PROTOCOL

Title: PPMI Mapping Meaningful Symptoms and Impacts in People with Prodromal Parkinson's Disease (PPMI Mapping Symptoms)

Sponsor: Michael J. Fox Foundation for Parkinson's Research

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PPMI Mapping Meaningful Symptoms and Impacts in People with Prodromal Parkinson's Disease (PPMI Mapping Symptoms)

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1. PURPOSE OF STUDY

The Parkinson Progression Marker Initiative (PPMI) is a broad program consisting of the primary in-clinic study (PPMI Clinical), as well as other complementary initiatives conducted under the program that will contribute to PPMI's overarching goal to identify markers of disease progression for use in clinical trials of therapies to reduce progression of PD disability.

The purpose of this study is to conduct an observational, non-interventional, qualitative interview study in individuals with prodromal Parkinson's disease/ Dementia with Lewy bodies (DLB) and controls in order to evaluate potential symptoms and/or impacts of prodromal PD/DLB and ultimately help inform clinical outcome assessment development in this stage of disease.

1.1 Primary Objectives

To evaluate patient-perceived potential symptoms of prodromal PD/DLB that are meaningful and personal impacts of symptoms, if any. This cross-sectional study will:

(A) Identify and characterize potential symptoms of earliest PD/DLB. Potential symptoms are defined as any changes from personal normal/baseline in the past 5 years;
(B) Evaluate personal meaningfulness of symptoms with classification of present/bothersome vs. important; and
(C) Explore actual and anticipated functional and psychological impacts of potential symptoms.

2. STUDY OUTCOMES

This study aims to identify potential symptoms and impacts of prodromal Parkinson's disease that are perceived as meaningful by participants. To achieve this, symptoms and impacts from the Prodromal PD/DLB cohort will be compared with case matched controls to see if statistically significant differences exist in the reported symptoms and impacts between these two groups.

3. BACKGROUND AND RATIONALE

Parkinson's disease (PD) and Dementia with Lewy bodies (DLB) are devastating neurodegenerative disease and current therapies have shown limited ability to prevent or delay disease progression.[1] One challenge in the development of new treatments has been an inability to monitor PD/DLB with enough precision to evaluate early treatment efficacy.[2,3] Current clinical outcome measures (COAs) do not perform well in early PD/ DLB and there is an urgent need for novel COAs based on items that are clinically meaningful to patients. Actionable qualitative data can guide COA development and establish clinical meaningfulness. New symptom mapping methodology developed in the WATCH-PD study offers the ability to capture qualitative/quantitative data simultaneously using a hybrid data collection approach that bridges the gap between pure qualitative and pure quantitative data. These methods will be used to identify meaningful symptoms and impacts in this study cohort and compare to controls.

4. STUDY DESIGN

This is an observational, non-interventional, qualitative interview study. Participants from the PPMI study found to be eligible will be invited to participate in this study. Participants who consent will be asked to complete an online questionnaire quantitatively and qualitatively evaluating individual PD experiences and a follow up online interview exploring these experiences in depth.

5. STUDY POPULATION

This study will include people with and without prodromal PD/DLB who are also participating in PPMI. We expect to enroll up to 100 participants, approximately 40-50 with prodromal PD/DLB and 40-50 healthy controls (no neurologic disorder and no first-degree relative with PD).

6. RECRUITMENT METHODS

Participants enrolled in the PPMI Clinical study will be invited to participate in this study via an email

7. PARTICIPANT ELIGIBILITY

Participants will be eligible for inclusion in this study if they meet all the following criteria.

7.1 Inclusion Criteria

Group A – Prodromal PD/ DLB

1. Enrolled in PPMI Clinical study Prodromal cohort and meets any of centrally determined predictive criteria associated with risk of PD/DLB, such as RBD, hyposmia, dopamine deficit, and alpha-synuclein pathology.
2. Male or female age 60 years or older.
3. Able to provide informed consent.
4. English speaking.
5. Able to participate in Zoom online interview via computer or tablet.

Group B – Control group

1. Enrolled in PPMI Clinical study Healthy Control cohort (no neurologic disorder and no first-degree relative with PD) or control participants outside of the PPMI study
2. Male or female age 60 years or older.
3. Able to provide informed consent.
4. English speaking
5. **Case matched** to Group A on basis of approximate age, gender, country of residence, co-morbidities, and race/ethnicity.
6. Able to participate in Zoom online interview via computer or tablet.

7.2 Exclusion Criteria

– Group A - Prodromal PD/DLD

1. No exclusion criteria for this study.

– Group B - Control Group

1. Significant neurologic or psychiatric disease as determined by the study team

8. OBTAINING INFORMED CONSENT

Eligible participants enrolled in PPMI Clinical study will be invited to participate in this PPMI Mapping Symptoms Study via the RSRB approved email. The email will briefly describe this study and provide contact information for someone from the study team. Participants who after speaking with the coordinator appear eligible will be invited to participate in this study. The participants will be sent an eConsent form and scheduled for an interview with the study investigators.

The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g., read only, de-identified-only data views) for other users. Potential participants will participate in the consent process via an eConsent, obtained remotely with a remote consent process, and accessible on personal electronic devices such as computer, portable tablets, and smartphones.

During the remote consent process, the study team will request verbal permission to send the eConsent via email. The request will state: “Because URMC can’t control the security of email once we send it, we need your permission to email you. Do you want to receive the link to the eConsent via email?” The permission will be documented. The email will not include PHI.

The identity of participants will be verified to ensure that the person electronically signing the informed consent is the participant who will be participating in the research study. Study coordinators will provide each participant with a unique passcode, either in person or through a phone call or zoom meeting. This passcode will be saved as part of the participant’s research record. At the time of accessing the eConsent, the participant must enter their assigned passcode. Matching passcode responses will grant entry to the eConsent, while non-matching responses will block an individual from accessing the eConsent.

As part of the eConsent document, potential participants will be provided with the contact information for a study team member in the event that they have any study-related questions. The procedures and requirements of the study, together with any potential hazards/risks, and the freedom to withdraw from participation in the study at any time, will be detailed to each potential participant as part of the consent process.) for their records.

Participant signatures will be obtained using a typed signature. Once the consent form is signed and submitted, participants will be able to receive a print out of the paper copy, download a PDF, and/or receive an email with a PDF attachment of the signed consent form. The study coordinator will electronically record in REDCap that consent has been verified.

A copy of the signed consent form will be required before any study activities can begin and a signed copy will be provided to the participant for his or her records.

9. PARTICIPANT ID ASSIGNMENT

All participants will use their assigned PPMI study ID. The PPMI Participant ID number will be used to identify a participant on all study related documentation, but will be redacted from maps sent to participants.

10. STUDY PROCEDURES

Data collection will consist of a pre-interview survey via Redcap followed by a 1:1 online interview via Zoom video conferencing. Participants who are interested in the study will speak with the study coordinator and complete the eConsent before the pre-interview survey will be sent out to participants. The pre-interview survey will be sent out about one week prior to the online interview. Items identified in the survey will be used to pre-populate the symptom map to facilitate discussion in the online interview.

The survey will include the following:

1. **CURRENT DEMOGRAPHICS** including age, employment status, gender, race/ethnicity, country, current medications, current health diagnoses.
2. **OPEN RESPONSE** items to identify any persistent or recurrent changes from normal the participant has experienced in the past 5 years; and
3. **MULTIPLE SELECT** items to identify if the participant experienced any common symptoms of Parkinson's; and
4. **PERSONAL RATING** of current health.

Items for #3 will be derived from recent literature and the consensus conceptual model, which has been conducted to identify the most common symptoms of early Parkinson's.

Interview

The interview will be conducted by trained researchers (Neurology Fellows/NPs) and will use symptom mapping to explore any changes from normal (defined as the individual's self-perceived usual baseline), with a focus on changes occurring in the past 5 years. Symptom mapping is a novel qualitative interviewing technique that allows the participant and researcher to co-create a visual symptom hierarchy for each participant.[4-6] As shown in Figure 1, participants in the online interview will be assisted to create a visual map of their personal symptom experiences, with all symptoms hierarchically ordered from most to least bothersome. They will discuss specifically what about each symptom is important and how it impacts them. If not mentioned spontaneously, participants will be probed on specific symptoms common to PD. People with Prodromal PD and controls will both receive the same interview and Interviewers will be blinded to group. To minimize bias, participants will be asked to describe all changes from normal in the past five years, regardless of whether they feel it is a symptom of Parkinson's or not.

Devices/Technology Requirements

All participants will need to have access to a Computer with Zoom, camera and microphone capabilities for video conferencing. For patients without a computer, a tablet or smartphone may be used for the online interview.

Duration
The interview is expected to take approximately 90 minutes based on prior studies. Participants will be offered a break mid-way and as needed to reduce fatigue.

Interview Protocol
The interview will be conducted as follows:

1. **IDENTIFY AND DESCRIBE SYMPTOMS (SPONTANEOUS).** Participants will be asked to identify **all changes from personal normal, in particular those occurring** in the past 5 years. Symptoms that are most likely not a PD symptom may be attributed to a specific health condition the participant has in the map. Participants will be asked to identify approximately when they thing the symptom started.
2. **IDENTIFY AND DESCRIBE IMPACTS OF SYMPTOMS (SPONTANEOUS).** Next, participants will be asked to explain in what ways they are affected by the symptoms they have described. This step may occur contiguously with step one.
3. **PROBE FOR COMMON PD/ DLB SYMPTOMS (PROBED)**. Next, participants will be asked to consider any common symptoms of Parkinson's disease that we're not spontaneously mentioned, and to identify if these are present or not. Symptoms to be probed will be derived from review of the literature in early PD populations and top symptoms identified through a conceptual model. (**Table 1**).
4. **RANK CURRENT BOTHERSOMENESS OF THE SYMPTOM**. After identifying and describing all changes from normal, participants will be asked to rank symptoms by presence and bothersomeness.
5. **RATE PERSONAL IMPORTANCE OF THE SYMPTOM**. Lastly, participants will be asked to rate each symptom based on how important it is to them, regardless of how bothersome it may be at present. RATING: (0=not important; 1=less important; 2=moderately important; 3=very important, as shown on the next page.

Copies of maps (PDF) may be returned to participants if desired via email.

11. RISKS TO PARTICIPANTS

The most common risk associated with web-based cognitive data collection is that study participants may feel anxious about completing the study tasks. It is possible, although unlikely, that some people may experience discomfort with revealing personal thoughts and behaviors relating to their possible PD/DLB diagnosis, PD/DLB symptoms and/or feelings about the PPMI study. Participants also might feel interview fatigue due to the length of the interview. There is a risk of disclosure of private information by participating in this study. However, safeguards are in place to reduce the risk of this happening. In addition, participants are provided with a link to the privacy policy which further describes how their study information is kept private. Data will be securely transferred between the study team and PPMI cores (designated study teams who collect, store, and handle study information) for the required workflows under the PPMI program. Any study data that is made available to

researchers external to PPMI will be coded and will not contain identifiers. While every effort will be made to maintain confidentiality, there is a small risk that information may be disclosed. There may be other privacy risks that the study team may not have foreseen.

Breach of confidentiality. Measures to protect privacy and confidentiality include:

- **Data storage**: Electronic and digital data including data files, audio and video files, transcribed interviews, and data management files (e.g., MS WORD, SPSS, and ATLAS.ti or Nvivo files, CSV) will be stored on the primary-investigator and co-investigator's computer and the University of Rochester secure shared drive and BOX account. BOX is an online data repository, which is HIPPA compliant and secure per UR policies for storing protected health information. These are password protected and only available to study personnel. Audio files and video files will not be destroyed at the completion of the project and may be used for educational purposes. De-identified transcripts and analysis records will be kept indefinitely. Printed materials (e.g., print versions of study questionnaires, or written artifacts from interviews or focus groups) will be kept in locked offices located at the University of Rochester and University of Massachusetts at Dartmouth. Consent forms, receipts, printed transcripts and field notes will be stored in separate locked, file cabinets to further reduce the risk of identifying participants.
- **De-identification of data**: Each participant will maintain the unique study identifier that was provided by the PPMI study team when the participant enrolled in this study. The paper linking the participant's name to their study identifier will be kept on a separate sheet of paper, which will be stored in a locked file cabinet in the Center for Health + Technology. A dataset containing identifiable information will be maintained separately from other study data. This data set will not contain the unique study identifier. The numeric identifier will be used instead of names on all study materials, with the exception of the consent forms and contact information. After completion of the study, transcription of interview data via the U of R approved vendor Landmark, and conclusion of analysis, any linking identifiers for the participant to their study I.D. will be removed and links destroyed, thus eliminating the ability to link participant identity to study data. Use of demographic descriptions of the sample population, and quotations included in the final report, will be done in a manner that does not place participants at risk for identification.
- **Protection of privacy in virtual visits:** Participants will be instructed in the consent form to avoid conducting virtual visits in locations where their personal privacy could be compromised, or conversation overheard. Zoom technology uses internal end-to-end encryption that protects transmitted digital data.
- **Protection of privacy in emails and text-messages:** links to the Zoom meetings will be sent via text or personal email. These messages will not contain PHI, but will indicate date and time of visit with a link to the meeting.

Embarrassment. Participants may choose not to answer questions or stop the interview at any point.

Interview fatigue. Potential fatigue during interviews will be addressed by making participants aware at the start of the interview that fatigue may occur, and that they can take a break or stop at any point.

Confidentiality of interviews: All information revealed by participants during interviews will be kept confidential, excluding the following: suicidal/homicidal ideation, threat of harm to self or others, and suspected or witnessed abuse, which will be reported via 911 to emergency services.

12. POTENTIAL BENEFITS TO PARTICIPANTS

There are no direct anticipated benefits to study participants in this study. However, new information may be generated by the study that will support development of better treatments for Parkinson's disease. Participants will be offered copies of their personal symptom maps as a form of reciprocity. The deidentified maps will be shared with participants via email.

13. COSTS FOR PARTICIPATION

There will be no cost to the study participant for participating in this study.

14. PAYMENT FOR PARTICIPATION

Participants who complete the 1:1 interview will receive $100 dollars for their time.

For this study, we will use a participant payment system called Participant Payments. The system allows three ways to provide payment. Participants can choose: a reloadable debit card; direct deposit; or mailed paper checks. The study team will help participants create a "participant profile" in the system. In order to provide payment, a participant will need to enter his or her name and date of birth into his or her participant profile. Depending on which payment method he or she chooses, an email address and banking information may also be needed. If a participant already has an Advarra account (because he or she is in another study that uses this system), his or her existing profile will be used to provide payment.

15. PARTICPANT WITHDRAWALS

Study participants will be informed during the consent process that they have the right to withdraw from the study at any time without prejudice and may be withdrawn at the Investigator's or Sponsor's discretion at any time. Any information that has already been collected prior to the study participant's withdrawal will not be removed.

16. ADVERSE EVENTS

There will be no adverse event reporting as part of this web-based interview study. All data collected as part of this study are for research purposes only and not for clinical care purposes. There will not be any routine medical monitoring of the data collected nor any reports run looking at trends and/or worsening of a participant's condition requiring medical intervention.

17. PRIVACY AND CONFIDENTIALITY

The privacy of participants will be protected in that each person will have the option to voluntarily choose whether to participate in this study. The information being collected will be outlined during the consent process.

18. DATA AND SAMPLE SHARING AND STORAGE FOR FUTURE USE

Additional data collected for this study will be maintained and stored indefinitely at the University of Rochester and University of Massachusetts at Dartmouth on secure, password protected systems. All study information will be accessed only by those who require access as pertains to the individual's role on the study. All organizations responsible for data storage and review will observe the highest precautions to ensure data integrity and security.

Data collected for this study may be transferred and shared across participating PPMI Cores including the Site Management Core at the Institute for Neurodegenerative Disorders (New Haven, CT), and the Statistical Core at the University of Iowa (Iowa City, IA) for conducting analyses as pertains to the study including, but not limited to, enrollment, compliance, study outcomes and, in combination from the data received from other PPMI Program related studies, to enable modifications to the predictive prodromal eligibility criteria. All PPMI data will be incorporated into the PPMI database to create a fully harmonized PPMI database.

Data obtained during the conduct of this study will be sent by the CTCC to the Laboratory of Neuro Imaging (LONI) in Los Angeles, California to be stored indefinitely for research purposes as outlined in the data transfer agreement. Research data will be made available to researchers to conduct analyses related to PD and other disorders. Researchers will be required to comply with the PPMI data agreement to receive data. All personally identifiable information will be removed before it is shared outside the study.

19. ANALYSIS PLAN

Interviews (approximately 40-50 per group) will be audio/video recorded and transcribed. All 1:1 interviews will be audio/video recorded and transcribed verbatim.[7] Verified interview transcripts and qualitative survey data will be entered into NVIVO or comparable QDA software. Interview and survey data will be analyzed using descriptive and content analysis techniques.[8] A codebook will be developed inductively and iteratively to provide consistency to the coding. Cognitive interviews, symptom maps, and qualitative survey responses will be coded by trained research assistants/interviewers under supervision and guidance from Dr. Mammen. In compliance with new FDA guidelines for rigor in qualitative research, two coders will be used during content coding to verify symptom/impact frequencies and bothersomeness scoring. For interviews, the unit of analysis will be approximate sentences.[9] Where incomplete sentences existed, data will be coded at the level of meaningful phrases or speaker turn. Analysis of data will be contiguous with data collection.

Primary Analytic Goals

Goals will be to (1) identify and quantify symptoms and aspects that are important to people with and without prodromal PD/DLB; (2) identify and quantify impact of symptoms on activities of living and daily functioning (3) to identify any statistically significant between group differences or patterns of symptoms between Prodromal PD/DLB and HC; and (4) Evaluate for themes in narratives that contribute to understanding what makes symptoms meaningful from the patient perspective (irrespective of prodromal PD status).

Secondary analysis goals

To correlate symptoms maps with the biological characteristics of the participants, specifically Neuronal Synuclein Disease (NSD) and NSD integrated staging system (NSD-ISS).

Coding of Maps
Symptoms in maps will be coded using the following Likert scale:

4 = Symptom is present & **MOST bothersome** to me
3 = Symptom is present & **SOMEWHAT bothersome** to me
2 = Symptom is Present & **LESS bothersome** to me
1 = Symptom is Present *but* **NOT bothersome** to me
0 = Symptom is **NOT Present** *but* still important to monitor
88 = Symptom is **NOT important** to me
99 or "." = Symptom is not mentioned

Qualitative: Content coding of symptoms maps will be used to identify types, characteristics, and bothersomeness of meaningful symptoms and impacts. Thematic analysis of narratives will be used to identify important or recurring ideas, common experiences and perceptions of symptoms and impacts, or contributing factors. Coding of maps will be conducted in four phases: (1) Open coding to develop a comprehensive list of symptoms; (2) Re-coding using the derived symptom checklist, in which symptoms are indicated as not present using "." or present and meaningful by PRS score (PRSS; range 0-4); (3) Open coding to develop a comprehensive list of impacts; (4) Re-coding with derived list of impacts as for #2, but with impact indicated as present or not present.

Quantitative: Chi-square tests will be used to evaluate between group differences in prevalence of symptoms and impacts. Analyses adjusting for potential covariates (e.g. demographic characteristics, current health status) based on logistic regression modeling will be considered exploratory. Any missing data is expected to be minimal and analyses using actual responses with no imputation of missing data is planned.

Coding of Transcripts
Thematic analysis of transcripts will be conducted. For interviews, the unit of analysis will be approximate sentences. Where incomplete sentences existed, data will be coded at the level of meaningful phrases or speaker turn. Coding of interviews will include: (1) Open and *in vivo* coding of interviews to identify recurrent concepts and ideas; and (2) Pattern coding to develop overarching themes and thematic structure.[8,10] Analysis will focus on identifying common ideas that explain what makes symptoms meaningful to patients, irrespective of prodromal PD/DLB status.

Expected Analytic Output
Outputs from analysis will include (1) a table of symptom frequencies for Prodromal PD/ DLB group versus control group; (2) a similar table for impacts; (3) statistical significance of between group differences; and (4) table of Themes identified from analysis of narrative with supporting quotes.

Rigor and Validity
We will use the following strategies to minimize bias and promote transparency: (1) member checking during interviews and verifying interpretations with subsequent participants, (2) search for discrepant evidence, (3) peer debriefing and feedback, (4) use of reflexive memos,

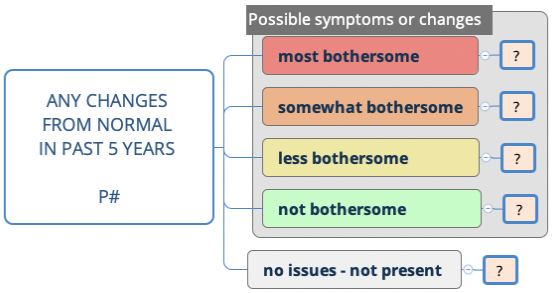
and (5) maintaining an analytic audit trail.[11] All findings and interpretations will be iteratively reviewed and refined with Dr. Adams and Dr. Mammen.

Feasibility

PPMI will provide a large database of potential participants for the planned study and will assist with identifying case matched controls. Total per participant time is estimated at <3 hours. Technology requirements are minimal and prior work demonstrates that the approach is feasible and well-received by participants.

20. SUPPORTING FIGURES

Step 1 & 2: Map any changes from personal normal in past 5 years



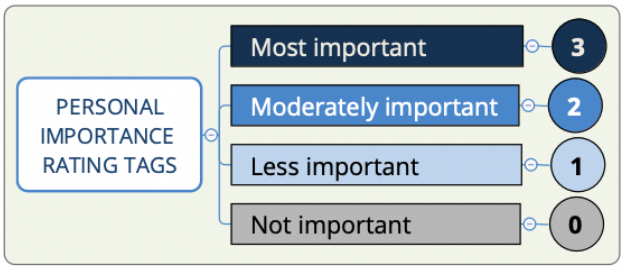
Label	Value
Most bothersome	4
Somewhat bothersome	3
Less bothersome	2
Not bothersome	1
No issue – not present	0

Step 3: Integrate possible symptoms of PD/DLB not spontaneously mentioned

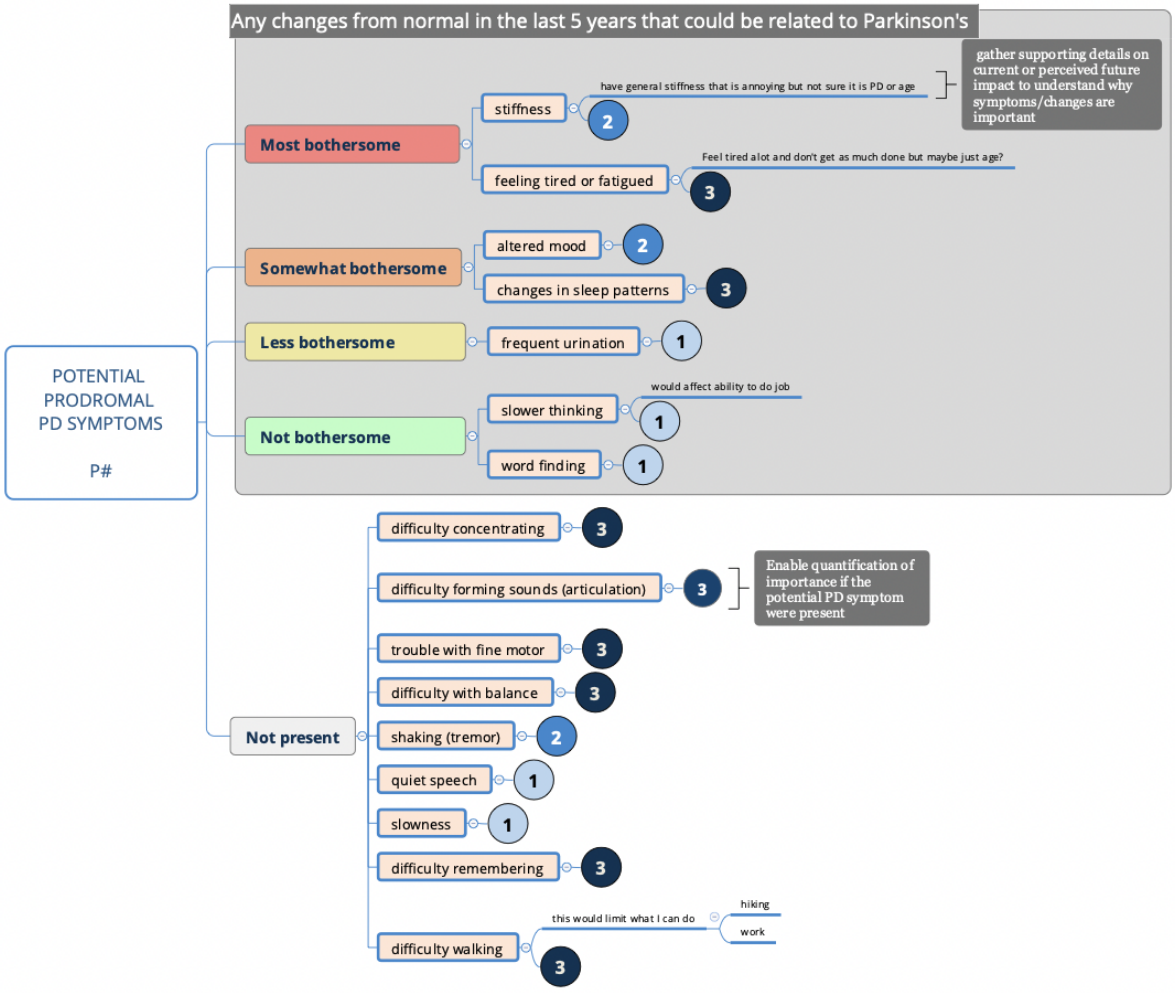
MOVEMENT CHANGES	THINKING CHANGES	SPEECH CHANGES
Shaking (tremor)	Changes in thinking	Changes in your speech
Sense of internal tremor	Difficulty concentrating on things	Changes in your voice
Trouble with hand dexterity	Slower thought process	Quiet speech
Changes in handwriting	Difficulty remembering things	Monotone speech
Slower movements overall	Difficulty coming up with words in a conversation	Difficulty pronouncing things
Changes in your balance	Trouble making decisions	
Changes to your walking	Mental fogginess	**MOOD CHANGES**
Increased stiffness in muscles/joints	Trouble with depth perception	Changes in mood
Stooping posture	Getting lost or trouble finding way	Feeling more anxious
Decreased range of motion		Feeling more depressed
Loss of general coordination	**SLEEP CHANGES**	Less interested in things
Decreased arm swing when walking	Trouble getting to sleep	More easily frustrated
Decreased facial expressiveness	Trouble staying asleep	More negative feelings/emotions
Muscle cramping or spasming	Poor sleep quality	Decreased pleasure in things
Restless legs	Active dreaming (kicking, shouting)	Mood swings
Twitching movements	Excessive daytime sleepiness	Impulsive behaviors
		Changes in your personality
DIGESTIVE CHANGES	**URINARY CHANGES**	**SENSORY CHANGES**
Excess saliva	Urinary problems	Changes in vision
Dry mouth	Frequent urination	Changes in smell
Issues with swallowing pills or food	Getting up often at night to urinate	Changes in sense of taste
Choking when eating or drinking	Urinary incontinence	Changes in hearing

Constipation		Changes in your skin sensation
	SEXUAL CHANGES	Increased pain
OTHER CHANGES	Trouble achieving orgasm	Fatigue or lack of energy
Low blood pressure	Loss of sexual interest	Shortness of breath
Feeling lightheaded or dizzy	Erectile dysfunction (men)	Feeling of weakness
	Vaginal dryness (female)	Altered temperature tolerance

Step 4: Rate all symptoms by the personal importance



Example of finished map of potential symptoms for prodromal PD/DLB



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