

Bilateral Closed Loop Deep Brain Stimulation for Freezing of Gait Using Neural and
Kinematic Feedback

SAP

NCT04043403

December 11, 2024

Statistical design and power

Our previous data revealed that 13/15 (~87%) freezers had at least one freezing episode during the SIP task (mean number of freezes = 4.9, STD = +/- 2.5)¹⁹. Previous studies found an average of 66% improvement in freezing metrics between ineffective and effective stimulation conditions^{48,53}. A power analysis (paired t-test) using the mean number of freezes with ineffective/NO DBS (4.9, STD = +/- 2.5, from above) and a 65% improvement from effective stimulation shows that the smallest sample size required for significant outcomes is 9 subjects with freezing during SIP (alpha=0.05, power=0.8, assuming only 87% of patients will freeze during tasks). Higher gait arrhythmicity has been found to distinguish PD freezers from PD non- freezers^{25,52}. A power analysis (paired t-test) using the improvements in gait arrhythmicity (21.54, STD = +/- 24.52 unpublished) from OFF DBS to effective neurostimulation in 9 PD freezers during the SIP task shows that the largest sample size required for significant outcomes is 12 subjects during stepping without freezing in SIP (alpha =0.05, power =0.8).

A linear mixed effects model will be run for each variable and used to compare gait arrhythmicity, percent of time freezing, shank angular velocity, UPDRS-III, quantitative measures of bradykinesia/tremor and number/frequency of adverse events, and questionnaire sub-scores. Linear mixed effects models will be used to compare number and duration of freezing episodes between conditions per each task.