

Running head: ENHANCING PARKINSON'S DISEASE MENTAL HEALTH RESEARCH

ENHANCING PATIENT ENGAGEMENT IN PARKINSON'S DISEASE MENTAL
HEALTH RESEARCH

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Abstract

Neuropsychiatric complications of PD (e.g., depression) are primary contributors to reduced quality of life amongst people with PD (PWP). Thus, ongoing mental health research to develop effective treatments for psychiatric conditions associated with PD is crucial toward improving the lives of PWP. Common problems faced in mental health clinical trials include reluctance to take part in research, early dropout, and inaccurate and/or under-reporting of emotional concerns. These factors may impede the progress of clinical research, slowing development of effective mental health treatments for PWP. Developing a better understanding of these barriers represents important steps towards optimizing care for PWP. The objectives of this qualitative study were to 1) identify barriers and facilitators to participation in Parkinson's Disease (PD) mental health research, 2) describe factors that influence study dropout, and 3) develop tools to enhance accuracy of self-report and participant retention in PD mental health clinical trials. The overall purpose of this research was to improve the quality of PD mental health research by gaining insight from direct engagement with PD advocates, including PWP and their carepartners. Three focus groups (N=16 total, 4-6 participants per group) were completed between December 2017 and March 2018 (Phase 1), transcribed, and analyzed via qualitative thematic analysis. Specific deliverables were developed in response to key themes, and two additional focus groups (Phase 2) were completed in June and July 2018 to gather further input and to revise research tools, methods, and procedures. Limited knowledge about the common and central role that neuropsychiatric symptoms play in overall PD management was identified as a key barrier to engagement. Perceived stigma was reported to be a major driver of self-report bias. Peer-to-peer research ambassador programs, improved educational materials regarding PD mental health, quarterly wellness newsletters, and mixed-media testimonials from

prior study participants were examples of tools that may enhance the longevity and quality of PWP participation in mental health research, based on focus group results. Deliverables from this project may support the collection of high-quality clinical trial data, ultimately improving available mental health care resources for PWP.

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Introduction

Neuropsychiatric Complications of Parkinson's Disease

Parkinson's disease (PD) is a chronic, progressive neurodegenerative disorder that primarily affects the central nervous system. More specifically, it is a disease of the motor system, and its primary symptoms include tremor (e.g., shaking of hands, arms, legs, face, or jaw), rigidity (e.g., stiffness of arms, legs, or trunk), bradykinesia (slowed movement), and postural instability (impaired balance and coordination; NIH, 2017). Most people with PD also experience non-motor problems such as depression, anxiety, sleep abnormalities (e.g. insomnia), psychosis, and cognitive impairment. While both motor and non-motor aspects of PD significantly impact quality of life as the disease progresses, non-motor, neuropsychiatric complications make a larger contribution to decline in health-related quality of life (Forsaa, Larsen, Wentzel-Larsen, & Alves, 2008).

Depression in Parkinson's Disease

Among non-motor factors, depression is a main determinant of reduced quality of life (Behari, Srivastava, & Pandev, 2005; Schrag, Jahanshahi, & Quinn, 2000) and the most frequently reported non-motor complaint amongst people with PD (Cummings, 1992). Depression has an estimated incidence rate between 4% and 75% (Allain & Mauduit, 2000), and findings often depend on the survey site and survey method; however, the Global Parkinson's Disease Survey (GPDS) found that depression was a significant predictor for reduced health-related quality of life (GPDS, 2002; McDonald, Richard, & DeLong, 2003) and that approximately 50% of a sample of 1000 PWP from six different countries met criteria for depression (Reijnders, Ehrt, Weber, Aarsland, & Leentjens, 2008). Moreover, PWP experience depression at rates approximately twice that of the general public and at a significantly higher

rate than what has been found in studies focused on people diagnosed with other medical conditions (Tandberg, Aarsland, & Cummings, 1996). Depression in PD (dPD) directly impacts quality of life in ways that are not necessarily distinct from depression in the general population. However, dPD is specifically associated with increased likelihood of executive dysfunction (Santangelo, Vitale, Longo, Cozzolino, Grossi, & Barone, 2009), psychiatric comorbidity (Menza, Robertson-Hoffman, & Bonapace, 1993), and a course of PD symptom development in which depressive symptoms emerge prior to motor symptoms (Leentjens, Van den Akker, Metsemakers, Lousberg, & Verhey, 2003). Whether depression onset occurs prior to or after the progression of motor symptoms of PD, the impact on quality of life remains significant.

McDonald, Richard, and DeLong (2003) describe two primary etiological theories about the onset and recurrence of depressive symptoms in PWP. Depression in PD can be understood to originate as a reactive response to the psychosocial stressors associated with PD and its progressive, chronic nature (e.g. loss of mobility and capacity to engage in previously enjoyed activities), and it can be understood as a consequence of the neurodegenerative processes of PD. The reactive theory proposed that PWP and their carepartners have difficulty adapting to the changes that occur following a PD diagnosis, including reduced physical capabilities, loss of job, increased caregiving burden, or keen sensitivity to realities of having an incurable, neurodegenerative disease, contributing to the onset of depression. This association between stressors and development of depressive symptoms is supported by findings that those with early-onset PD (i.e., before age 65) experience higher rates of depression than those with more typical age of onset, as it is possible that earlier onset involves more perceived occupational, financial, and physical costs.

However, dPD cannot be explained solely as a response to psychosocial stressors. The neurodegenerative theory suggests that dPD may result from degeneration of subcortical nuclei (e.g., ventral tegmental area, hypothalamus) in a pattern similar to neurological changes seen in depression in other populations. Degeneration in these subcortical nuclei may produce a decrease in levels of dopamine, serotonin, and norepinephrine, neurotransmitters which impact mood, appetite, energy levels, motivation levels, and sleep (Parkinson's Disease Foundation, 2017). Furthermore, as degeneration of subcortical nuclei happens on a variable basis, differing between each individual PWP, it may help explain why not all PWP develop depressive symptoms in the same way or at all. Whether PWP develop depressive symptoms as a reaction to the psychosocial stressors that come along with PD, because of neurodegenerative processes, both, or for unrelated reasons, PWP are at increased risk and therefore have increased need for adequate, effective mental healthcare.

Despite the body of evidence establishing a clear relationship between depression and PD, dPD is still broadly under-diagnosed (Shulman, Taback, Rabinstein, & Weiner, 2003) or ineffectively addressed by healthcare providers (Ravina et al., 2007). This is especially problematic, as dPD is associated with increasing the rate of deterioration in both physical and cognitive domains (Starkstein et al., 1992), overall decrease in quality of life (GPDS, 2002), and increase in carepartner distress (Martinez-Martin et al., 2007). Effective treatments can only be delivered if depression is first detected. The intervention must then be competent and informed by current standards for best practice. Lack of clinicians who are knowledgeable of the high comorbidity rates between depression and PD, geographical limitations on access to specialty PD care, transportation barriers, and limited empirical clinical research on treatments for dPD all

contribute to the significant challenge of providing to the highest quality of mental health care to PWP (Cheng et al., 2007, Dobkin et al., 2013; Swarztrauber, Graf, & Cheng, 2006).

Unique Challenges Faced in Mental Health Clinical Trials for PD

While the negative impact of depression and challenges of meeting the mental health care needs of PD people continue to be better understood, there remains a need for controlled clinical research that can inform the development and implementation of effective treatments for depression in PD patients. Thus, it is important to understand and address typical challenges that affect clinical trials for mental health interventions among the PD population. Participant attrition in longitudinal trials and inflated placebo response rates on follow-up evaluations are two key challenges researchers face when designing controlled clinical trials, and these challenges threaten to compromise the validity of results if left unaddressed.

Placebo responding.

Placebo response (i.e. inaccurate self-report) is well-documented in PD clinical research and may be influenced by a variety of factors in the context of mental health research. Low mental health literacy (e.g., not fully understanding the various ways in which depression and anxiety may present in PD) and stigma may be two key factors that contribute to this phenomenon in PD mental health research (Dobkin et al., 2013). Additionally, participant self-report on follow-up evaluations may be influenced by a desire to present as doing well, a desire to please the researcher or research team, or perception of certain performance expectations. If these phenomena occur, then the resulting self-report of mental health symptoms is likely to be inaccurate.

The placebo effect has been established as a problematic phenomenon in clinical trials for PD (Lou et al., 2013) and similarly threatens internal and external validity. Medical trials in

which measures of motor functioning are used to measure outcome have consistently demonstrated the significant impact of placebo responses, and expectancy plays a key role in placebo responses (Lou et al. 2013). This relationship between expectancy and placebo response may be mediated in part by the dopaminergic system's involvement in phenomena such as anticipation and motivation (Goetz et al., 2008). As manipulation of the dopaminergic system is a key target of pharmacological interventions for PD, it is particularly concerning that dopaminergic system activation via expectancy, anticipation, or motivation may in fact make it difficult to reliably observe therapeutic impact of active treatment conditions. In the context of mental health research, placebo responding refers to improvements in measures of mental health in non-treatment conditions. While motor function is not the primary outcome, improvements on self-report measures of mental health indicate that placebo response applies to symptoms of depression and anxiety as well. Participants in PD mental health clinical trials may experience demand expectations while engaging in a study that may lead to placebo responding. They may have their own strong expectations of improving, or they may aim to demonstrate that they are improving as a means of pleasing the researchers. Additional factors that may influence placebo responding include personality, self-efficacy, and stress (Lou et al. 2013).

Dropout and study attrition.

Differential attrition (e.g., more drop-outs in the control vs. experimental condition) is also a noteworthy threat to validity in randomized-controlled trials in which participants are not blind to group assignment. Participants, aware of their condition assignment, may elect to withdraw from the study after understanding that they are in a control group.

Dropout rates and retention difficulties present barriers to the development and dissemination of effective mental health treatments for the PD population. Study attrition

threatens internal and external validity in clinical trials, possibly resulting in biased outcomes. Once attrition reaches 20%, bias is likely to result, so researchers working on studies with high attrition rates often must spend more time and resources to recruit more participants to maintain sufficient power to achieve valid results (Marcellus, 2004).

Strategies for addressing dropout and attrition.

Yet, the literature has identified factors that may decrease the likelihood of problematic study dropout and increase the likelihood of continued engagement among individuals who are elderly and/or diagnosed with progressive neurological diseases. These factors include: research staff qualities (e.g., motivated, empathic, flexible), respect for patients (e.g., communicated value for ideas and time commitment of participants, check-in phone calls, flexible scheduling), inclusion of active control conditions, tech-supported visit reminders, and up-front scheduling (e.g. laying out schedule for entire study involvement from the beginning; Bedlack, Richard, & Merit, 2009). Among clinical trials for Parkinson's disease, predictors of poor recruitment and retention include older age, male gender, lower education, lower verbal intelligence, poorer cognitive performance, significant functional impairments, number of comorbid conditions, poorer physical health, non-english speaking, non-Caucasian population, and perception of being a "guinea pig." (Picillo, Kou, Barone, & Fasano, 2015).

Additional retention strategies for clinical trials include offering regular participant reminders and contacts, offering flexible appointment times, reducing the research burden on participants (e.g., using online data collection vs. in-person), training research staff on factors that affect retention, developing systems for tracking the patient (e.g., multiple contacts), using relevant appointment reminders, providing effective incentives (e.g., monetary), offering alternatives to complete withdrawal from the study, and training staff to use build relationships

and rapport with participants (e.g., sending handwritten envelopes, sending birthday cards) are all routine methods for improving retention in clinical trials (Page & Persch, 2014).

The Current Study

Successfully enhancing ongoing patient engagement in Parkinson's disease mental health research has many potential benefits, including optimization of the quality and generalizability of clinical trial data. In the short-term, enhanced patient engagement in PD mental health clinical trials may improve the rate at which clinical trial results can be translated into larger scale implementation, and it may accelerate dissemination of accessible, effective specialty mental health care for the PD community.

In this study, focus groups and in-depth individual interviews were utilized to directly engage with PWP and caregivers of PWP. As crucial stakeholders with unique insights into the aforementioned challenges, PWP and their caregivers were asked to provide input on factors that may impact engagement, attrition, and inaccurate self-report (i.e., placebo effects) amongst PWP participating in clinical trials. If patient engagement in clinical trials is to be enhanced, it is essential that PWP play a central role in the development of tools or procedures that may be helpful towards these aims.

Through ongoing contact and engagement with PD advocates, this study aimed to 1) Identify barriers and facilitators to PD mental health research programs, 2) understand factors that affect study dropout, and 3) to develop tools for enhancing the accuracy of reporting and participant retention in PD mental health trials. Overall, this focus group study design was employed to effectively elicit feedback from primary stakeholders on issues related to participant attrition and inaccurate self-reporting to help generate valuable feedback and to provide

pragmatic insight into how such problems may be effectively addressed in ongoing and future PD mental health clinical trials.

Methods

Participants

Participants in this study were recruited from the Robert Wood Johnson Medical School Department of Psychiatry and Neurology from a pool of individuals who had previously expressed interest in promoting PD mental health research at Rutgers, and from a pool of U.S. military Veterans who had participated in a mental health PD clinical trial conducted in association with a Veterans Affairs Healthcare setting. Recruitment occurred between October 2017 and March 2018, and the final focus group occurred in July 2018.

In order to recruit a sample of PWP and carepartners that was diverse in terms of age, duration of PD diagnosis, and degree of involvement in clinical trials, inclusion and exclusion criteria were kept broad. Below, Table 1 represents the inclusion and exclusion criteria.

Table 1	
<i>Inclusion and Exclusion Criteria</i>	
Inclusion Criteria	<ul style="list-style-type: none"> • Confirmed diagnosis of PD according to NINDS research criteria (Gelb et al., 1999) • Or carepartner of someone with confirmed PD diagnosis. • Between ages 35-85.
Exclusion Criteria	<ul style="list-style-type: none"> • Unstable medical or psychiatric conditions (Determined during the telephone screening interview and in consultation with Principal Investigator)

Recruitment Methods

Purposive sampling was utilized to recruit PWP and carepartners for PWP with interest in participating in clinical research for PD and mental health. Research staff completed all screening and consenting processes. Initial screens were performed over telephone, and informed consent processes were completed in person at Robert Wood Johnson Medical School prior to the beginning of each focus group.

The sample was composed of individuals who had previously participated in past mental health research treatment trials at Rutgers and with the U.S. Department of Veterans Affairs New Jersey Healthcare System. Research staff members reached out to these potential participants via telephone to begin the recruitment and consenting process. A telephone screening form was utilized to collect demographic data and to screen for eligibility to participate in the study.

Procedure

This qualitative study utilized a single-category design. Focus groups and in-depth individual interviews were utilized as data collection methods, and they were facilitated by trained members of the study staff. A Focus Group Discussion guide was developed and used by mediators to guide discussion in both focus group and individual interviews. This Focus Group Discussion Guide is included in Appendix A. In addition to moderating group discussion, group facilitators acted as scribes, taking written notes to document observations, key statements, or factors affecting group dynamics (e.g., group members arriving late or having to leave early). All focus groups and individual interviews were audio recorded using digital audio recording devices.

Research staff members initially corresponded via telephone with participants to discuss availability and to establish times that would work for focus groups of three-to-five individuals.

Veterans with PD were initially asked to attend a focus group in-person, however distance and inclement weather interfered with these plans. Veteran focus groups were instead conducted via Veterans Affairs National Telephone System (VANTS), a platform for secure group telephone-based conferencing. Participants who did not agree to take part in an audio-recorded focus group or who were unable to attend focus groups in person were given the option to complete an individual, in-depth interview via telephone.

A total of five focus groups were completed, with three occurring in-person and two occurring via telephone conference through VANTS. A total of three in-depth individual interviews were completed via telephone. Focus groups were conducted to the point of saturation (i.e., when new observations or topics were no longer being introduced to discussion; Krueger & Casey, 2000). The intent of this recruitment approach was to fully capture the range of experiences and opinions relevant to the issues of reliability of self-report and attrition in clinical trials within a particular domain of stakeholders (i.e., PWP and carepartners of PWP).

Data collection was completed over two phases. The first phase focused on the identification of key themes related to participant engagement and accuracy of self-reports in clinical trials. Once identified, these themes became the basis upon which tools, procedures, and methods were developed for the purpose of enhancing patient engagement in PD clinical trials. A second phase of data collection focused on eliciting feedback on these deliverables in focus group and individual interview format. The procedures for these two phases of data collection and data analysis are reviewed.

Phase I of Data Collection

During the first round of data collection, three focus groups and two in-depth individual interviews were completed. Recorded content was analyzed and used to develop education tools

or procedures that can be implemented in current and ongoing clinical trials as means of enhancing participant retention and validity of participant self-report data. Krueger and Casey (2000) suggest that smaller groups (e.g. four to six) are indicated when participants have had in-depth experiences related to the topic of focus and when researchers hope to provide enough space for each participant to share relevant insights and experiences. Therefore, first round focus groups were comprised of four to five individuals.

Focus groups were led by members of the research staff. Staff were trained to conduct the group effectively, and they utilized a semi-structured focus group discussion guide with pre-selected questions and suggestions for additional probing questions. Each focus group was co-facilitated by members of the research staff, and facilitators used interviewing skills as needed to encourage participation and to ask unplanned clarifying or expanding questions when appropriate. One was designated as the primary moderator, and one was designated as the primary note-taker. During focus groups, facilitators aimed to involve group members and to encourage them to express their opinions, observations, and ideas. Light refreshments and/or lunch were provided prior to each in-person group, and participants were given the option to take brief break approximately halfway through each group. Focus groups were run for approximately 60 to 90 minutes, a length of time suggested for groups that include geriatric and/or disabled individuals (Barrett & Kirk, 2000). Participants were instructed that they were free to leave or to not answer a question if they become uncomfortable at any point and were given the opportunity to ask clarifying questions about what to expect.

Two individuals completed individual interviews in the first phase of data collection, as they were unable to attend the focus groups for logistical reasons. A research staff member interviewed them by telephone using the same discussion guide used in the focus groups. The

interviewer kept abridged written notes from the conversation, highlighting important themes and comments, and these interviews were audio-recorded.

Following completion of these initial focus groups and individual interviews, the audio recordings were transcribed word-for-word in preparation for data analysis. These transcripts kept the identity of speakers anonymous, and the raw data (i.e., digital recordings) were securely stored in locked file cabinets in a locked office to ensure the maintenance of the participants' confidentiality. Only the PI and relevant research staff members had access to research data and records.

Phase II of Data Collection

Following completion of the first phase of data collection, the research staff utilized QSR International's NVIVO 12 qualitative analysis software to aid in the detection of primary themes. The data analysis process is described in detail in the "Data Analysis" section below. Once deliverables were developed based on these themes, participants were invited to participate in a second round of focus groups and individual interviews. No new additional participants were recruited, and participants from the first round were contacted via telephone to discuss their interest. Two additional focus groups and one individual in-depth interview were completed, with one focus group occurring over the phone using VANTS and involving veterans specifically.

The protocol for these focus groups and individual interview were identical to those used in the first phase of data collection. However, research staff developed an additional semi-structured discussion guide to be used in the second phase. Discussion focused on the deliverables. For each deliverable, participants were asked to discuss their initial reactions, what they liked, what they didn't like, and about any suggestions they may have; and facilitators

managed time to ensure that each deliverable received adequate feedback. The audio recordings from these interviews were then translated by research staff into verbatim transcripts in preparation for additional analysis.

Data Analysis

All audio recordings were transcribed into verbatim transcripts to enhance the validity and interpretability of the data during the analysis phase. To facilitate qualitative analysis of the collected data, NVIVO 12 was used. Transcripts were imported into NVIVO 12, and emergent themes were entered into the database as “nodes” (codes) to be applied to relevant portions of text. Guest, Namey, and MacQueen (2012) defined themes as “units of meaning that are observed (noticed) in the data by a reader of the text” and codes as “textual description of the semantic boundaries of a theme or a component of a theme.” Once themes were identified by the research staff, brief definitions and coding guidelines were generated as well, forming the basis of a “codebook” describing all identified themes. Throughout the coding process, themes were discussed between research staff members, leading to revision and refinement. The process of determining inter-rater reliability, as described in the below section, also resulted in revision of the codebook. NVIVO 12 also allowed for visualization of theme frequencies and for comparison of code frequencies across participants characteristics (e.g. years since PD diagnosis).

Inter-rater Reliability

To ensure the reliability of the identified themes in each transcript, inter-rater reliability was calculated. The literature suggests that a kappa coefficient of .80 suggests “good” reliability between independent raters (Guest, Namey, & McQueen, 2012). Following initial data collection, a research staff member created an initial code book containing themes that emerged

from interviewer notes and transcripts. Each identified theme was then defined with instructions for when the code should and should not be applied to text from focus groups and interviews. NVIVO was used to create this codebook. Once this staff member created the first draft of the codebook, a second staff member independently used the codebook to code a particular focus group. Then, NVIVO was used to calculate kappa coefficient, which was identified as .44 upon first attempt. This was considered to be an insufficient level of reliability, so the two staff members reviewed the codebook together to refine codes and to resolve discrepancies in coding approaches.

Once the codebook had been updated, each staff member independently coded a second focus group. Inter-rater reliability for this second comparison generated a Kappa coefficient of .82 when calculated based on entire paragraph agreement (i.e., raters labeled the same codes within the same paragraph) and .73 when calculated using sentence agreement (i.e., raters labeled the same codes within the same sentence). This suggested good inter-rater reliability, and the revised codebook was applied to all remaining data. A new codebook was generated following phase II of data collection, as the prompts for discussion had changed and direct feedback for deliverables was elicited. Two staff members coded one focus group, and Inter-rater reliability was calculated for the result. Kappa coefficient was .79 when counting entire paragraphs and .77 when counting sentences, again indicating good reliability.

Results

Participants

Participants in this study ranged between ages 48 and 76 years of age. Five women and eleven men participated, and two out of 16 participants were carepartners for individuals with PD. 87.5% of the sample identified as white, and 12.5% of the sample identified as black.

Participants had been diagnosed with PD for between 25 and 2 years prior to the study, and most had volunteered for previous clinical trials (range of 0 -9 PD clinical trials; 0 -2 PD mental health clinical trials). Additionally, five Participants were veterans of the United States Military. This basic information is summarized in Table 2.

Table 2	
<i>Sample Demographics (n=16)</i>	
Age Range	48-76
Gender	Female: 5 Male: 11
Range of PD Duration	2-25 years
Range of Number of Clinical Trials Completed	1-9

Phase I: Data Analysis

Qualitative analysis of the data collected from focus groups and individual interviews resulted in the emergence of several key themes related to the enhancement of patient participation in mental health clinical trials for PD. Focus group discussions were structured to focus on three main domains: 1) factors that influence level of engagement in ongoing PD mental health clinical trials, 2) factors that influence the likelihood of drop out from PD mental health clinical trials, and 3) factors that influence level of participant honesty when completing self-report psychometric measures and clinician-administered psychiatric interviews. See Table 3 for a summary of the key themes within these domains and the frequency with which they were discussed in group and individual interviews during Phase I of data collection. Below, these key themes are described in detail.

Table 3	
<i>Key Themes – Phase I of Data Analysis</i>	
Theme/Code	Number of Participants with Code Applied (%)
Enhancing Engagement	
Education of PWP and Care Providers about Neuropsychiatric Complications as Key Components of PD	6 (37.5)
Participant Attitude	10 (62.5)
<i>Participant Attitude - Commitment</i>	3 (18.75)
<i>Participant Attitude - Empowerment and Giving Back</i>	9 (56.25)
Benefits of Breakout Groups	8 (50)
Importance of Rapport with Study Staff	12 (75)
Personalized Study Procedures and Uniqueness of PWP	6 (37.5)
Regular Outcomes Feedback	8 (50)
Continuity and Predictability of Study Procedures	6 (37.5)
Dropout	
Embarrassment or Discomfort with Study Procedures	3 (18.75)
Non-PD Life Stressors	3 (18.75)
Overwhelmed by Study Procedures	3 (18.75)
Honest Responding	

Table 3 - continued	
Stigma and Discomfort	8 (50)
Fear of Declining Health and Mental Health	5 (31.25)
Feared Consequences of Honest Responding	3 (18.75)
Mistrust or Uncertainty of the Intent of Questions	3 (18.75)
Phase I: Suggested Study Procedures	
Increasing peer support for study participation.	12 (75)
Preamble	7 (43.75)

Domain 1: Enhancing Engagement

Several key themes within the domain of enhancing engagement in PD mental health clinical trials were identified that provided insight into factors that support ongoing participation in clinical trials and factors that contribute to dropout or disengagement from clinical trials. Participants discussed the ways in which the attitudes, beliefs, and personal values of clinical trial participants impact level of engagement, factors that influence dropout, specific elements of clinical trial procedures that encourage participation, helpful qualities of staff members, and the importance of addressing lack of knowledge of the neuropsychiatric complications of PD through education of PWP and their care providers.

Education of PWP and care providers about neuropsychiatric complications as key components of PD.

A significant theme was the importance of educating PWP and their care providers that neuropsychiatric complications of PD are common, central components of the disease process. Participants identified improved education efforts as being important toward increasing engagement of patients in PD mental health clinical trials while also noting the barriers that lack of knowledge and awareness provides. For example, the majority of military veteran participants in this study discussed their experiences of attending medical appointments for depression and anxiety for years before their PD was eventually diagnosed by their Veterans Affairs (VA) healthcare providers. Participants noted that increasing provider knowledge of PD to include the full spectrum of symptoms (including neuropsychiatric) would have led to earlier diagnoses of PD. Participants felt that an earlier diagnosis would be validating to a patient's experience of having confusing motor and non-motor symptoms and that it may motivate them to consider participating in clinical trials that target non-motor symptoms. This would especially be the case if researchers worked alongside care providers to inform them of ongoing clinical trials that patients may qualify for. Several participants commented on their experiences of learning more about the full spectrum of PD symptoms and how education has increased their ability to manage PD, engage in effective treatment, and pursue clinical research opportunities.

"I didn't know I had Parkinson's. I just knew that I was very anxious and [had] many symptoms of depression, apathy, not doing a lot of things...But then when I got the Parkinson's diagnosis it all started to make sense that this was an organic condition caused by what's going on in the chemistry of my brain. And there were specific things that I could do to treat that, including antidepressants and CBT focusing on specific things for Parkinson's patients."

“It never crossed my mind, the reason (I wasn’t doing well managing my PD) was because I was depressed.”

Limited knowledge of neuropsychiatric complications of PD was therefore identified as a key barrier to initial PD diagnosis, early engagement of PWP in mental health treatment for neuropsychiatric problems secondary to PD (e.g., depressive disorders, anxiety disorders), and proactive involvement in PD mental health clinical trials. Participants indicated that they were often unaware that they were experiencing neuropsychiatric problems to begin with, and that they were not aware that their depression was core feature of PD even after being diagnosed. Given the importance of addressing lack of knowledge among PWP and the providers, participants further emphasized the need for better education. PWP were unable to even consider engaging PD mental health clinical trials of treatment with knowledge of their PD diagnosis and the full range of potential non-motor, neuropsychiatric complications.

“It gets back to the education again. You know a lot of us have been saying that Parkinson's is a pretty mysterious disease. It's got all these different aspects to it, and I'm beginning to think more and more that these (mental health) issues we're talking about today are just as or maybe even more important to a lot of us than the motor complications.....(We need to learn more) because it really affects our happiness.”

“I got involved with a Parkinson's neurology (group) but none of them (doctors) ever asked me if I wanted to volunteer for a clinical trial. Not that I could recall anyway.”

Participant attitude.

As shown in Table 3, the majority of participants identified a participant's attitude as an important factor that impacts level of engagement in PD mental health clinical trials. Their discussion included a focus on participant attitudes, values, and beliefs related to clinical trial engagement. As noted by one participant, the attitude or perspective of a particular participant may have a significant impact on their degree of engagement in a PD mental health clinical trial that they are trying for the first time, and this attitude may even contribute to early dropout.

"I think (some) people are more prone to dropping out...meaning that they don't continue for the whole study. They suddenly become unreliable and they don't complete the study. Barring of course of their being physically ill and they're in a hospital or something. Otherwise I have a feeling, yes there are people who will be like that"

Below, specific attitudes that appear to enhance engagement and retention in PD mental health clinical trials were commonly identified by participants are described in greater detail as more specific themes within the overarching theme of participant attitude.

Commitment.

Mental health clinical trials for PD routinely involve patient interaction with members of the research staff. Within both medical and mental health clinical trials, these interactions may involve direct interaction with a clinician or care provider. Some participants indicated that making a personal commitment to the research staff member or clinician provided motivation to continue engaging in the study. One participant shared about how this commitment to a study

therapist for a mental health clinical trial had motivated him to continue, even when initial therapy sessions had not resulted in significant change.

“I felt I made a commitment to [my therapist] for the 10 sessions, and I wanted to honor that. And even if I hadn't gotten something out of it yet at the second or third, you know maybe seventh or eighth would be a breakthrough for me, so I wanted to hang in there.”

In addition to the potential helpfulness of having a personal commitment to study staff, participants also described that an attitude of following through on commitments in general was conducive to continued engagement in study procedures.

“I wouldn't commit to it unless I was passionate about it and that I [knew I] could stay through the end of the study.”

Participants indicated that having a value for maintaining commitments motivates them to continue engaging in study procedures, sometimes in the absence of significant immediate positive results. These individuals noted that to have verbally committed to a study therapist, clinician, or research assistant provides motivation to continue engaging despite any difficulties experienced related to the study intervention itself, perceived lack of improvement, or general life stressors.

Empowerment and giving back.

Across all focus groups and interviews, many participants described that possessing a strong desire to “fight back” against PD and to make a contribution to the PD community as a

whole motivated them to take part in mental health clinical trials. For some participants, maintaining an attitude of empowerment and proactivity was identified as a generally important part of the process of managing PD. It was also identified as a facilitator for continued PD mental health clinical trial engagement.

“I think there has to be a more positive attitude. In other words, focus needs to be on what you can do and not what you can't.” (i.e. “You can choose to actively participate in clinical trials”

“If I have a little bit of communication skill and I can help somebody who's standing in the middle of this disease and terrified by it and they can help themselves a little bit, I want to do it. That's my way to contribute without having you know six years of college or things like that, so I would do anything I could to help make someone's life just a little bit more comfortable.”

For other participants, an attitude of wanting to contribute and fight back against PD for current and future generations was a motivator for participating in clinical trials. This attitude was described both as a motivator for joining clinical trials and a motivator for continuing to engage through the duration of the protocol. Some participants also suggested that lack of an attitude of empowerment or of desiring to give back may be associated with a hesitance to participate in clinical trials or increased likelihood of dropping out of the study. Additionally, participants who endorsed a value for contributing to PD research indicated that being informed of the ways in which their participation aides the progress of ongoing research is helpful.

“It's a terrible thing physically. So, so I contribute to these things because I don't want anybody else to have to deal with it. It sucks.”

“I want to fight this thing as best I can. I want to do it for all the other people out there who have Parkinson's... I just want to participate and help others and help myself.”

Benefits of breakout groups.

As shown in Table 3, half of all participants discussed the helpful role that support groups or break-out groups may play in enhancing engagement in PD mental health clinical trials. Regarding support groups, participants indicated that they had had positive experiences connecting with fellow PWP in their lives, and they suggested that incorporating similar mechanism in clinical trials might reduce the likelihood of early dropout from a study. Participants also described that break-out groups may be helpful to include in ongoing studies, allowing participants in ongoing trials to connect with one another, discussing any challenges, observations, or needs. Veterans with PWP noted that this would also be helpful for veterans in general coping with chronic illness. Additionally, increasing partnership with existing PD support groups or communities to spread awareness of PD mental health clinical trials was identified as an important step toward enhancing participation. While the use of group modalities was recommended, participants also identified potential drawbacks. They suggested that these groups should be facilitated by people who are well-trained, that they should remain optional, and that groups should not be overly crowded.

“If you feel as though you're part of the broader community that's dealing with Parkinson's, so that there's ... a sense of almost, community, that would be a good thing. And I think that would apply no matter what the nature of the trial was ... For myself like if I felt that was part of a larger endeavor, that would be encouraging and would maintain interest.”

Importance of Rapport with Study Staff.

A majority of participants described rapport with members of the research staff or research clinicians as an important factor affecting their level of engagement in the study. The importance of rapport was discussed across all first-round focus groups and individual interviews, and participants also identified distinct factors that influence rapport with research staff and clinicians. Empathy was specifically identified as a crucial factor that promotes the development of strong rapport between participants and research staff members or clinicians. Whereas research staff members that come off as overly detached, cold, or insensitive to the experience of the participant may be undermining rapport, research staff members that intentionally utilize active listening skills and show genuine interest in the experience of the PWP are more likely to enhance rapport through interactions.

“Well I think the fact that the person is listening to you and can say something that indicates that they heard and understood what you were saying. That's absolutely critical.”

“For some reason I felt that they exude a little bit of empathy... They really showed an interest. It didn't seem like they were robots.”

Additionally, the ability of the research staff member or clinician to convey a clear value for the participant's privacy and to outline guidelines for how their information will be kept confidential was identified as a factor that may increase rapport.

“And I think, I know you're asking me for one aspect. I don't know if part of rapport would be confidence - confidence that my information will be respected and protected...”

Overall, participants reinforced the importance of rapport with their research staff member, study doctor, or study therapist, often sharing personal examples of relationships with staff members that had been crucial in encouraging honest and engaged participation. Additional qualities of research staff members include flexibility, interpersonal skills, and a high degree of perceived competence.

“So you know the flexibility and the connection with [my therapist] has always been a helpful part to keeping me around.”

“The relationship is the most important thing. Now how you go about enhancing that or developing that that's a whole other question, but from my point of view that's what's really critical.”

Personalized study procedures and uniqueness of PWP.

While participants described a wide range factors that impact level of engagement of PWP in mental health clinical trials more broadly, they also described several themes highlighting the importance of viewing each participant as a unique individual with unique needs. As shown in Table 3, several participants shared that clinical trials are most effective in engaging their interest and participation when they have a clear perceived personal benefit and when the member of the research team describes the potential benefits of participation in a way that is personalized to the PWP and his or her symptom profile. To the extent possible, communicating the potential for tangible personal benefit and acknowledging the unique circumstances of the PWP were proposed as ways to effectively increase engagement in clinical trials.

“But you’ve got to sell me. I mean you’ve got to sell me why this is. Especially if I’ve got a full-time job and I’ve got a family and you’re asking me to give my time. I’ve gotta understand how this is going to affect me personally.”

Relatedly, the theme of uniqueness of each PWP’s PD symptom profile emerged from comments of several participants. They described that PD mental health clinical trials would benefit from encouraging staff members to recognize this uniqueness and reference it during recruitment and participation. Participant perception that their unique PD symptoms are being adequately understood and addressed is an important factor affecting level of engagement.

“You need to know the person. I think every [person] is different so you need to know that person, exactly what she'd like or what he'd like; ...and make different treatments for everybody. Because everybody's not the same.”

“There's an expression I've heard a few times - you meet one person with Parkinson's and you've met one person with Parkinson's. Because everyone's Parkinson's is different both from a physical perspective and a mental perspective.”

Regular outcomes feedback.

Half of all participants discussed their desire for ongoing feedback from the research team about any progress being made in the study. They shared that lack of feedback from research staff members about study progress related to recruitment and outcomes can contribute to a sense of disconnection from the study and decreased engagement. One carepartner of a PWP identified that lack of feedback or contact from a research team about his progress in the clinical trial and the value of his participation affected his degree of engagement in the study:

“I was surprised because he was always gung ho to do it, and all of a sudden he didn't want to do it...But like he said, they never gave him anything to let him know that it's really helping them. That the things that they need they are getting.”

Additionally, several participants described that receiving feedback promotes a sense of contribution and reminds them that their commitment to the study has directly helped the research staff to make progress toward recruitment goals or key findings.

“If there some sort of a piece of feedback that can come back to a participant and say, “thank you” first. Second of all, ‘look at all the cool stuff your time and effort gave to us’ so that when it's time for researchers to lift the hood and get to work, ‘this is what you gave us.’ I think that's absolutely essential.”

“I know myself like I've followed to some degree the clinical trials [that I've participated in]. And if you knew a little bit sooner what, if any, information there was, that would be helpful. And I would imagine would be more of an incentive to participate yourself.”

Continuity and predictability of study procedures.

The theme of continuity and predictability was another important theme identified through discussion of factors that affect engagement in clinical trials. Multiple participants indicated that they feel more engaged in an ongoing clinical trial when they have clear expectations of the time frame of the study and when members of the research team are consistent in their efforts to reach out and connect with participants about next steps. Participants shared examples of times in which they felt confused after lack of clear communication from research staff members, and they indicated that more regular communication and clearer methods for reminders of upcoming study procedures would have made them feel more engaged. Furthermore, participants indicated that having specifics regarding appointments (e.g., therapy session, follow-up interview) and having details of what will occur both increase the predictability of the study participation, thereby increasing level of engagement.

“If I don't hear from you within six months after I've given you a pint of blood and answered all kinds of questions and had a three-hour session I don't want to know it anymore. I forget about it. “

“You know what I mean like it's, ‘well we'll do it in three weeks, we'll do it in five weeks, we'll do it in seven weeks.’ it doesn't put you in any schedule. But if you know that next Wednesday or in two weeks from now on Wednesday we'll be interacting again, it makes a difference.”

Domain 2: Dropout

The second round of focus groups also keyed in factors which may contribute to early dropout from PD mental health clinical trials. The focus group discussion guide included direct queries about factors that may lead a participant in a clinical trial to consider dropping out and potential strategies for preventing dropout. Themes related to dropout are described in detail below.

Overwhelmed by study procedures.

When discussing factors that may lead to dropout, several participants shared that study procedures themselves in medical and mental health clinical trials for PD may contribute to a sense of overwhelm that may discourage active participants from continued participation. Activities such as cognitive exercises, follow-up interviews, psychotherapy appointments, blood samples, travel times, and doctor's visits may be physically or mentally demanding to the point that participants become concerned that continuing would be too overwhelming. Two participants shared about their experiences in mental health clinical trials involving CBT.

“I think for me, when I first started studying all this, it became overwhelming to me...And for a while I thought that it might be a little bit too involved for me, that I couldn't understand all this stuff that that they were trying to teach in this clinical trial.”

“For me it was just for a little while it was overwhelming... I needed to put more hours into it to throughout the week because there were all these goals, and it was just too much for me at first. Like I said, I'm so glad that I didn't give up, which I came close to. I'm so glad I didn't.”

Non-Parkinson's Disease life stressors.

Some participants shared that factors that are not directly related PD or study procedures themselves may contribute to a patient considering dropping out of a PD mental health clinical trial. Pre-existing commitments to work or family may make it difficult to attend study procedures or to complete follow-up interviews:

“I have a wife, I have two kids, both of them are in college, I have a very demanding job; And sometimes it's just simply hard to go (to study-related appointments). It's just impossible for me to get there on a regular basis.”

For others, life stressors related to finances, relationships, or work may be stressful to the point that continuing to commit to study participation begins to feel overwhelming. PD may directly impact a person's work and financial situation, or these psychosocial stressors may be

present independently of PD. In any case, participants described that financial problems in combination with PD symptoms may increase stress and depression to the point where it is difficult to remain in mental health clinical trials:

“A lot of times, when people have Parkinson's, they can't work or they have a problem with working different jobs. Some of them might not be able to get work and they wouldn't have the finances to be able to take the time to do this (participate in a clinical trial). ...All of that can also cause depression worrying about it all...But finances I think and depression both cause people possibly to drop out.”

Embarrassment or discomfort with study procedures.

Some participants indicated that discomfort or embarrassment related to study procedures may sometimes be significant enough to influence them to consider dropping out from a clinical trial. This potential effect was described as more likely to occur if the research staff member has not developed trust and rapport with the participant. Participants who find self-report measures or follow-up questions overly personal or invasive and who do not experience rapport with their interviewer or clinician may decide to drop out of a study if they perceive that it will continue to be uncomfortable. Specific suggestions to address this embarrassment or discomfort related to answering personal questions during follow-up interviews include orienting the participant properly to their freedom to choose not to respond to questions and offering direct validation that certain questions may be uncomfortable or embarrassing to answer.

“I have a feeling that it might be lack of experience with a study and maybe they're asked questions that they suddenly don't want to answer. You know, it seems too private to them. It feels invasive... I think the fact that they're reminded that they don't have to answer anything that feels uncomfortable might help.”

Domain 3: Honest Responding

In addition to the domain of enhancing patient engagement in clinical trials, participants in focus groups and individual interviews were asked to discuss factors that facilitate and inhibit accurate responding when completing self-report measures or clinical interviews as a part of clinical trials. Key themes within the domain of accuracy of responding included the impact of stigma regarding mental illness, fear of declining physical and/or mental health, feared consequences of honest responding, and the perceived intent of a researcher's questions.

Stigma and discomfort.

Regarding reasons that participants may not respond accurately, participants indicated that stigma, embarrassment and discomfort may influence patient responses when asked about their symptoms. Participants remarked that they may feel embarrassed to talk about personal experiences that they may not typically discuss in their everyday lives. These topics may include medically relevant data, such as frequency and quality of bowel movements, or topics relevant to mental health, such as level of interest in sexual activity, overall mood, or feelings such as guilt or worthlessness. Reluctance to discuss these topics may impact a patient's responding. Acknowledgement of the potentially uncomfortable or embarrassing nature of particular questions by research staff members was viewed as a helpful and rapport-building step that promotes honest responding. Furthermore, Participants identified that stigma and discomfort

related to their medical and mental health symptoms and help seeking behavior in general may prevent PWP from participating in PD clinical trials in the first place.

“Just to emphasize how important it is to break through the stigma of asking for help. A lot of veterans... have the idea that asking for help like this is not ‘manly’ or it's not something that we want to deal with. [We have] got to break through that.”

“You know, I'm sure that maybe some people are embarrassed about discussing how deep their depression is, or they may not think that it's ‘manly’”

“The only time I think I was not really honest with my neurologist or the clinical trial people is when I think they were asking me about compulsivity, and I was embarrassed that I was having this eating disorder.”

Veteran participants also noted that military culture contributes to stigma regarding mental health and discomfort about being portrayed as “weak” when sharing about personal struggles.

“With military we're always hoping to put our best foot forward and not to show any weakness, but sometimes, you know, we have to get around the stigma attached to mental illness... We have to be open about it and discuss this with our family and health care team. Even though, some people may be reluctant to share because you know especially if you're the father and you have people depending on you, you don't want to seem to be weak or needy, but this is stuff that has to be dealt with just like any other illness.”

Fear of declining health and mental health.

Another key theme related to accurate responding was participant knowledge of PD as a progressive condition affecting their responses during follow-up data collection. Some participants shared that interfacing with medical or mental health professional could be an intimidating meeting, as they would be concerned that they would get news that their health is declining.

“I can't tell you how many times on the way to my doctor's office I tried to memorize the seven times tables so that I did well on the MOCA... Because inside me I say well if I can't do my seven times tables I must be going downhill fast...Feeling like you're failing I think is what contributes to dishonesty.”

Anticipating that a self-report questionnaire or clinical interview will assess change in symptoms appears to invite concerns about what it would mean to find out that PD is progressing or that an intervention has not been helpful. These private concerns may then impact patient self-report, as patients desire to present themselves as improving or at least not declining. In response to these concerns, participants noted that being informed that symptoms often fluctuate in intensity and frequency would help to normalize the experience of observing a lack of improvement in symptoms for a particular time period.

Feared consequences of honest responding.

Some participants described that feared consequences of honesty may impact accuracy of responding. In the case of clinical trials involving mental health intervention and assessment,

some participants highlighted that they may hold back from sharing about certain symptoms for fear that they would be removed from the study, removed from a treatment condition (e.g., medication), or that research staff may overreact to the apparent severity of a reported symptom or experience. Participants also suggested that providing informed consent and setting clear guidelines for participation and exclusion criteria would be useful in reducing such fears.

“But I guess the reason I was afraid to [tell my doctor about my impulsive behaviors] was not only embarrassment but also fear, was that they might take me off that medicine; because I think it was making my PD better and able to, you know accomplish more things.”

Mistrust or uncertainty of the intent of questions.

Participants also indicated that the perceived intent of a research staff member’s question may impact their degree of comfort when responding. Participants shared that uncertainty about the intent of a question may cause them to be somewhat guarded in their responses, especially when a follow-up question appears to be especially personal (e.g., level of sexual interest) or not obviously related to PD or the intervention being tested. Fear that a question is being asked a means of excluding someone from a trial or discomfort with not knowing the value or intent of a question in general are important factors to address when attempting to increase accurate responding on patient self-report measures. Participants suggested that research staff members should preemptively make the intent and value of measures and individual questions known as a means of increasing the level of openness and honesty in responding.

“I think maybe, just in general before the interview is done in person or online, an explanation of like... ‘why are we asking you these questions?’ would be useful to put people, you know to make it not like we're trying to pick your brain or whatever or report you or kick you out of the study; but these are important elements of what's going on with Parkinson's that we need to track.”

Phase I: Suggested Study Procedures

Increasing peer support for study participation.

A majority of participants identified that peer support promotes improved patient engagement in PD clinical trials. Specifically, they shared that peer advocates may be effective in recruiting for clinical trials and also in helping to support active participants. One participant shared about the usefulness of peer advocates, especially for PWP who are in early stages of PD or were recently diagnosed:

“I think that is a good idea, because you know I think we all realize that especially when you're first diagnosed you feel very isolated and the symptoms of PD exacerbate that if you don't get a good neurologist and get a good routine of medication and exercise and everything. So, to have contact with people that are functioning and living as well in life as they can would be really helpful especially to people who are trying to take part in clinical trials that are struggling with their symptoms or whatever. So, I think that'd really be a big plus, something like that.”

Participants identified that PWP who have participated in clinical trials and experienced improvement to their quality of life are uniquely positioned to offer support and serve as a motivating example. Participants further suggested that including peer advocates for specific ongoing clinical trials would help to increase patient engagement by providing these patients with a contact person that they can relate to and who is perceived as more trustworthy and less motivated by potential bias:

“I think the research group should be able to say, ‘why don't you call this person (peer ambassador)? He or she is a person that's participated in multiple studies on this, this, and this; and talk to them or shoot them an email or what have you. Just engage with them and talk through what it is that you don't feel [comfortable with]. They're not going to heavy sell you, they're not going to bother you. They're there to answer your questions. They're your support structure just like anybody else.’ And I'm sure all of us would do that.”

Participants also described that peer advocates should be properly trained by members of the research staff. In addition to being able to personally relate to patients, it was evident that peer advocates should also be knowledgeable of study procedures and key concepts and knowledge related to the clinical trial. Participants indicated that peer advocates should be able to be able to communicate with study patients using relatable language. One participant highlighted qualities of the “ideal” peer advocate:

“So, to me if you're looking for that ideal person it's someone who has, I would say, the ability to understand the conceptual aspects of what it is that you're trying to accomplish. And, but at the same point they have to be able to communicate that to the recipient in a language that the recipient can understand.”

Furthermore, potential limitations of peer advocacy were noted. It was noted that many PWP may be hesitant about participating as a peer advocate, as they would be anxious or uncomfortable in the role. Some participants reported concerns that they would not have enough knowledge about the study itself or that they would not be able to communicate effectively. However, several acknowledged that this initial anxiety would likely reduce with time and experience as a peer advocate.

“I'd be scared, I think, in the beginning. But then, once I become comfortable with it I can do that I think. But in the beginning, I'd be shy or afraid. Fear, I think, is my obstacle.”

Finally, participants shared that it would be important for patients and peer advocates to be able to opt in and out of peer-to-peer interactions according to their preference. Autonomy to set personal boundaries (e.g., method of contact, setting windows of availability) was identified as an important aspect of any peer advocate program with a clinical trial.

Preamble.

Participants also described that receiving messaging prior to completing self-report forms or answering self-report questions would be helpful in supporting accurate responding. The preamble theme captured participants' specific suggestions for what would be helpful to communicate, and it also captured participant experiences of messaging from research staff that had been effective in the past. Participants indicated the importance of being reminded that they may elect not to answer anything that they feel uncomfortable answering rather than providing an inaccurate answer. Additionally, participants described the usefulness of anticipating potential reasons for not responding accurately, for example, one participant stated:

“If there were some way of emphasizing that in the instructions... ‘you might have some inclination to want to either not perfectly disclose or to say what the researchers are looking for’ that type of the thing. Yeah, I guess to my mind that would be a [helpful] possibility.”

Multiple participants noted the importance of being reminded that they have autonomy in deciding how much they wish to disclose. It was important for participants to feel that their reasons for not responding accurately were understandable and that it was acceptable for them to choose not to respond over providing an answer that is meant to reflect what they perceive the research team is “looking for.” This kind of preface was also described as a way to prepare participants for when particularly uncomfortable questions may occur in the interview or questionnaire.

“Let me drive the decision. Just at least in the beginning, let me know there will be questions that may be personal... Because you hit me with the personal up front, you may lose me or you may alienate me a little bit.”

Phase II: Deliverable Development

Following data analysis of phase I of data collection, several procedures, and tools were developed (See Table 4). In response to key themes identified in Phase I and participant suggestions, a sample role description for a peer-to-peer ambassador position within mental health clinical trials, a sample preamble to self-report forms, and sample newsletter with fictional PWP testimonial, and a sample calendar of events were developed. See Appendix B for examples of these deliverables as they were presented to participants for feedback and discussion. Templates of a newsletter and calendar of events for PD clinical trials provided by the Parkinson’s Clinical Trial Companion , which was developed by the Michael J. Fox Foundation at the 2017 Parkinson’s Disease Education Consortium, were referenced and modified in the development of the newsletter and calendar of events deliverables in this mental health study (Parkinson’s Disease Education Consortium, 2017).

Table 4	
<i>Deliverables Developed Following Phase I Data Analysis</i>	
Deliverable	Brief Definition
Newsletter	<ul style="list-style-type: none"> Sample template of a quarterly newsletter for a PD mental health clinical trial with content including a PWP testimonial, FAQ section, recruitment progress figures, and message from the study investigator

Table 4 - continued	
Testimonial	<ul style="list-style-type: none"> Fictional written testimonial of a PWP sharing about his experiences engaging in a PD mental health clinical trial and encountering common barriers (e.g., stigma, lack of education)
Calendar of Events	<ul style="list-style-type: none"> Sample template of a calendar of events for a PD mental health clinical trial containing specific time-frame and description of what to expect during each follow-up procedure
Peer-to-Peer Ambassador Role Description	<ul style="list-style-type: none"> Sample role description of a peer-to-peer ambassador role, including potential duties and aims of the role
Preamble	<ul style="list-style-type: none"> Sample written preamble description in long and short forms addressing common participant concerns and factors that affect honest responding and meant to facilitate rapport-building between participant and research staff

Phase II: Data Analysis

Following completion of the second phase of data collection, a new codebook was developed, as these interviews utilized a unique set of questions and probes and involved direct feedback for drafts of deliverable tools and procedures. Content codes were identified and applied to in order to capture key themes identified in the content of participants' discussion, and structural codes were also applied to capture all feedback directly related to questions about the deliverables themselves.

Participants across two focus groups and one individual interview reviewed and discussed five selected tools and procedures, with focus group moderators encouraging feedback and suggestions related to each deliverable. Below, key feedback generated from these interviews are described.

Testimonial.

Participants were asked to provide feedback on the fictional testimonial that was embedded within the draft of a quarterly newsletter. This testimonial included a fictional testimonial from a male PWP who had engaged in a PD mental health clinical trial after being informed that his chronic struggles with depression were related to his PD diagnosis. This testimonial was generated with the intent of reflecting common concerns and experiences noted in Phase I of data collection, and a sample can be viewed in Appendix B. Participants described several aspects of the testimonial that they found engaging and helpful. For example, it was important for the author of the testimonial to come off as authentic in his or her story. Participants described that fictitious testimonials or testimonials that appear to be vague, anonymous, or “sugar-coated” are less engaging and may even be disengaging. Thus, the importance of including real stories from real PWP or researchers was highlighted. However, the ability of a testimonial to be empowering and to inspire hope that participation in a clinical trial or in mental health treatment more broadly may be beneficial was also identified as an important element of enhancing participant engagement. Additionally, acknowledgement of the difficulties and challenges faced by PWP in general and as participants in a study was identified as an important aspect of effective testimonials. Similarly, participants noted that specific focus on mental health, including the impact of untreated depression and anxiety on PD progression and the benefits of engaging in mental health care, is important toward addressing stigma associated

with mental health issues. Overall, the importance of relatability was emphasized. Participants agreed that an effective testimonial is one in which participants can individually relate to the experiences, struggles, and hopes communicated through the writer's story.

"So I think that messaging piece you have to be very careful about how you construct it, and how you work it in, but sometimes I think it's a little bit of more of a raw message is important because it's going to be tough to deal with. You can't sugarcoat it too much."

"I was just going to say I don't remember, not that I have read a zillion testimonials, but I don't remember seeing introduced the whole notion of mental health, depression, anxiety that kind of thing. So, I think that's really good that that's incorporated here."

Participants also provided feedback related to the format and structure of a testimonial. Regarding structure, several participants noted that inclusion of brief summaries (e.g., key bullet points) of the content of testimonial may be useful for readers with a preference for reviewing key elements without having to read the entire piece. The inclusion of pictures and "eye-catching" elements when possible was also identified as an effective way to draw attention to a testimonial. Furthermore, Participants indicated that video testimonials are an engaging format, allowing for PWP to feel more connected with the person sharing his or her story.

"[Video testimonials are] very helpful and impactful and really important."

“I saw a couple videos of Michael J. Fox interviewing people, a basketball player, a sculptor, and he talked about what their life was like now as opposed to what it was before; and it was done with a lot of respect and it resonated with me. These people weren't feeling sorry for themselves. They were lamenting the fact they had Parkinson's but they were talking about how they were trying to work their way around it day to day. It just being video, seeing their faces helped me.”

Newsletter.

In response to the draft of a newsletter for PD mental health clinical trials, participants identified several factors that impact engagement in the newsletter format. Specially, participants recommended that study's with “cool” or “clever” titles or acronyms may effectively attract initial interest in reading more about study participation and also increase likelihood that a regular newsletter would be read by active participants. Participants also suggested that the content of any newsletter be “patient-centric” in content in in format. It was suggested that content such as testimonials from PWP and photos of PWP or the study team be presented first as a means of increasing interest in reading out other aspects of the study, including recruitment targets, outcomes feedback, or other study information.

“So maybe the arrangement is that the patient stuff leads off first. Because that creates a connection with the person first and then maybe you stay engaged through the whole other pieces.”

Furthermore, participants suggested that newsletters should serve the function of keeping active participants informed of any progress being made towards data collection and analysis, as lack of any updates can leave participants feeling disconnected. Increased awareness of recruitment progress through a newsletter was also identified as a way to help spread knowledge of a study within the PD community by encouraging existing participants to inform other PWP about the study.

“I mean I don't know if they release interim information or that kind of thing... Because a lot of times it feels like a complete mystery to me as to how things are coming along. It's a big-time gap from when it starts to when you know when they say we're going to complete this study.”

The majority of participants suggested that newsletters should be developed and distributed on a quarterly basis and that participants would ideally be given the option to choose between email and paper versions. Other suggestions included the inclusion of pictures and brief bios of study staff members, sharing general positive facts about how clinical trials have resulted in innovation and benefits for PWP, using jargon-free language when possible, and being very specific when sharing early outcomes or recruitment figures.

Peer-to-Peer ambassador.

In response to a description of a potential peer-to-peer ambassador role in connection with a clinical trial, participants provided feedback about the usefulness of the role itself and suggestions about how it could be effectively implemented. Connection was a key theme within this discussion, as participants identified that being able to connect with someone who has had

shared experiences can keep a participant engaged when things are difficult. This benefit was identified in phase I of data collection, and it was reinforced in phase II as participants continued to identify peer-to-peer ambassadors as being potentially in a unique position to help PWP who are struggling with completion of study procedures and may be considering dropping out of a clinical trial.

“I think it's not easy, you know, and I think everybody needs this even if you're not in a study! It'd be great to have an ambassador checking in on you, you know, to see how you're doing on a day-to-day basis. That's what we do in our support groups right? We check in on each other and see what we can do together to move forward.”

“If they (peer ambassadors) help them (participants) out and say, ‘Hey listen I went through the same thing, and in fact just two weeks ago I felt the same way and these are some of the things that I did,’ then maybe some of your ideas or some of your thoughts could really help them.”

One veteran participant even shared his personal experience of being in a peer ambassador role.

“So a lot of it (being a peer ambassador) is me talking to them over lunch or coffee and discussing what's going on and how they can work around some of their Parkinson's issues right now and still stay in the study. So, I think it's really important to have somebody like this especially if you're having a tough time.”

In addition, participants described that the scope of the peer ambassador role should be clearly defined for both the ambassadors and the participants. Stigma related to discussing mental health and non-motor symptoms of PD was acknowledged as a factor that impacts potential peer ambassadors as well, affecting each individuals comfort level with certain topics if they were to come up in a conversation with a patient or active participant. Thus, participants suggested that clearly defining the scope of ambassador role and making sure that individuals do not feel forced to discuss topics that are outside their knowledge base or that make them uncomfortable would be helpful. Specifically, participants suggested that well-designed training and support structures would be crucial for any peer ambassador program within a clinical trial. Participants mentioned that concerns about saying the wrong thing, being unprepared to answer a patient's question, and lack of quick access to study staff members might make them cautious to participate. Thus, training on the front end followed by ongoing support would be important. Initial "ride-alongs" in which a staff member is present on the call or in-person with the ambassador were suggested as a way to reduce initial anxiety and to ensure that peer ambassadors were performing within their expected scope. Additionally, participants stated that having the freedom to opt in and out of interactions with the patient and to interact remotely as opposed to in-person would be important.

"I was thinking also the ambassador would serve more to help people get into the program and then at that point whatever professionals are involved they would take over more of that role. Like if there's an ongoing need for mental health or that kind of thing that they might be better situated to provide that."

However, other participants noted that having access to a peer ambassador throughout involvement in a PD mental health clinical trial would be beneficial toward keeping them involved in the study.

“I think it's not easy, you know, and I think everybody needs this even if you're not in a study! It'd be great to have an ambassador checking in on you, you know, to see how you're doing on a day-to-day basis. That's what we do in our support groups right? We check in on each other and see what we can do together to move forward.”

“Maybe you can help that person (a participant) identify some of the reasons why people drop out of the trial when they feel like nothing is doing them any good, [when] they don't really have that person to talk to. If you (the peer ambassador) help them out and say, ‘Hey listen I went through the same thing, and in fact just two weeks ago I felt the same way and these are some of the things that I did,’ then maybe some of your ideas or some of your thoughts could really help them.”

Calendar of events.

Participants indicated that a calendar of events detailing what to expect as a participant in a clinical trial is helpful in providing a sense of predictability and structure that may enhance level of engagement. Some shared about their own past clinical trial experiences in which staff members had effectively communicated a plan for study procedures going forward and how this had been practically helpful toward reminding them of when scheduled follow-up interviews

were going to occur. High levels of perceived organization, as evidenced by a calendar of expected schedule for events, was described as an element that may make a participant more likely to consider enrolling in a study.

“The fact that you laid the steps out and it was almost a process made it a lot more palatable. So that I knew, you know, Wednesday nights at 5:30 I'm gonna have my conversation with [my therapist]. So that it almost becomes an item on your schedule that you're investing your time in....I think the more you can do to give people everything that's coming down the highway at them to expect I think more so the better. I think this is really good.”

Participants noted that regular reminders and information from study staff supports continued engagement.

“The more we do that with positive reinforcement the better. You know I think that the letters or the e-mails that I get from the Parkinson's Foundation and from Fox insight, from Michael and everybody. That all helps because you know you're not alone know, and this disease makes us feel a lot of times like we're alone.”

Participants also communicated that overly informative or complicated calendars or schedules may be overwhelming to read. Suggestions were made for simple and jargon-free reminders of upcoming study procedures. Additionally, providing both electronic and paper versions depending on participant request and offering contact numbers for staff members who

can offer clarification or assistant were identified as suggested changes to the provided calendar draft.

Preamble.

As two versions of a written preamble to the completion of measures were presented in each phase II interview, participants shared their preferences and suggestions about how to improve the initial draft. Clear guidelines around the importance of honest responding and clarifications about feared consequences of honesty were identified as important messaging. Highlighting the importance of honest self-reporting on quality of data analysis while normalizing that some participants may want to present themselves as doing better than they really are was also described by several participants as a way to promote accurate responding.

“I think a notation about the accuracy of the answers affecting the outcome of the study without it becoming too much of an academic construct of a question... ‘We rely on your honest assessment of where you are and we're not gauging or meriting you based on your answer. We're trying to make a determination on how people like you are experiencing the disease’”

Participants also commented on the role of written and spoken language in the preamble. Research staff members sharing the preamble prior to data collection were encouraged to not simply read from it, but to engage with the PWP and to paraphrase when possible to increase rapport. Additionally, referencing specific language from the informed consent was recommended as a way to remind each participant of the broader scope of their study participation as they complete follow-up measures. Regarding the format of the preamble,

participants agreed that using larger, highly visible font for key points was useful, and they suggested combining long- and short-form versions into a single document to allow participants with either preference to have both options available. Participants indicated that facilitating engaging conversation regarding written subject matter was important toward increasing honest responding.

Additional Findings

Participants also described several minor themes relevant to enhancing patient participation in PD mental health trials. Several participants described that transportation issues may impact PWP willingness to consider participating in clinical trials. Participants pointed out that lack of being able to drive, lack of access to reasonable transportation means, or fear about distance and timing of a commute all impact engagement. Participants suggested that tele-mental health interventions would be preferable for those with the aforementioned concerns.

Relatedly, participants identified integration of technology as a way to increase patient engagement in mental health clinical trials. Technologies such as smart phone applications, wearable technologies, video conferencing, and social media (e.g. Facebook) were identified as ways to improve recruitment methods and to sustain participant engagement in the trial. Use of the “TED Talk” format was also mentioned by two different participants as both a medium that they would be interested to use when sharing about their own PD experiences and as a medium that they would find engaging. During Phase II of data collection, participants noted that reading testimonials about engagement of PWP in mental health treatment was rare, and the link between PD and neuropsychiatric symptoms could be better represented using technology.

Messaging based on stage of PD progression.

As previously described, many participants recounted early lack of awareness regarding the neuropsychiatric complications of PD. Participants recalled that initial diagnosis of PD was often delayed and preceded by incorrect diagnoses. They often did not think of changes in mood, concentration, and anxiety to also be related to PD, and thus they did not consider mental health treatment as an important aspect of improving quality of life with PD. While participants noted that increased awareness of neuropsychiatric symptoms over time was helpful, several expressed that they would have benefited from becoming aware sooner during the earlier stages of PD progression. They stressed that education and destigmatizing mental health issues are crucial in engaging PWP at early stages of the disease.

PWP in earlier stages of PD reported that their attitudes toward engaging in clinical trials were key in motivating them to participate. Several participants identified that a desire to contribute to the broader PD research community and a commitment to give back to current and future PWP were key in motivating them to continue engaging in clinical trials.

“I do it (engage in clinical trials) so that my grandkid doesn't have to deal with what I have to deal with. And people don't have to do it because it's a terrible thing. It's a terrible thing up here (points to head). It's a terrible thing physically. So, so I contribute to these things because I don't want anybody else to have to deal with it. It sucks.”

Participants with later stages of PD also shared increased value for receiving updates on any outcomes or early analysis. They indicated the importance of feeling as if their participation has value or tangible impact and the downsides of not being reminded of the value of their contribution.

“Because sometimes you just feel like, you know, you feel like you are contributing something that’s, hopefully some part of the piece to the puzzle of working on the cure or improving symptoms for people with PD; but when you do these clinical trial tests and you don't get much feedback it just feels like it's, you know, you dropped into a black hole or something like that.”

Veterans with PD.

As two focus groups were completed with solely veterans with PD, several factors unique to veterans with PD were identified. Veterans indicated significant concern about the lack of education and open communication about the role of neuropsychiatric complications in PD in the VA Health care system. For example, veteran participants noted that neuropsychiatric symptoms of PD are rarely discussed and rarely assessed for by their medical providers. Furthermore, even once diagnosed with PD and/or a mental health problem, veterans noted that awareness and availability of mental health clinical trials was scarce. Participant feedback also focused on ways in which VA healthcare providers had been delayed in diagnosing PD or unaware that PD frequently included non-motor neuropsychiatric complications. Veterans described:

“It gets back to the education again. You know a lot of us have been saying that Parkinson's is a pretty mysterious disease. It's got all these different aspects to it, and I'm beginning to think more and more that these [mental health] issues we're talking about today are just as or maybe even more important to a lot of us than the motor complications...[We need to learn more] because it really affects our happiness.”

“I got involved with a Parkinson's neurology (group) but none of them (doctors) ever asked me if I wanted to volunteer for a clinical trial. Not that I could recall anyway.”

“I noticed that, from my experience since I took a long time to be diagnosed that I had Parkinson's, that even in the VA system they got neurologists and stuff that's not really aware how to treat a person with Parkinson's and to identify [it] ...”

Veterans also identified that access to peer research advocates who are also veterans would be helpful toward increasing engagement in PD trials. Veterans with PD recalled the benefit of connecting with fellow veterans even before PD, and they suggested that using this comradery and sense of shared experience to encourage veterans to consider mental health clinical trials would be helpful. One veteran shared:

“And that's how we can add value to this because sometimes the doctors can't, you know they are talking as experts and treatment plans and so forth but we're talking about what it's like to be in the foxhole. Right? You know if you talk to another veteran who's been through combat it's a lot different than talking to a historian that knows all about the battles but he was never there. So, I think that's what we can bring to the table: honest self-reporting, providing support to those that are overwhelmed.”

Further expanding on the benefits of peer support among veterans with PD, veteran participants in this study expressed interest in group psychotherapy interventions and suggested

that PD mental health clinical trials should include more group interventions. Veterans noted that value for camaraderie may attract veterans with PWP to consider engaging in group psychotherapy clinical trials.

“I was wondering if groups would be good for people with Parkinson's Disease...They have groups for about everything. And I wondered if that would go well with people was PD.”

“One idea might be group therapy clinical trials. We had the individual therapy (with a previous VA-based individual psychotherapy clinical trial), but maybe a group therapy could be involved too.”

Discussion

Overview

Inaccurate responding, recruitment difficulties, and early dropout in PD mental health clinical trials are factors that have the potential to threaten the validity of any results or findings, thereby acting as barriers to the development, refinement, and dissemination of effective treatments of neuropsychiatric problems secondary to PD. While these factors are also relevant to general clinical trials and mental health clinical trials, this study sought to directly engage with PWP and their carepartners to determine the ways in which these barriers uniquely impact PD mental health clinical trials. The three primary domains of focus throughout this study included 1) enhancing engagement in PD mental health clinical trials, 2) dropout, and 3) factors that influence honest responding. Below, Figure 1 and Figure 2 visually represent the key themes identified in this study during Phase I of data collection across the three primary domains.

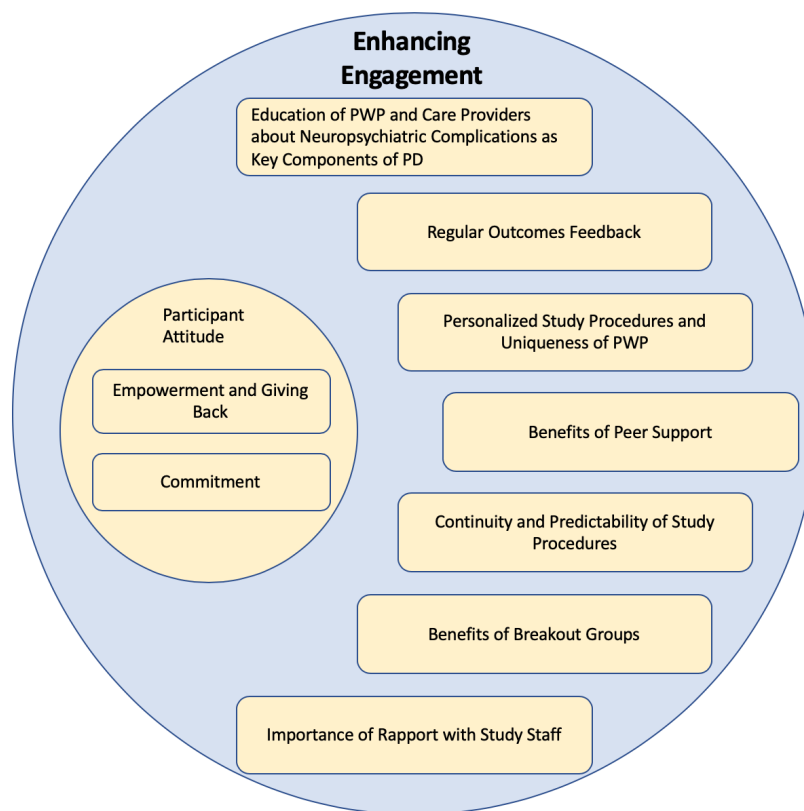


Figure 1. Key Themes: Enhancing Engagement. This figure displays themes related to enhancing participant engagement in PD mental health clinical trials.

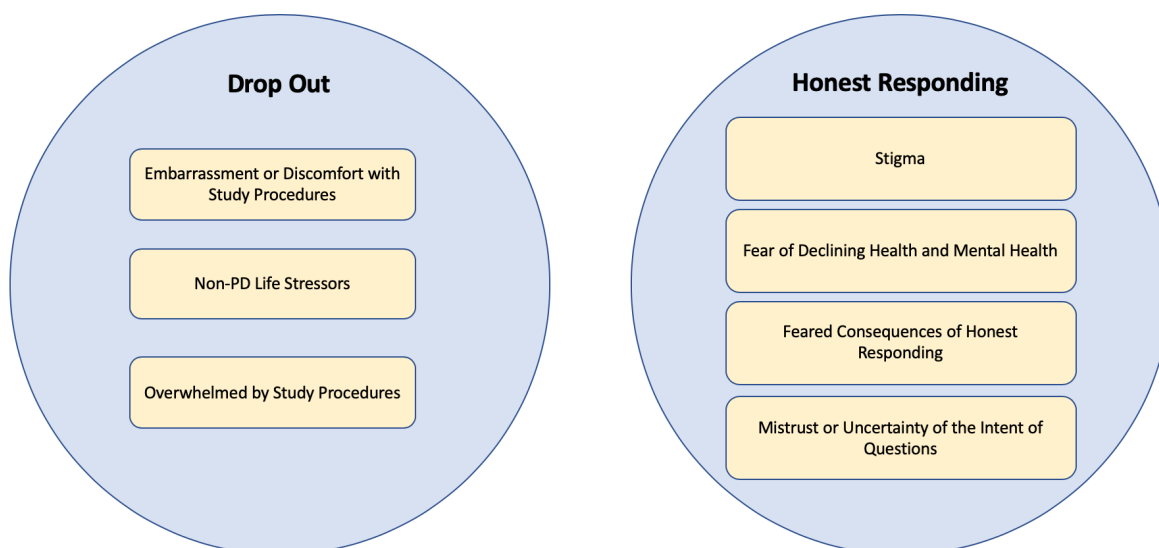


Figure 2. Key Themes: Dropout and Honest Responding. This figure displays themes related to accuracy of participant response and participant dropout in PD mental health clinical trials.

Deliverables

The results of this study included the identification of key themes related to engagement, dropout, and accurate reporting of PWP in mental health clinical trials for PD. These themes were then translated into tools, procedures, and materials as deliverables that can be referenced and applied in ongoing and future PD mental health clinical trials. Below, the potential applications of these deliverables and implications of key themes are described in greater detail.

Impact on PD Mental Health Clinical Trials

The findings and deliverables developed in this trial may be used to enhance the quality of ongoing and future PD mental health clinical trials. As attrition from clinical trials and inaccurate self-reporting may impact the validity of trials and slow progress toward of developing effective, novel interventions for addressing non-motor, neuropsychiatric complications PD, the continual improvement of tools, methods, and procedures to enhance participation in these mental health trials is crucial. Existing toolkits, such as the “Trial Resources Pack” developed through the Parkinson’s Disease Education Consortium aim to equip researchers to effectively use best practices and tools to improve recruitment and retention in clinical trials. However, the results of this study suggest that mental health clinical trials face unique challenges and barriers to recruitment, retention, and accuracy of participant self-report. Thus, the hope is that the aforementioned deliverables will be applicable to addressing these unique challenges and may inform the modification of existing gold-standard research tools.

Enhancing Engagement

Research has suggested that level of trust between patients and providers, altruism, and personal health benefits are the key domains impacting the decision of PWP to take part in clinical trials generally (Picillo, Kou, Barone, & Fasano, 2015). The results of this study

indicated that these factors affect also impact the decision-making processes of PWP regarding PD mental health clinical trials. Similarly, barriers to PWP participation clinical trials generally, such as transportation difficulties, cognitive impairment, or lack of trust in the provider or institution (Picillo, Kou, Barone, & Fasano, 2015), were also observed in this study. However, this study provided additional insight into factors that uniquely affect participation of PWP in PD mental health clinical trials.

Educating PWP and care providers about neuropsychiatric complications of PD.

The results of this study suggested that the neuropsychiatric complications of PD, including increased symptoms of depression and anxiety, often go undetected or are misattributed by PWP and their providers in early stages of disease progression, thereby directly impacting the number of PWP who may consider participating in mental health interventions. Moreover, neuropsychiatric complications such as depression are often not understood as core features of PD despite evidence suggesting that PWP experience depression at significantly higher rates compared to other groups (Tandberg, Aarsland, & Cummings, 1996) and that depressive symptoms often emerge before motor symptoms by several years (Leentjens, Van den Akker, Metsemakers, Lousberg, & Verhey, 2003). This lack of awareness contributes to sub-optimal assessment and treatment of dPD and other non-motor symptoms; thus, it is crucial to continue improving education of PWP and PD care providers so that these core, non-motor symptoms receive equal attention and management as motor symptoms (e.g., tremor, rigidity).

Education of providers and PWP about these common non-motor symptoms of PD was commonly identified by participants as an effective way to increase knowledge amongst PWP and to increase the likelihood that they will consider mental health treatment options. Veterans with PD in this study particularly indicated that their VA providers often lacked knowledge

about how to diagnose PD, neuropsychiatric complications of PD, and relevant mental health interventions and clinical trials for PWP with depression or other psychiatric problems.

However, this need for education extends beyond VA healthcare settings, and this study suggests that significant efforts to better educate providers, PWP, and the broader PD community would help to increase interest and engagement in PD mental health clinical trials, thereby increasing the accessibility and effectiveness of specific mental health treatments for PWP (e.g., telehealth psychotherapy, cognitive behavioral therapy for dPD).

Additionally, the use of peer support was identified as useful means of increasing awareness of non-motor symptoms of PD, educating PWP about treatment options, and supporting continued engagement in mental health clinical trials. A peer-to-peer ambassador role such as the one developed and discussed in this present study may be effective if applied in efforts to spread awareness of neuropsychiatric complications of PD and mental health clinical trials by partnering with community care providers (e.g., VA hospitals) and existing PD community resources (e.g., support groups).

Researchers and clinicians with expert knowledge about neuropsychiatric complications of PD also have a role to play in efforts to educate PWP and their providers about neuropsychiatric complications of PD. They can support overall recruitment efforts by seeking out opportunities to train and educate providers about PD diagnosis, common mental health concerns, and ways that providers can facilitate engagement of their patients in clinical trials; and they may also offer PD community workshops or events to spread awareness,

Furthermore, newsletters and testimonials connected with PD mental health clinical trials would also likely help increase awareness of trials in the community. This study suggests that testimonials that are authentic, relatable, and delivered in multimedia formats are likely to be

engaging to PWP at various levels of interest in mental health clinic trials. Mental health and mental health treatment were identified as topics associated with significant stigma, and likewise testimonials of PWP directly addressing this stigma may help researchers in their recruitment and retention efforts for mental health clinical trials. Given the extent to which stigma impacts both recruitment and retention efforts in PD mental health clinical trials, it is important that researchers utilize the power of testimonials of PWP and of employing creative, multimedia newsletters to effectively acknowledge and address barriers to engagement in mental health clinical trials.

Promoting retention and reducing dropout.

Given the progressive, neurodegenerative nature of PD and the potential for decline in memory and cognitive functioning, increasing the sense of predictability and continuity is likely to support continued engagement of participants in mental health clinical trials as well. The calendar deliverable was developed as a means of providing a template for researchers to use when informing participants of all upcoming procedures, including specific dates and times for interventions (e.g., psychotherapy session) and follow-up interviews. Participants indicated that receiving assistance from research staff through conversation and through use of a calendar of events would promote retention and consistent engagement in study procedures. Given that cognitive decline is another key non-motor symptom of PD, researchers would benefit from incorporating tools or procedures in ongoing PD mental health clinical trials that are meant to help support participants in planning ahead, forming clear expectations, and to help reduce missed appointments or follow-up interviews due to confusion or forgetfulness.

Overall, participants endorsed a variety of attitudes and reasons that promote continued engagement and retention in clinical trials. Whether participants reported engaging in mental

health clinical trials due to a personal commitment made to the research staff, a desire to “fight back” against PD and to be empowered, or a clear sense of the ways in which the trial may be of personal benefit, they noted that feeling valued and connected to the study was a motivating factor. Furthermore, inclusion of progress being made in relevant PD clinical research may promote feelings of value and hope amongst participants. Quarterly newsletters containing recruitment progress, or any early outcomes, are likely to help researchers to help their participants to feel as if they are making a meaningful contribution. The sample template of a newsletter and testimonial included with this study provides one example of how these tools may be implemented in a PD mental health clinical trial. They may be modified as needed depending on the study and may help reduce premature treatment dropout and general study attrition.

Increasing Honest Responding

The development of a preamble to self-report measures as a means of increasing the likelihood of honest responding reflected this study’s efforts to address difficulties with response accuracy in mental health clinical trials. The concept of a preamble (and the sample deliverable developed for this study) may be adapted and developed by future studies to address common participant concerns about answering questions of a personal or stigmatized nature (e.g., questions about mood symptoms) and to facilitate rapport with their interviewers. The results of this study suggest that participants who feel that they are seen as unique humans with fears and discomforts rather than as test subjects are more likely to respond accurately or to refrain from responding rather than responding inaccurately. In this way, using clear, consistent, and jargon-free language when consenting a participant and informing them of what to expect when answering self-report questions supports the likelihood that they will be more comfortable

responding honestly or elect to not respond if not feeling comfortable (rather than responding in an inaccurate way).

Additionally, use of a peer-to-peer ambassador program or break-out groups to facilitate peer support in the context of mental health clinical trials may also support honest responding. As commonly noted amongst participants in this study, reasons for inaccurate responding included fear of declining functioning, feared consequences of honesty, and stigma or discomfort with the subject matter. Studies that can successfully implement supportive peer connections that promotes normalization of these concerns while reinforcing the importance and value of honest responding are likely to increase the validity of their results. PWP are uniquely positioned to understand the experiences of fellow PWP experiencing non-motor neuropsychiatric complications of PD, and they may play a critical role in helping others to overcome the barrier that stigma represents when participants are asking to honestly disclose information about their mental health that often goes unshared or misrepresented.

This study's deliverable outlining a peer-to-peer ambassador role included specific guidelines for ensuring that peer ambassadors feel adequately trained and supported. However, additional research is recommended to complete program evaluations of peer ambassador programs implemented within active clinical trials, so that their effectiveness may be assessed and their procedures refined. Additionally, it is likely that the practical application of peer-to-peer ambassadors in a study for the purpose of enhancing the quality of patient engagement would require researchers to adequately reflect on the resources available for training and support of ambassadors, the scope of the ambassador role, and the extent to which privacy and confidentiality apply to peer-to-peer interactions.

Limitations

This study recruited 16 participants from within a primarily metropolitan area on the east coast of the United States, and participants identified primarily as white or black. It is possible that this relatively small sample size introduced biases or omitted certain significant perspectives and experiences, thereby decreasing the generalizability and external validity of this study's findings. However, key themes were identified by detecting common topics and experiences that emerged across all focus groups and individual interviews, supporting the validity of identified themes. Furthermore, deliverables were then offered back to participants for feedback and revision in an effort to 1) address any biases that influenced researchers when identifying themes and translating them into deliverables and 2) to increase the acceptability of deliverables for as broad a range of PWP as possible.

Additionally, this study only incorporated two carepartners. Thus, carepartners as a relevant group of stakeholders may not have been adequately involved. It is possible that recruiting enough carepartners in order to conduct focus groups comprised solely of carepartners would be an effective way to gain their unique perspective on what may enhance PWP participation in mental health clinical trials for PD.

Furthermore, while recruitment materials were developed to reach a wide range of PWP, including those with no previous affiliation with this study's principal investigator or her research program, the entire sample was ultimately comprised of individuals whom had previously engaged in related clinical trials or whom had voiced willingness to participate in studies associated with this principal investigator's PD mental health research program. The results of this study may have had greater generalizability and external validity had recruitment efforts focused on including PWP who had no experience with clinical trials at all or who had dropped out of mental health clinical trials. It is possible that this study's sample may have been

biased toward individuals with interest and favorable attitudes toward PD mental health clinical trials and PD research more broadly.

Conclusion

Overall, this study allowed for PWP and carepartners of PWP to provide direct input into the development of deliverables that may enhance the quality of patient engagement in mental health clinical trials. As the unique challenges of PD mental health clinical research are addressed through the continued application and refinement of research tools and procedures that promote increased validity of results, the pace at which effective and novel treatments for neuropsychiatric complications of PD (e.g., telehealth CBT for dPD) are developed and disseminated will be increased. As these effective treatments are developed and established as evidence-based, care providers for PD will be better equipped to support their patients in improving their quality of life with regard to mental health. On a broader scale, increasing the evidence base for novel, effective mental health treatments for PD may also eventually increase patient accessibility to treatments, as their insurance plans will be more likely to offer coverage, thereby incentivizing community providers to seek specialized training. As the PD mental health research community continues to enhance the validity of clinical trials, PWP are likely to directly benefit from increased access to effective, novel interventions for the neuropsychiatric complications of PD.

However, it is essential that efforts to educate PWP and their care providers regarding the neuropsychiatric complications of PD continue in community and academic settings, as lack of knowledge of the core non-motor symptoms of PD and lack of awareness of PD mental health clinical trials represent significant barriers to the advancement of effective PD-focused mental health interventions. The hope of this study is that its findings, tools, and procedures may be

distributed throughout the PD community to promote the continued development of effective assessment and treatments of neuropsychiatric complications of PD. As the significant impact of the neuropsychiatric components of PD become better understood in the PD community, it is essential that equal commitment, time, and attention be paid to completing high-quality PC mental health clinical trials for the optimization of PD care.

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Appendix A

Focus Group Discussion Guide

1. Welcome/Initial introduction

- Introduce yourself, the note-taker, and any other research staff present in the room. Thank group for volunteering to take part in important research.
- *Thank you for agreeing to participate in our research. We appreciate your willingness to be here today and to help us understand how we can improve mental health research for people with Parkinson's disease.*
- *The purpose of this research is to improve the quality and reliability of Parkinson's disease (PD) mental health research so that more effective, accessible mental health interventions may be developed and utilized by people living with PD and their family members.*

2. Privacy and Confidentiality

- *We would like to make audio recordings of these focus groups so that we can capture the group's experiences, opinions, and ideas. No names will be attached to the focus groups and the digital recordings will be kept in a locked file cabinet in a locked room. Transcriptions of our discussion will be made, but individual participants will not be linked to specific comments.*
- *If you feel uncomfortable with a particular question, you have the right to refrain from answering; and if you wish to leave the group at any point, you are free to do so.*
- *We value your privacy and confidentiality, so we ask that information shared in this group conversation be kept in this room. Please respect each other's right to confidentiality, and do not discuss content from this group after we have finished today. We'd like everyone to feel more confident being accurate and honest as possible.*
- *If you have any questions during this group or afterward, you may contact a research staff member like me or Dr. Roseanne Dobkin, the Principal Investigator for this study. Our contact information is provided in the consent form, and we can provide it to you today as well.*

3. Logistics

- *We will meet for about 1.5 hours with one 5-10 minute break halfway through our discussion.*
- *We have provided snacks (or lunch) and beverages for you, so help yourself as we talk.*
- Share the location of the bathroom and the nearest exit

4. Ground rules/Orienting

- Ask the group if anyone has participated in a focus group before. Explain that focus groups are a useful way to improve clinical research, and that they are becoming more and more common.

- *We ask that only one person speaks at a time. There will likely be times when you have something to say as someone else is sharing, but please wait until they have finished to do so. The moderator will make sure that everyone has the chance to share what's on their mind.*
- *There are no right or wrong answers, and it is okay if the group does not come to a consensus. We are just gathering information.*
- *If you have something to say, please share it regardless of how similar or different it is to what someone else has shared. We'd like to get each of your views and experiences.*
- *Please silence cell phones if possible, and refrain from having side conversations.*
- *Please keep our conversation confidential*
- *Does anyone have any initial questions or suggestions before we begin?*

5. Turn on Digital Audio Recorder

6. Introductions

- *First, I'd like us to go around the room and introduce ourselves. Please share your name and indicate if you have PD or are a caregiver for someone with PD.*

(Note to Moderator: As discussion begins, aim to allow people time to think before answering the questions and don't move on too quickly if there is silence. Use the suggested probes and questions to guide the discussion across topics of interest. Allow conversation on a particular topic to continue as long as new information is being shared, and move on once the content of what is shared begins to seem repetitive.)

7. Questions Guide

- Introductory Question:
 - *I'd like to ask you to take a moment to think about your experiences with mental health care for PD. Some of you may have participated in clinical trials or cared for someone who has, some may have received care from a mental health provider, and some of you may not have received mental health care at all. Do any thoughts or experiences come to mind? Would anyone be willing to share?*
- Guiding Questions:
 - *One topic we'd like to focus on today is understanding people's experiences of participating in mental health trials for people with PD. Specifically, we'd like to know more about reasons that people drop out of trials and reasons why they don't.*
 - *For those that have signed up for clinical trials or had a family member who did so, what was that experience like? What things did you consider?*
 - *For those who haven't been involved in clinical trials, have you or someone you care for thoughts about it? What was that experience like? What factors did you consider?*
 - *What would motivate you to take part in a mental health clinical trial?*
 - *If you have been involved in a trial, was there anything that you found helpful toward participating? (possible probes: research staff qualities, technology, reminders, incentives)*
 - *If you have not been a part of one of these trials, what would be helpful? What would make it easier for you to participate?*
 - *Is there anything that made it difficult to participate? (possible probes: time commitment, travel, research staff qualities, discomfort with intervention)*
 - *If you have not taken part in clinical trials, what do you imagine would make it difficult to do so? What kept you from participating?*
 - *Why might people drop out?*
 - *What can be done to prevent dropout?*

Take a 5-10 minute break

- *Another topic we'd like to focus on is accuracy in reporting in clinical trials. In other words, we'd like to know how to help participants in clinical trials to give accurate, unbiased responses during evaluations.*
- *What is it like for you to answer questions about your personal experiences?*
- *What is it like for you to answer questions about your mental health?*
- *Is there anything that helps you to feel more comfortable sharing? (possible probes: research staff qualities, format of interview, psychoeducation)*
- *What makes it difficult to provide complete, unbiased responses? (possible probes: stigma, wanting to please the research staff)*
- *What might help in this regard?*
- *What role might PWP and caregivers (acting as research advocates) play in addressing many of the barriers that we've discussed in today's discussion?*

- *In what way might it be feasible for PWP and caregivers to play a direct role in participant retention and improving the accuracy of participant responses?*
- *What types of strategies would be useful?*
- *What types of strategies would you be comfortable with?*
- Concluding Question:
 - Of everything we discussed today, what would you say are the most important issues regarding participation in mental health clinical trials for Parkinson's disease?

8. Conclusion

- *That concludes our focus group. Thanks for participating. This was a very useful discussion, and we hope that you found it interesting as well. Your participation is invaluable to this study, so contact us if you have any additional comments, questions, or complaints. You can speak to me after we finish meeting, or you can contact our PI for the study, Roseanne Dobkin, by email or telephone at a later time. As a reminder, what was shared today will be kept confidential, and your identity will not be connected to comments you've shared. Please remember to protect the confidentiality of your fellow group members as well.*

Materials and supplies for focus groups

- Sign-in sheet
- Extra Copies of consent forms
- Name tags/tags
- Pads & Pencils for each participant
- Focus Group Discussion Guide for Facilitator
- 1 recording device (1 backup recording device preferred as well)
- Charger/batteries for recording device
- Notebook and pens for note-taking
- Refreshments

Appendix B

MENTAL HEALTH CLINICAL TRIAL NEWSLETTER

Study Update for Participants and their Families

Issue: June 2018



Inside this Issue

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Testimonial/FAQ	Page 3

Contact

[Insert contact name]

[Insert contact number]

[Insert contact email]

OR

[Insert Study Website URL]

QUARTERLY RECRUITMENT UPDATE

Dear Valued Participant,

Our research team would like to thank you for your continued participation in this study. We recognize the commitment and flexibility required to take part in a study like this, and we truly appreciate your willingness to be a part of something that we hope will benefit the wider community of people living with Parkinson's Disease and their loved ones. In this newsletter, our goal is to keep you updated on our study's progress and to share stories of how your involvement will positively impact the Parkinson's community.

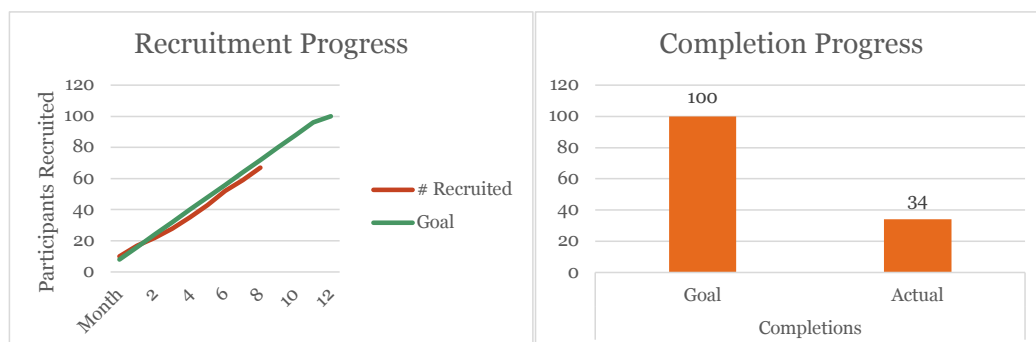
At this stage of recruitment, we are excited to share that we have recruited 64 out of 100 participants and approximately 50% of recruited participants have completed all study procedures. This is a promising milestone for the study, and we could not have done it without your contribution!

In this newsletter, you will see an updated timeline for the remaining study milestones, a brief testimonial from a participant in mental health clinical trials, and frequently asked questions. We hope that it will be informative and encouraging, and please contact us if you have suggestions for future newsletters.

Best Regards,

Study Staff

MENTAL HEALTH CLINICAL TRIAL STATISTICS



STUDY TIMELINE



DON'T FORGET!

- Inform our research staff if you make any changes to your medication regimen, including changes to dosage and adding or removing medications.
- Follow-up Interviews will be completed at one month, two months, three months, five months, and one year after your first interview
- If you ever need help mailing, scanning, or faxing self-report forms, don't hesitate to contact your research staff!

Ready to Keep Fighting



Barry's Story

When I was first diagnosed with Parkinson's Disease (PD) 10 years ago, I was completely taken by surprise; but I decided very quickly that I would try to do what I could to face this disease. I worked closely with my treatment team and set out to adapt to all the physical changes that I would face, and I was determined to fight back.

In many ways, I felt fortunate that I was still able to do many of the things that I enjoy with friends and family, including fishing, playing tennis, and walking our dog around the neighborhood. However, after a few years I couldn't help but feel like everything took more and more effort. I began to lose interest in staying proactive, and I chalked it up to being stressed about work. When I eventually retired, I thought the extra free time would help; but I couldn't help but feel like I was losing my desire to fight the disease. One day, my neurologist suggested that what I was experiencing may in fact not just be about stress, but rather depression. She let me know that a colleague of hers was currently recruiting for a clinical trial testing out a treatment for depression, and I told her I'd think about it. I had never thought of myself as someone who would become "depressed," and I wasn't sure if therapy was for me. Eventually, I agreed to participate, and looking back now I'm very glad I did.

What I didn't realize at the time was that depression is very common among people with PD, even emerging before major motor symptoms for some people. That was certainly the case for me. Participating in therapy was scary and uncomfortable at first, but it eventually made me realize that fighting this disease meant that I needed to accept help from other people sometimes. I learned about how to get the most out of each day and how recognize when PD was affecting my mood. Now I feel like I have more tools to manage when I feel tired or discouraged, and I'm ready to keep fighting.

Frequently Asked Questions

Q: When will I receive my compensation?

A: Once you finish your 9-month follow-up interview, we'll mail you a check!

Q: When is my next appointment?

A: Refer to your study timeline or call a research assistant at the number listed in this newsletter.

Q: What if I'm just too busy to participate?

A: We understand that life sometimes gets busy, and we are happy to be as flexible as possible to work with your schedule. Please give us a call!

Thank you for your participation in the [Mental Health] study!
You are making an important contribution to Parkinson's disease research.

What is the Purpose of this Document?

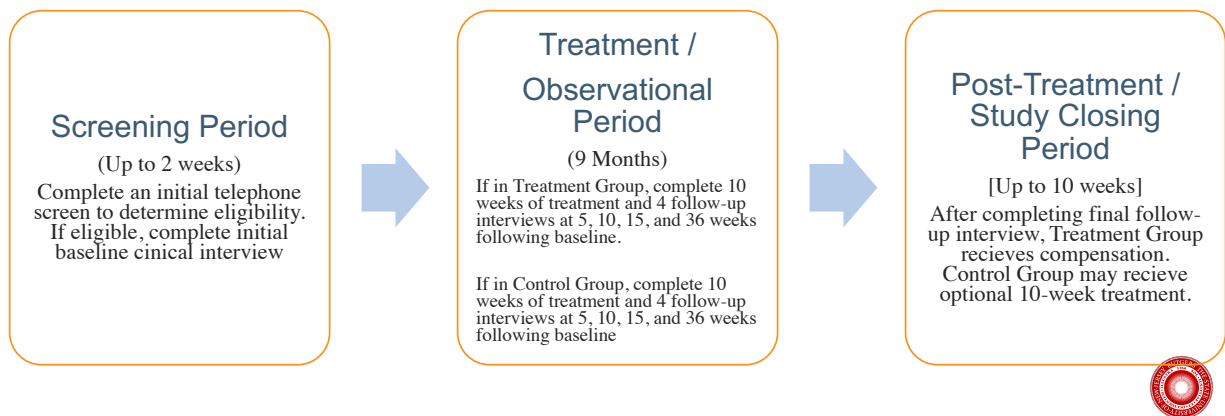
This is a calendar that provides you with an overview of the activities involved in each visit of the [Depression Treatment] study. Please use this calendar as a guide for your participation in this study. As always, our study team is here to answer any questions. Please contact [Insert Name] at [Phone/Email] with any questions or concerns.

What to Expect in this Study?

- > You will complete five follow-up interviews in total, all completed via phone call.
- > Your participation will last approximately nine months in total.
- > You will receive a 10-week telephone-based treatment for depression called cognitive behavioral therapy.
- > You will speak with your study therapist weekly while in treatment, and you will interact with another research staff member to coordinate follow-up interviews at the following time points after completing your initial interview: 5 weeks, 10 weeks, 15 weeks, 36 weeks
- > Will you will be compensated with \$XXXX upon completing all follow-up interviews.

Study Structure and Timeline

Below is a timeline outlining the stages of study participation and a description of what expect at each stage.



Peer-to-Peer Ambassador

Introduction:

Some participants have shared that interacting with peers who had taken part in mental health clinical trials for Parkinson's Disease (PD) encouraged them to consider participating themselves. While physicians and researchers may have knowledge of PD, its treatment, and available clinical trials, people living with PD are the ultimate experts; so, we have decided to include peer ambassadors as members of the research staff for this study. Below is an explanation of the purpose of peer-to-peer ambassadors, a description of the role, and a list of eligibility requirements to be an ambassador.

Purpose of Ambassador:

The primary purpose of the peer-to-peer ambassador is to enhance participant engagement in this study by acting as a liaison between research staff and participants. The ambassador will provide support, answer questions, and offer encouragements to participants from the perspective of a person with Parkinson's who has participated in clinical trials previously. Interactions between ambassador and participant are meant to promote a sense of connection and community, to reduce stigma and discomfort, to encourage honest self-report, and to provide support for those that are feeling overwhelmed.

What to Expect:

If you agree to become a peer-to-peer ambassador for this study, you may engage in any of the following activities:

- Complete initial training with a member of the research staff.
- Contact potential participants via telephone or email.
- Complete initial phone screens.
- Present the study at local PD community events, including support groups and research conferences.
- Make periodic check-in calls to participants to express desire to be contacted.
 - Discuss any concerns related to the study
 - Answer questions about the study
 - Offer support and perspective from personal experience
 - Facilitate communication between participant and other staff or Principal Investigator as needed.

Eligibility Requirements:

- Diagnosis of Parkinson's Disease
- Previous participation in mental health clinical trial or mental health treatment.

Preamble Draft – Long Version

Today we'll be completing our _____ follow-up Interview. I'll be asking questions about a variety of topics. While some questions may seem familiar and relevant to Parkinson's Disease (PD), such as questions about your motor symptoms, others may seem unexpected or less clearly related to PD. The reason we ask such questions is that PD is a complex disease, including non-motor symptoms such as depression and anxiety. Furthermore, each individual may experience PD in a different way, experiencing some symptoms more intensely than others. Asking questions that cover a variety of topics allows us to capture the full range of experiences that people with PD participating in this trial may report.

You may find some of the questions to be personal or uncomfortable and then prefer not to answer. Some participants have shared that they have been afraid that choosing to not answer a question would mean that they would not be able to take part in the study any more. We want to let you know that you are not obligated to answer questions and that there is no penalty for choosing not to respond to a particular question. You can let us know that you would prefer to skip the question or to come back to it later.

Participants have also shared that they have sometimes felt pressure to present themselves as doing better than they really are during follow-up interviews. Some have reported feeling pressure to present themselves as doing well so that the research staff will be pleased; and others have shared that they sometimes experience anxiety about declining health when answering follow-up questions, leading them to feel uncomfortable responding accurately. While these experiences are completely understandable, it is important that you answer as accurately as possible so that we can know for sure if our intervention is having an impact.

Finally, remember that there is not right or wrong answer when responding. There is not a way that you are "supposed" to respond, so feel free to be answer honestly for all questions. If you have any questions regarding the meaning or motivation of a question, please let the research staff know so that we can clarify any confusion.

Key Points:

- > **There is no right or wrong answer.**
- > **If you find a question uncomfortable, you are not obligated to answer.**
- > **There is no consequence for choosing not to answer a question.**
- > **Even if you are not feeling better, we'd like to know. We can be most helpful to you when you are honest!**

Preamble Draft

Today we'll be completing our _____ follow-up Interview.

What can you expect?

- You will be asked questions about your experiences over the past _ days, including questions about Parkinson's Disease symptoms, mood, anxiety, and other related topics.
- The interview will take approximately ____ Minutes

Key points to remember:

- **There is no right or wrong answer. The best answer is an honest one.**
- **If you find a question uncomfortable or embarrassing, you are not obligated to answer.**
- **There is no consequence for choosing not to answer a question.**
- **Even if you are not feeling better, we'd like to know. We can be most helpful to you when you are honest!**