05070013

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of Nebraska
Enrollment	20 participants

Plain Language Summary

This study is testing whether a smart brain stimulation device (deep brain stimulation, or DBS) can be programmed to improve sleep in people with Parkinson's disease by responding in real time to brain signals during the night.

You may be eligible if...
- You are 18–80 years old and have had Parkinson's disease with motor symptoms for at least 4 years
- Your motor symptoms (tremor, stiffness, slow movement) are severe despite medication
- Your medical team has already recommended deep brain stimulation surgery
- You have no major cognitive problems or severe depression
- You are able to receive ongoing neurological care at the study site

You may NOT be eligible if...
- You have a pacemaker, cochlear implant, or other implanted electrical device
- You have had prior brain surgery
- You are pregnant
- You have a history of significant alcohol or drug abuse
- You have untreated or severe depression

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (10)

- Signed informed consent
- Diagnosis of Idiopathic Parkinson's disease (PD) with motor symptoms present for a minimum of 4 years
- Severe motor symptoms (e.g., motor fluctuations, dyskinesia, tremor, bradykinesia, rigidity) despite optimized medical therapy, that warrant surgical implantation of deep brain stimulation (DBS), according to standard clinical criteria
- Unified Parkinson's Disease Rating Scale (UPDRS-III) score off medication 20 to 80, and improvement of at least 30% in UPDRS-III score on medications, or tremor-dominant PD (score \>/= 2 on UPDRS-III tremor sub-score) or tremor in addition to other motor symptoms that are treatment-resistant and result in significant functional disability
- Appropriate trials of oral PD medications resulting in inadequate relief of motor symptoms as determined by a movement disorders neurologist, and stable dose of anti-PD medications for 30 days prior to study enrollment

... and 5 more (see full listing online)

Exclusion (12)

- Any medical condition considered to elevate risk for surgical complications, such as coagulopathy,, uncontrolled hypertension, history of seizures, heart disease, inability to undergo general anesthesia, or anticoagulant medications that cannot be safely discontinued for perioperative period
- Pregnancy (women of child-bearing potential must have a negative urine pregnancy test prior to surgical procedures)
- Significant untreated depression (Beck Depression Inventory-II, BDI-II \> 20 or Geriatric Depression Scale, GDS, score \> 8)

• Personality or mood disorder symptoms that investigators believe will interfere with study requirements

• Required ongoing treatment with electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), or diathermy

... and 7 more (see full listing online)

Locations (2 total)

University of Nebraska Medical Center, Omaha, Nebraska, United States
University of Pennsylvania Health System, Philadelphia, Pennsylvania, United States