Title: The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson

Disease PI: Kyle Mitchell, M.D.

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## Research Summary

**State your primary study objectives**

The purpose of this study is to determine if a "one stop" interdisciplinary benchmark clinic model impacts patient engagement with self-care (primary outcome), treatment compliance, caregiver burden, and/or clinical outcomes (falls, ER visits/hospitalizations, Parkinson's disease motor disability) compared to standard subspecialty care.

**State your secondary study objectives**

To develop a single-day comprehensive care clinic for people with Parkinson's disease, to address care fragmentation, increase patient engagement, and improve outcomes.

Travel burden and schedule limitations prevent patients from reaching all necessary skilled therapists with training in PD and may negatively impact long term outcomes and engagement with treatment plans.

**Please select your research summary form:**

Standard Research Summary Template

This is the regular (generic) research summary template which is required for all regular applications (unless your protocol fits under the other research summary templates in this category). Use of these instructions is helpful for ensuring that the research summary contains all necessary elements.

## Standard Research Summary

**Purpose of the Study**

- Objectives & hypotheses to be tested

Does a "one stop" interdisciplinary benchmark clinic model impact patient engagement with self-care (primary outcome), treatment compliance, caregiver burden, and/or clinical outcomes (falls, ER visits /hospitalizations, Parkinson's disease motor disability) compared to standard subspecialty care?

## Background & Significance

- Should support the scientific aims of the research

Parkinson's disease (PD) management is complex, and medication management alone is not sufficient. Non-motor complaints are often more disabling than motor symptoms. Neurologists are time-limited in their ability to address all aspects of this disease. An interdisciplinary clinic provides comprehensive exposure to allied health professionals and immediate interventions, which are already established as helpful individually (e.g. physical therapy for falls prevention, speech therapy for aspiration prevention). Travel burden and schedule limitations prevent patients from reaching all necessary skilled therapists with training in PD and may negatively impact long term outcomes and engagement with treatment plans.

Published studies of interdisciplinary clinics to date have an expert center and community referral model: 1. see neurologist 2. Get referrals to needed allied health specialties for a later date. This so-called "hub-and-spoke" care model in the Netherlands improved outcomes and lowered cost [1] but developing a similar network is challenging in the United States, where geographic distance and competing hospital networks may fragment care.

We developed a single-day comprehensive care clinic for people with Parkinson's disease, to address care fragmentation, increase patient engagement, and improve outcomes. Patients are evaluated by social work, physical therapy, occupational therapy, speech therapy, pharmacy, and a physician's assistant in a scheduled rotation. After these evaluations, the team meets with the physician movement disorders specialist for a team discussion of care needs. Following this meeting, the physician meets with the patient to summarize the results and discuss ongoing care needs. The benchmark day lasts from around 8AM-1:30 PM with a built in 45 minutes for lunch from 12:15-1PM.

REFERENCE: [1] Bloem et al. Health Affairs 2017.

## Design & Procedures

- Describe the study, providing detail regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

- **Visit 1**: 0-3 months before benchmark clinic surveys on day of consent: approximately 30 minutes. Physical exam with Parkinson's disease motor disability score as part of normal clinic visit that day. Participants will be randomized on a 1:1 basis to experimental vs control groups after consenting and prior to the start of this study visit. Subjects will complete the pre-clinic quality of life, treatment adherence, and self-efficacy surveys at this visit.
- **Visit 2**: Benchmark clinic from 8AM-1:30PM: Patients see social work, physical therapy, occupational therapy, speech therapy, and pharmacy in a scheduled rotation for about 45 minutes each. Social work and pharmacy visits may be done earlier in the week depending on provider and patient availability**.** After these evaluations, the team meets with the physician movement disorders specialist for a team discussion of care needs. Following this meeting, the physician meets with the patient to summarize the results and discuss ongoing needs and action items and enter appropriate referrals and orders. The benchmark day lasts from around 8AM-1:30 PM with a built in 45 minutes for lunch from 12:15-1PM.

- **Visit 3**: 3-6 months Follow up study point surveys: approximately 30 minutes. The control group will not participate in the benchmark clinic (Visit 2) and instead, their physician movement disorders specialist will make allied health referrals as part standard clinical care during a physician visit on the same day as study visit 2. They will still complete visit 3.

The control group will not participate in the benchmark clinic (Visit 2) and instead, their physician movement disorders specialist will make allied health referrals as part standard clinical care during a physician visit on the same day as study visit 1. They will still complete visit 3.

**Selection of Subjects**

- List inclusion/exclusion criteria and how subjects will be identified.

Subjects will be from the patient population with Parkinson's Disease over the age of 30. Caregivers will be required for participation. All subjects must be able to provide consent. Subjects will be contacted first with the phone script by a study email address.

**Subject Recruitment and Compensation**

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

This study will be discussed with Parkinson's Disease patients when considering referring them to our already established benchmark clinic. All patients already scheduled for an upcoming benchmark clinic will be called or emailed to see if they would like to enroll.
Patients who are randomized to standard care will have the opportunity to participate in the benchmark clinic within 1 year but not as part of this study. 200 subjects will be enrolled (100 benchmark clinic and 100 controls for standard of care). Payment of the subject will be upon completion of visit 2 (the benchmark visit or standard visit)

**Subject's Capacity to Give Legally Effective Consent**

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

Subjects with diminished capacity will not be consented.

**Study Interventions**

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

There are no study interventions.

**Risk/Benefit Assessment**

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

There are no physical risks associated with this study. Comprehensive interdisciplinary care may help with the subjects engagement with Parkinson's treatment, prevent falls, help with swallowing safety, improve voice volume, and improve their ability to care for themselves.

**Costs to the Subject**

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

Subjects or their insurance provider will be responsible and billed for all costs related to your routine medical care, including co-payments and deductibles.

**Data Analysis & Statistical Considerations**

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

The primary outcome is change in composite score on the self-efficacy scale. We will compare within subject change in score and differences in changes between control and experimental groups using repeated measures ANOVA.

Power calculations were performed using the published mean and SD for the self-efficacy scale. 73 participants per arm (control/experimental) for a total of 146 participants provides an 80% power to detect a 1 point change, which is felt to be a minimal clinically relevant change. We plan to recruit 100 participants per arm to account for any dropout. The maximum possible capacity of our benchmark clinic is 250 people per year for logistical/scheduling reasons so our sample size was chosen as a realistic number given our power calculation, total capacity, and expected interest of participants.

Secondary outcomes include change in total weekly minutes exercised, change in "engagement score" from the patient engagement survey (Likert scale 1-5 choices converted to 0, 25, 50, 75, and 100 to calculate composite engagement score as a mean of all Likert scale items), and change in Zarit (caregiver burden score). We will also compare total amount of skilled therapy visits, hospitalizations and ER visits, falls, and number of contraindicated medication combinations between the groups. All of these analyses will also be done using repeated measures ANOVA.

Subgroup analyses for the above outcomes will be performed using MOCA as a measure of baseline cognitive status and MDS-UPDRS as a measure of baseline disease severity both performed as linear regressions.

All enrolled subjects who complete the study visits will be included for analysis. Eligibility requirements are minimal (only need a diagnosis of Parkinson's disease) and those who do not have a diagnosis of Parkinson' s disease will not be approached for this study, so we do not anticipate a significant number of ineligible

participants/screen failures. If for an unforeseen reason a participant is felt to not have a diagnosis of Parkinson's disease by a movement disorders specialist after enrollment, they will be removed from the study.

Estimated time to target accrual is 1 year with an accrual rate of 9 participants per arm per month.

RedCap and Duke Box will be used for data storage. A key will be used to link unique identifiers to participants responses.  The key will be used to track completion of longitudinal data, as well as to query Duke Health medical records for health utilization (e.g. ED visits) as a secondary study outcome. The file connecting Study ID with Duke MRN will be encrypted and stored on the Duke Movement Disorders secure folder on the neurology private drive and will be password-protected. Only the study investigators will have access to this file.