PHARMACY SYSTEMS OUTCOMES AND POLICY
COLLEGE OF PHARMACY

OFF Episode quality of Life Impact scAle (OFFELIA): Overview of the Development and Validation of a Measure of Quality of Life and Functional Impact of OFF Episodes in Parkinson's disease.

Maja Kuharic [1], Kanya Shah [1], Kent Hanson [1], Jonathan L. Nazari [1], Victoria Kulbokas [1], Ai Nguyen [1], Tara Hensle [1], A. Simon Pickard [1]

1 Department of Pharmacy Systems, Outcomes and Policy. College of Pharmacy, University of Illinois at Chicago. Chicago, IL, USA

INTRODUCTION

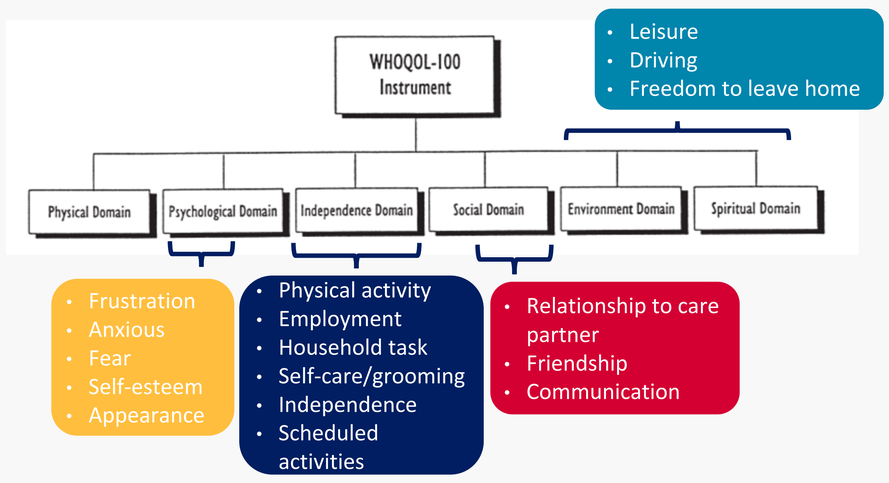
- The current standard of care for Parkinson's disease (PD) includes the use of oral carbidopa/levodopa. After years of taking carbidopa/levodopa patients may begin experiencing "OFF episodes", known as the re-emergence or worsening of PD symptoms (motor and non-motor) otherwise controlled by carbidopa/levodopa [1].
- "OFF-episodes" impact health-related quality of life (HRQL) and daily functioning in Parkinson's disease patients [2].
- Previous research has shown that commonly used patient-reported outcome assessments in PD may not adequately capture the impact of OEs on HRQL and associated functional impacts and disability [3].

OBJECTIVES

- This study aimed to **develop an instrument for measuring the impact of OFF Episodes on QOL and daily functioning in patients with PD (OFFELIA)** by examining the psychometric performance of candidate items, their reliability and validity in terms of the ceiling and floor effects, convergent validity, and the ability to discriminate among patients with various levels of OE severity.

METHODS

1 Conceptual model and identifying domains [4]

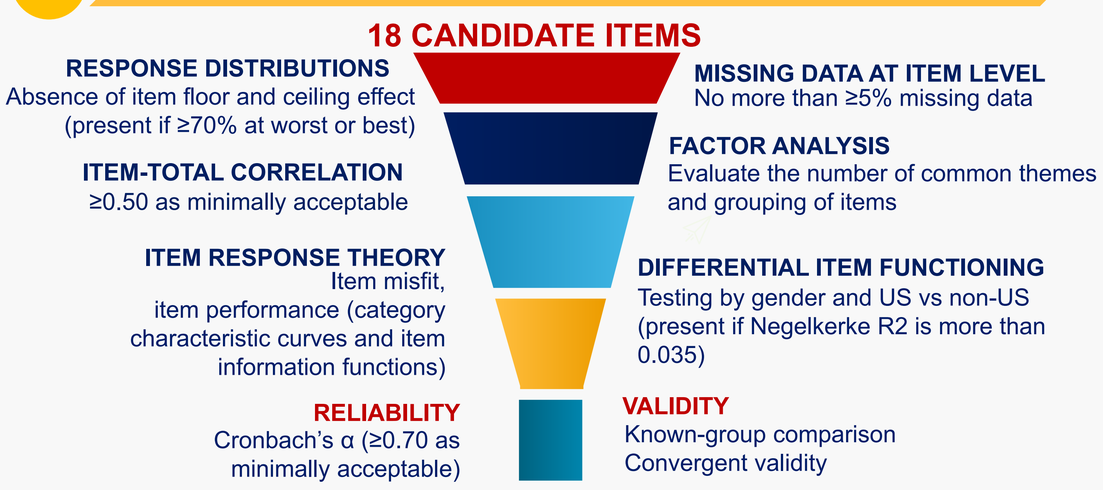


2 Item content and generation of candidate items [5,6,7]

The questionnaires were pilot tested by several patients with PD and their care partners from the practice of one of the physicians and several neurologists to ensure comprehension and content coverage.

3 Gather patient input and item improvement

4 Psychometric testing [8]



4 Item selection

REFERENCES

1. 2. Schrag A, Quinn N. Dyskinesias and motor fluctuations in Parkinson's disease. A community-based study. Brain. 2000;123 (Pt 11):2297-2305. doi:10.1093/brain/123.11.2297
2. Rahman, S., et al., Quality of life in Parkinson's disease: the relative importance of the symptoms. Movement disorders: official journal of the Movement Disorder Society, 2008. 23(10): p. 1428-1434.
3. Kerr, C., et al., Health-related quality of life in Parkinson's: impact of 'off' time and stated treatment preferences. Qual Life Res, 2016. 25(6): p. 1505-15.
4. Bonomi, A.E., et al., Validation of the United States' version of the world health organization quality of life (WHOQOL) instrument. Journal of clinical epidemiology, 2000. 53(1): p. 1-12.
5. Armstrong, M.J., et al., Impact of Off Periods on Persons With Parkinson Disease and Care Partners: A Qualitative Study. Neurology: Clinical Practice, 2021. 11(3): p. e232-e238.
6. Armstrong, M.J., et al., The experience of off periods: Qualitative analysis of interviews with persons with Parkinson's and carepartners. Clinical parkinsonism & related disorders, 2019. 1: p. 31-36.
7. Rastgardani, T., et al., Communication about OFF periods in Parkinson's disease: a survey of physicians, patients, and carepartners. Frontiers in neurology, 2019: p. 892.
8. Cappelleri, J.C., J.J. Lundy, and R.D. Hays, Overview of classical test theory and item response theory for the quantitative assessment of items in developing patient-reported outcomes measures. Clinical therapeutics, 2014. 36(5): p. 648-662.

RESULTS

- 569 individuals with PD completed the cross-sectional questionnaire "Impact and Communication on OFF Periods" while enrolled in Fox Insight, the data from, which was used to develop OFFELIA (Figure 1, Figure 2).
- The distribution of responses of 18 candidate items did not suggest floor or ceiling effects, except for a floor effect to the "Employment" item. Exploratory factor analysis identified two factors: first factor (13 items) represented functioning and the second factor (5 items) represented psychological well-being.
- Cronbach's alpha was 0.94 for Factor 1 and 0.89 for Factor 2, indicating an acceptable internal consistency level. The corrected item-total correlations were all above the minimum acceptable level of rho≥0.5, except for item "Employment" (rho=0.47)
- Item response theory results indicated that the response levels of most of the items were ordered and provided sufficient information to the overall measure, except Employment item. Differential item functioning results were classified as negligible.
- Overall, 15 items worked well, 2 items had mixed evidence, and 1 item performed poorly (employment). resulting in the 17-item measure with two main subscales: functioning (12 items) and psychological well-being (5 items). All results presented in Table 1.

Figure 1. Population Flow Diagram

Table 2. Respondent demographic and summary characteristics

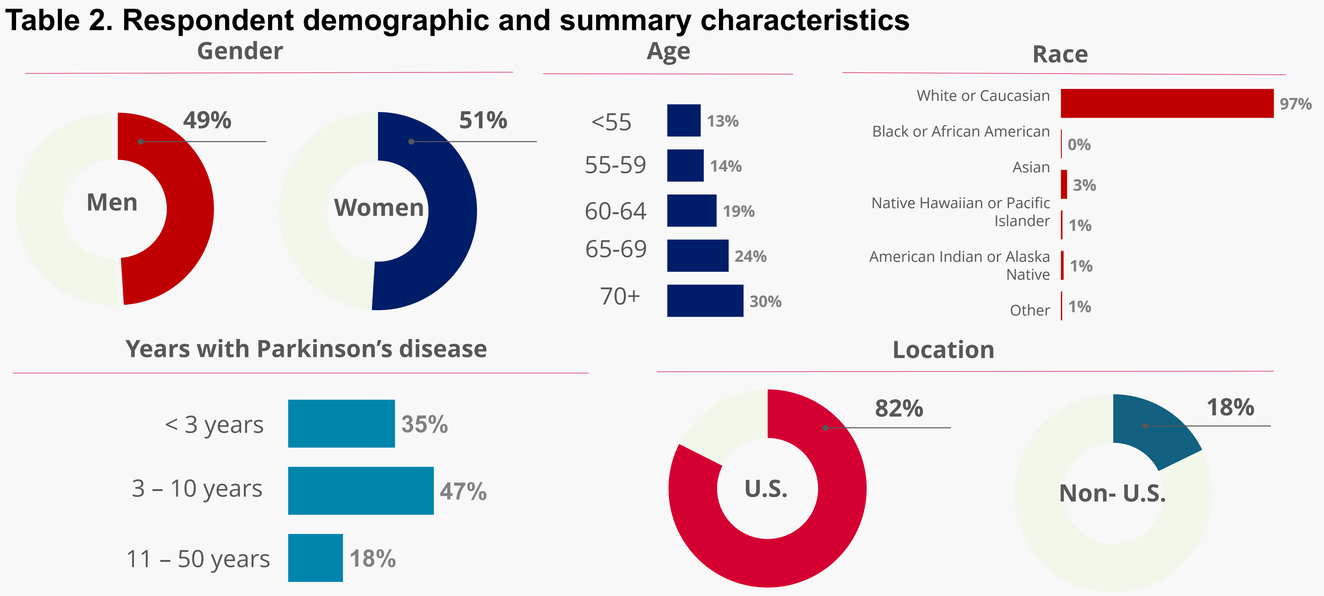


Table 1. Summary of psychometric analyses

Item Label	Distribution (Floor/Ceiling)	Missing data	Item-total Correlation	IRT (ordered)	IRT (misfit)	DIF (Sex)	DIF (Country)
FUNCTIONING (FACTOR 1)	How much are each of the following aspects of YOUR life impacted by OFF episodes? (Response scale 1-5; 1 = no impact, 5 = severe impact)						
Daily life	✓	✓	✓	✓	×	✓	✓
Physical activity	✓	✓	✓	✓	✓	✓	✓
Leisure/hobbies	✓	✓	✓	✓	✓	✓	✓
Employment	×	✓	×	×	×	✓	O
Relationship to care partner	✓	✓	✓	✓	✓	O	✓
Friendship	✓	✓	✓	✓	✓	O	✓
Household tasks	✓	✓	✓	✓	✓	O	✓
Driving	✓	✓	✓	O	✓	✓	✓
Self-care/grooming	✓	✓	✓	✓	✓	O	✓
Independence	✓	✓	✓	✓	✓	✓	O
Communication	✓	✓	✓	✓	✓	O	✓
Freedom to leave the home	✓	✓	✓	✓	✓	O	✓
Scheduled activities	✓	✓	✓	✓	✓	O	✓
PSYCHOLOGICAL WELL-BEING (FACTOR 2)	Rate level of agreement with following statements (Response scale 1-5; 1 = strongly disagree, 5=strongly agree)						
Frustration	✓	✓	✓	✓	✓	O	✓
Anxious	✓	✓	✓	✓	✓	✓	✓
Scary	✓	✓	✓	O	✓	✓	✓
Self-esteem	✓	✓	✓	✓	✓	O	✓
Embarrassed	✓	✓	✓	✓	✓	✓	✓

✓ Acceptable O Mixed Results × Not acceptable

CONCLUSION

- Initial evidence supports the validity and reliability of OFFELIA, a new instrument for evaluating the impact of OFF Episodes on quality of life and functioning in people with PD.
- OFFELIA demonstrates its potential to better capture impact of OFF Episodes and clinical benefits of new and existing therapeutic strategies. It can help clinicians assess the impact of OFF episodes and be essential to outcome measures in clinical trials to understand the potential value of interventions aiming to reduce OFF episodes.
- As such, OFFELIA presents a meaningful addition to existing QOL measures to improve patient-centered care and quality of life in people with PD and their caregivers.

"The Fox Insight Study (FI) is funded by The Michael J. Fox Foundation for Parkinson's Research. We would like to thank the Parkinson's community for participating in this study to make this research possible."

"Data used in the preparation of this article were obtained from the Fox Insight database (https://foxinsight-info.michaeljfox.org/insight/explore/insight.jsp) on 28/03/2022 . For up-to-date information on the study, visit https://foxinsight-info.michaelifox.org/insight/explore/insight.jsp."

Scan this QR code to download a copy of the poster

UNIVERSITY OF ILLINOIS CHICAGO