A Sneak Peak at the Development and Validation of a New PD Psychosis Scale: A Collaboration Between the MDS and 10 NPF Centers of Excellence

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Overview of the Project

• Psychotic symptoms are a frequent occurrence in PD, affecting up to 50% of patients often resulting in devastating social consequences. It is a poor prognosticator for morbidity and mortality in PD.

•The Movement Disorders Society commissioned a Task Force (Fernandez HH, Chair) to critique all available psychosis scales previously used in PD psychosis studies. Of the 12 psychosis scales critiqued by the Task Force none adequately captures the entire phenomenology of PD psychosis. None of the current scales contained all the basic content, mechanistic and psychometric properties needed to capture PD psychotic phenomena and to measure clinical response over time. Therefore, the committee recommended the development of a new PD psychosis scale.

•Given this, in collaboration with the Movement Disorders Society, we partnered with the NPF and its Centers of Excellence to develop a comprehensive, clinician-rated scale for psychotic symptoms in patients with PD.

•This project will represent an international, collaborative effort between organizations and several Parkinson Centers with the University of Florida NPF COE serving as the Coordination Center.

•Psychometric questions to be evaluated include the reliability of the scale (i.e., inter-rater, test-retest, and internal consistency) as well as its validity (i.e., convergent, divergent, factorial). This measure will have positive benefits with regards to symptom assessment, as well as assessing treatment response to pharmacological medications targeting these symptoms.

Methods

• A total of 120 PD patients with- and 60 PD patients without psychotic symptoms will be enrolled. 10 NPF COE sites will participate in this study, each collecting data from 18 patients (12 with psychotic symptoms, 6 without).

•The sample is anticipated to have an approximately even gender distribution and represent ethnicities characteristic of the respective catchment areas of each NPF COEs. Subjects must meet UK PD Brain Bank criteria for idiopathic PD. We will stratify for age at each center such that 50% of subjects will be above 70 years. As well, we will stratify for Hoehn and Yahr Stage to insure that we are adequately sampling illness severity. Only patients able to provide informed consent will be included. Concurrent treatment for psychiatric symptoms will not be an exclusion criterion.

•This grant will take a total of 2 years.

Scale Development

•***Initial Scale Development.*** A Writing Committee was formed. This committee is comprised of 7 members who are neurologists, psychiatrists and psychologists with expertise and interest in PD psychosis, and a statistician. The scale will be a clinician-rated measure that incorporates information from the patient, relevant caregivers, clinician judgment, and behavioral observation.

•***Preliminary Feedback from Patients***. The first scale version will be adminstered to a small sample of patients with psychosis and their caregivers to refine and focus questions as needed. This will be a qualitative process designed to improve the quality of the measure and ensure readability and comprehension of items by patients.

•***Informal Feedback and Discussion.*** The next step will be to circulate the draft instrument among The Steering Committee of the MDS Task Force on Rating Scales--an international group of expert neurologists, psychiatrists, and psychologists who will be asked to comment on: (a) content validity; (b) comprehensiveness; (c) overlap with other constructs, and (d) readability and clarity.

•"***Modified" Delphi Procedure***. Further content validation will be conducted via the Delphi technique (Adler & Ziglio, 1996) prior to the large scale clinical testing. The Delphi technique uses a highly structured and focused questionnaire approach to establish a consensus opinion among experts. The technique overcomes the disadvantages of conventional committee action (e.g., censored feedback) by allowing experts to provide relatively anonymous feedback in the context of measurement development.

•*Pragmatic assessment of the proposed scale*. After the 'final' PD psychosis scale has been developed, we will conduct "cognitive testing" (an assessment of scale pragmatics) to examine how individual items are interpreted/understood by patients. We will recruit a total of 30 patients distributed across participating NPF COEs.

•***Scale Validation.*** 10 NPF COEs will participate in the validation of the new scale.. Each participating NPF Center will have a target recruitment of 12 subjects with PD psychosis and 6 PD controls (i.e., not exhibiting psychotic symptoms) for a total of 120 cases and 60 controls. We will stratify for age and H & Y stage at each cohort. We decided against stratifying for cognitive level given the recruitment concerns associated with stratifying for a third variable, as well as the limited resources we will have in comprehensively assessing.

Participating Centers

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