Evaluating Participant Burden: Electronic Patient-Reported Outcome Assessment Completion Time in Clinical Trials for Parkinson's Disease

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Authors Laura Khurana, M.P.H.; Jessica Emerson, Ph.D.; Clario, eCOA Clinical Science and Consulting, Philadelphia, PA, USA

Background

- Neuropsychiatric symptoms are prevalent in patients with Parkinson's disease (PD), with up to 45% of PD patients developing depressive symptoms.[1]
- Regulators encourage safety monitoring for potential psychiatric adverse events in clinical trials, including depression.1 Thus, patient-reported outcomes (PROs) that measure HRQoL and depressive symptoms are becoming more important in clinical trials of PD treatments. Given the existing symptom and disease burden in this population, the incremental burden of clinical trial participation needs to be thoughtfully considered when incorporating PROs into PD trials.
- One measure of trial participation burden is the time needed for participants to complete required trial activities, including PROs.

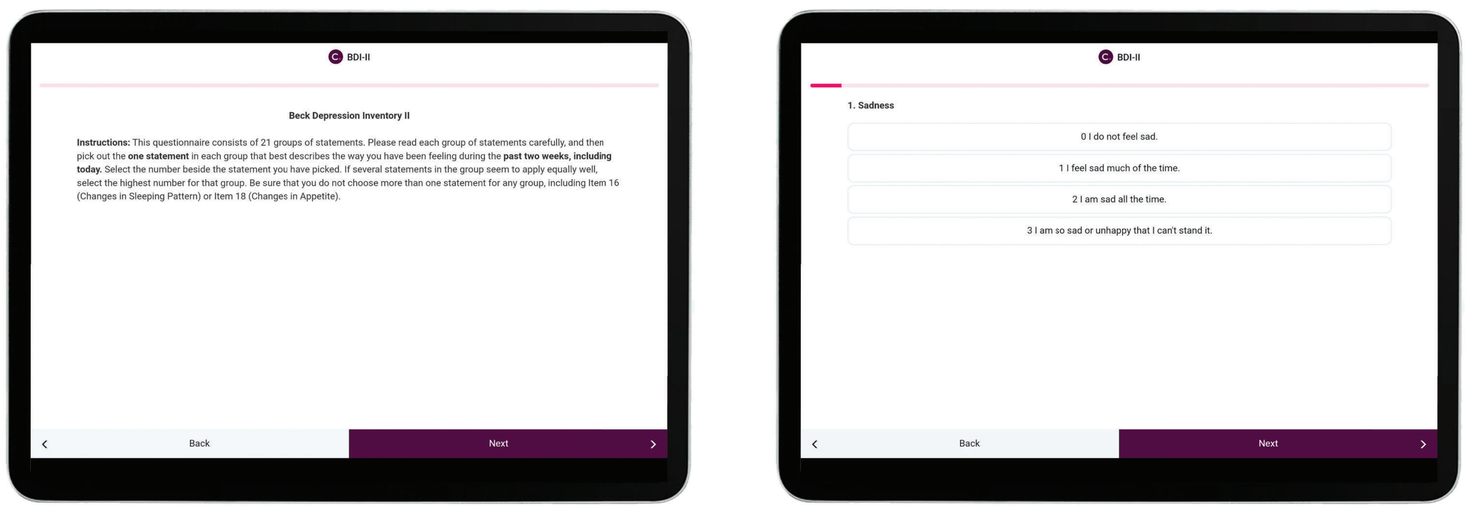
Objective

- The objective of this analysis was to explore whether PROs present a higher burden to participants with PD, compared with participants without PD, by leveraging metadata from an electronic PRO (ePRO) to examine time to completion.
- The Beck Depression Inventory – Second Edition (BDI-II) was selected; it is a 21-question PRO measure of depression severity and is commonly used in trials across many different disease areas. Estimated completion time for the BDI-II is 5 minutes.[2]

Methods

Operational ePRO metadata were analyzed to determine time to complete the BDI-II. A total of 1,639 records were analyzed; 101 records from 1 PD trial and 1,592 records from 6 non-PD trials. Each record represented one completion of the BDI-II on Clario's ePRO device (see Figure 1).

Figure 1. BDI on a Clario tablet



Results

- The 6 non-PD trials represented a variety of indications (Figure 2):
  - Osteoarthritis of the hip or knee (n=652)
  - Chronic hepatitis B (n=526)
  - Chronic low back pain (n=354)
  - Idiopathic hypersomnia (n=60)
- The non-PD trials included participants aged 18+ or 18-75 (n=6). The PD trial included participants aged 35-80 years.
- Participants in the PD trial took significantly longer to complete the BDI-II than non-PD trial participants (t=-2.0, p<.05): m=318s and 274s, respectively (Figure 3).
- Limitations of this research include the sample size; despite having over 1,600 records of data, only 101 of those records were from patients in the PD trial.

Figure 2. All studies: therapeutic areas and number of records

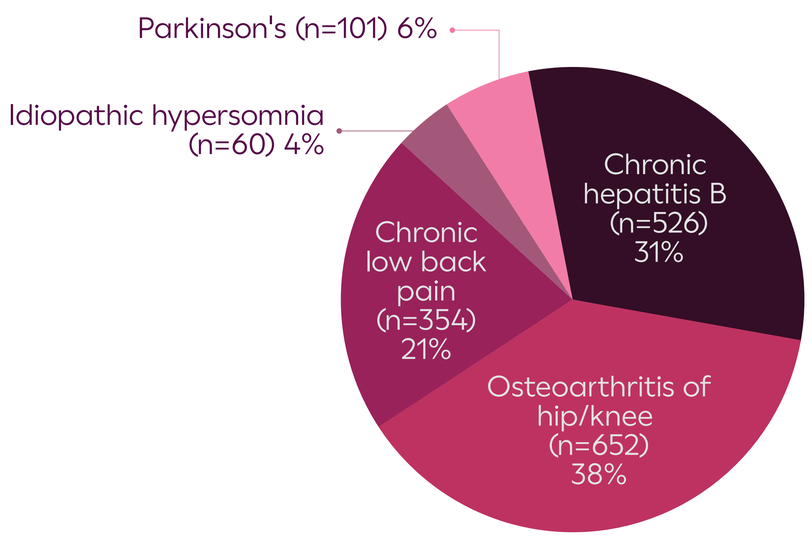
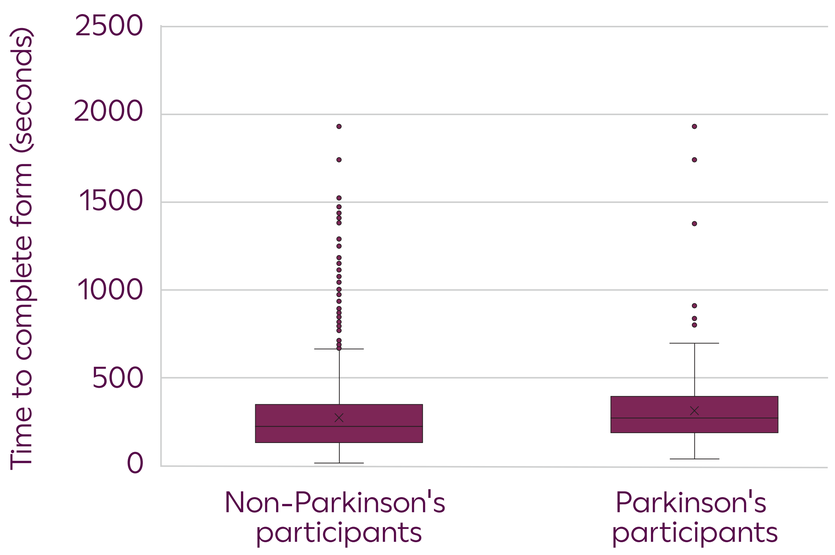


Figure 3. Time to complete the form



Conclusion

- This analysis suggests that clinical trial participants with PD take more time to complete the electronic version of the BDI-II than those without PD. This should be considered during protocol design, as the threshold for participant burden for PD trial participants may be lower than for other trial participants.
- We recommend that this analysis be replicated with PROs measuring other outcomes. To determine the extent to which these results are generalizable, this analysis should be replicated with PROs measuring other outcomes including with other patient populations with neurodegenerative diseases such as Alzheimer's disease.
- The comparative burden of other PROs measuring depression and related neuropsychiatric symptoms could be explored to help design studies that minimize the burden.

Clinical trial participants with PD take more time to complete the electronic version of the BDI-II than those without PD.

References

1. European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP). Guideline on clinical investigation of medicinal products in the treatment of Parkinson's disease. EMA/CHMP/330418/2012 rev. 2
2. https://www.pearsonassessments.com/store/usassessments/en/Store/Professional-Assessments/Personality-%26-Biopsychosocial/Beck-Depression-Inventory/p/100000159.html?tab=product-details

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