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Title of Protocol: The effect of MINGO (rice, mongo, moringa) as a nutritional supplement in patients with X-Linked Dystonia Parkinsonism (XDP) in Capiz, Philippines

Protocol Number: NCT03019458

Principal Investigator: Criscely Go, M.D.

Co-Investigators: None

Study Staff: MDSP members in the Philippines; Other healthcare providers and office staff, Sunshine Care Foundation staff and community advocates (CAs)

A linear mixed effects model will be used to determine if Mingo supplementation on top of regular diet would increase the BMI of XDP patients compared to regular diet alone. Baseline BMI, BFM scores, Eat 10 scores, and MGH SST scores, as fixed and random effects, will be incorporated into the model to adjust for their potential confounding effects. Data will be encoded in MS Excel 2007 and analyzed in R version 3.4.1, and using RStudio IDE, Version 1.0.153. All data will be analyzed by intention to treat.

Since this is a rare disease with a predefined number of 50, the study plans to have an acceptable power of 80% with the given limitation of 24 for the MINGO arm and 26 for the Control at the alpha level = 0.05. To achieve this power, we need to show an effect size of 2.23. The USCF Clinical and Translational Science Institute sample size calculator was used to find the effect size.