Use of the Modified Functional Status Questionnaire to Assess Functioning in Patients With Parkinson's Disease Psychosis Treated With Pimavanserin

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INTRODUCTION

- Studies in Parkinson's disease psychosis (PDP) have primarily focused on hallucinations and delusions; however, patients with PDP also face nonmotor symptoms, such as depression and sleep and behavioral disturbances, which can result in functional limitations and reduce health-related quality of life¹
- Patient-reported outcomes (PROs) are increasingly being collected in clinical trials, as they provide valuable information on the real-world impact of treatments from the patient's perspective
- Accurate assessment of activities of daily living (ADLs) and function in patients with PDP is essential for better informing PDP treatment; for this purpose, the International Parkinson and Movement Disorder Society has recommended the use of the Functional Status Questionnaire (FSQ)²
- In a prior phase 4 open-label study examining the impact of pimavanserin on ADLs and function in patients with PDP (NCT04292223), we utilized a modified version of the FSQ (mFSQ) as the primary outcome measure
- In this study, a significant improvement from baseline in the mFSQ score was observed at week 16 following treatment with pimavanserin
- In this post hoc analysis, we analyzed patient response on specific subdomains within the patient-reported mFSQ and correlated these findings to the Schwab & England ADL scale

© OBJECTIVE

To assess the impact of pimavanserin on different functional domains of ADLs and function using a patient-reported tool

□→□ METHODS

- Eligible patients were adults ≥40 years of age with a diagnosis of PDP, psychosis symptoms severe enough to warrant treatment with an antipsychotic agent, a Clinical Global Impressions–Severity (CGI-S) score ≥4, a Schwab & England ADL Scale score of 40%-80% (inclusive), and a Mini-Mental State Examination (MMSE) score ≥21 at screening and baseline
- Patients entered a 16-week single-arm, open-label study in which they were treated once daily with oral pimavanserin (34 mg)
- The mFSQ is a version of the FSQ that was modified to remove the work/performance domain, as this domain was not applicable to the patients in this study
- The 5 remaining domains assessed in the study were Basic ADL, Intermediate ADL, Psychological Function, Quality of Interaction, and Social Activity
- Mean change from baseline to week 16 was evaluated for all 5 mFSQ domains
- A mixed-effects model for repeated measures (MMRM) was used to estimate least-squares mean (LSM) change
- Correlations between the observed mFSQ values and the patient- and caregiver-rated Schwab & England ADL scales were also
 evaluated across postbaseline visits using Pearson's method

RESULTS

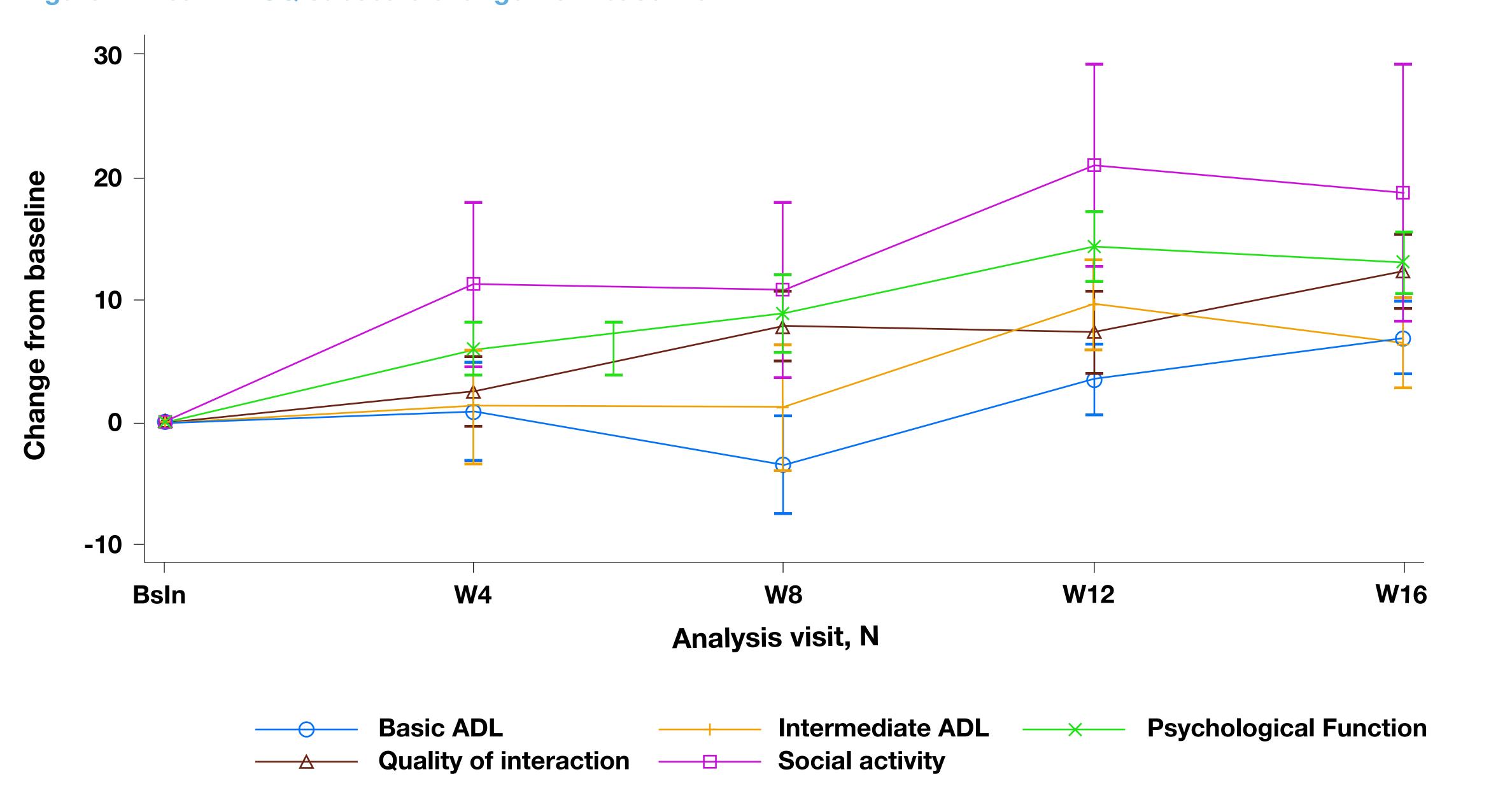
- A total of 29 patients were included in the analysis; the mean patient age was 70.2 years, 62.1% were male, 75.9%
- were not Hispanic or Latino, 51.7% had a spouse or partner as their primary caregiver, and 96.6% were living at home
- Patients' PDP were considered moderately severe at baseline; full baseline disease characteristics are listed in **Table 1**
- All mFSQ domains showed improvement at 16 weeks from baseline (**Figure 1**)
- The largest change was seen on the Social Activity subscale
- For each mFSQ domain, the LSM (SE) change from baseline to week 16 was as follows (Figure 2):
- Basic ADL (8.1 [2.41], p = 0.0031; n = 22)
- Intermediate ADL (7.0 [3.00], p = 0.0286; n = 21)
- Psychological Function (13.3 [1.94], p < 0.0001; n = 22)
- Quality of Interaction (12.3 [2.07], p < 0.0001; n = 22)
- Social Activity (25.8 [7.52], p = 0.0026; n = 18)
- mFSQ scores were strongly correlated with the Schwab & England ADL patient (**Figure 3**) and caregiver (**Figure 4**) scores; both scales showed a consistent trend of improvement among patients and caregivers
- Pearson's r values were 0.6 (p < 0.0001) for the patient's total score and 0.5 (p < 0.0001) for the caregiver's total score

Table 1. Baseline disease characteristics

| Characteristic | Pimavanserin 34 mg N = 29 |
|--|------------------------------|
| MMSE total score, mean (SE) | 24.9 (0.43) |
| mFSQ score, mean (SE) | 61.5 (2.97) |
| Schwab and England score (patient), mean (SE) | 65.4 (2.74) |
| Schwab and England score (caregiver), mean (SE) | 62.5 (2.85) |
| CGI-S score, mean (SE) | 4.1 (0.05) |
| GDS score, mean (SE) | 4.5 (0.5) |
| NPI delusions total score, mean (SE) | 4.3 (0.59) |
| NPI hallucinations total score, mean (SE) | 5.6 (0.44) |
| mFSQ – Basic ADL subscore, mean (SE) | 73 (2.88) |
| mFSQ – Intermediate ADL subscore, mean (SE) | 47.4 (5.76) |
| mFSQ – Psychological Function subscore, mean (SE) | 63.3 (2.53) |
| mFSQ – Social Activity subscore, mean (SE) | 49.4 (6.67) |
| mFSQ - Quality of Interaction subscore, mean (SE) ADL activities of daily living: CGI-S. Clinical Global Impression-Severity of Illness: GDS. Geriatric Depress | 74.3 (3.14) |

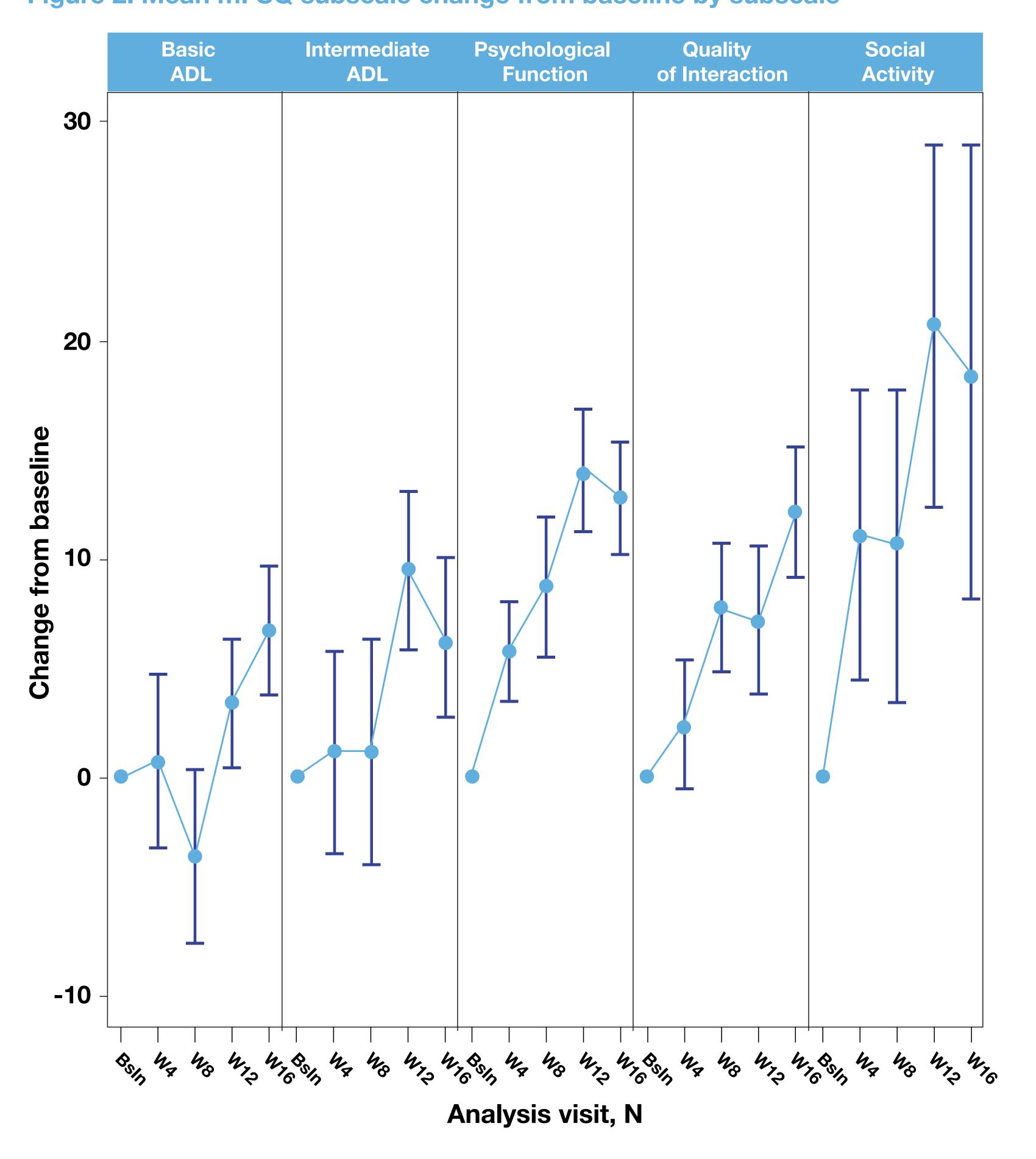
Disease Rating Scale; mFSQ, Modified Functional Status Questionnaire; MMSE, Mini-Mental Status Examination; NPI, Neuropsychiatric Inventory.

Figure 1. Mean mFSQ subscale change from baseline



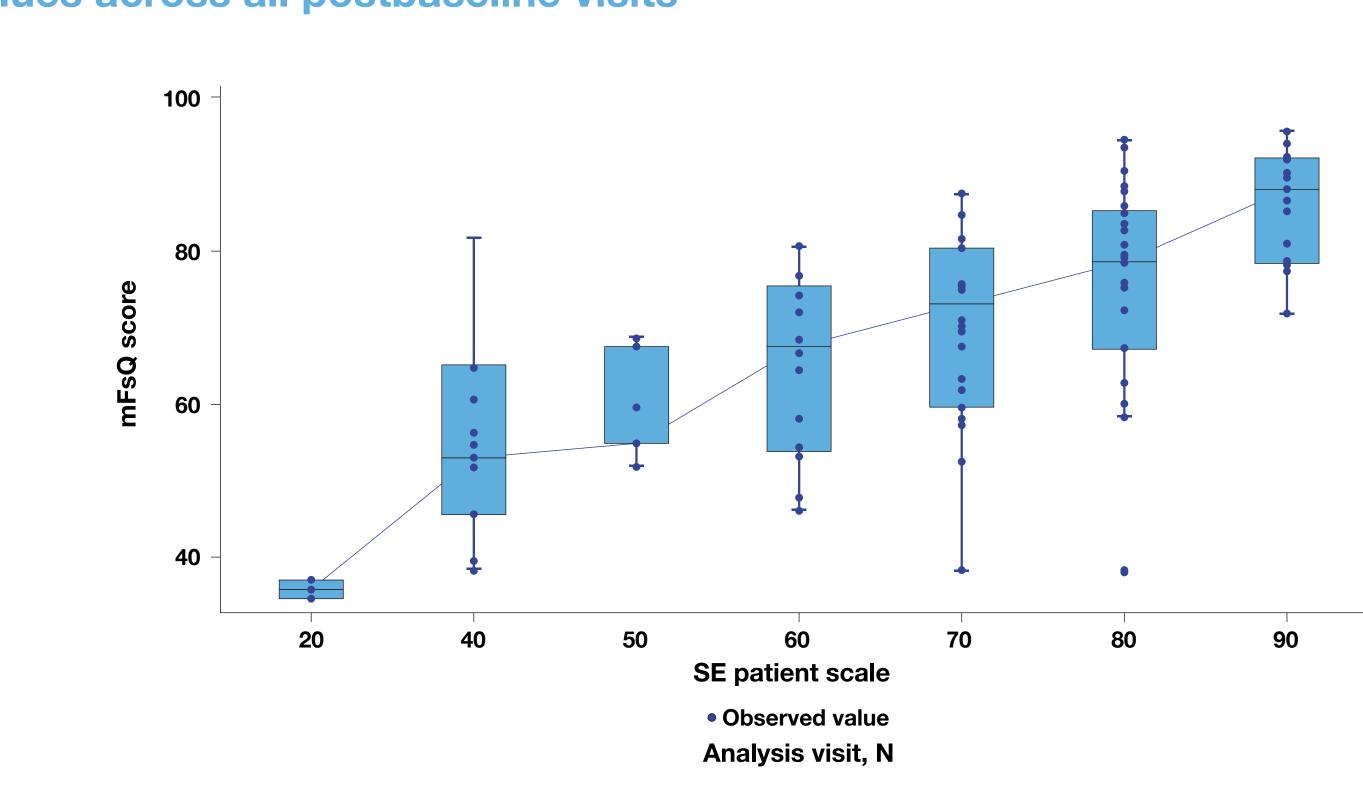
ADL, activities of daily living; Bsln, baseline; mFSQ, Modified Functional Status Questionnaire; W, week.

Figure 2. Mean mFSQ subscale change from baseline by subscale



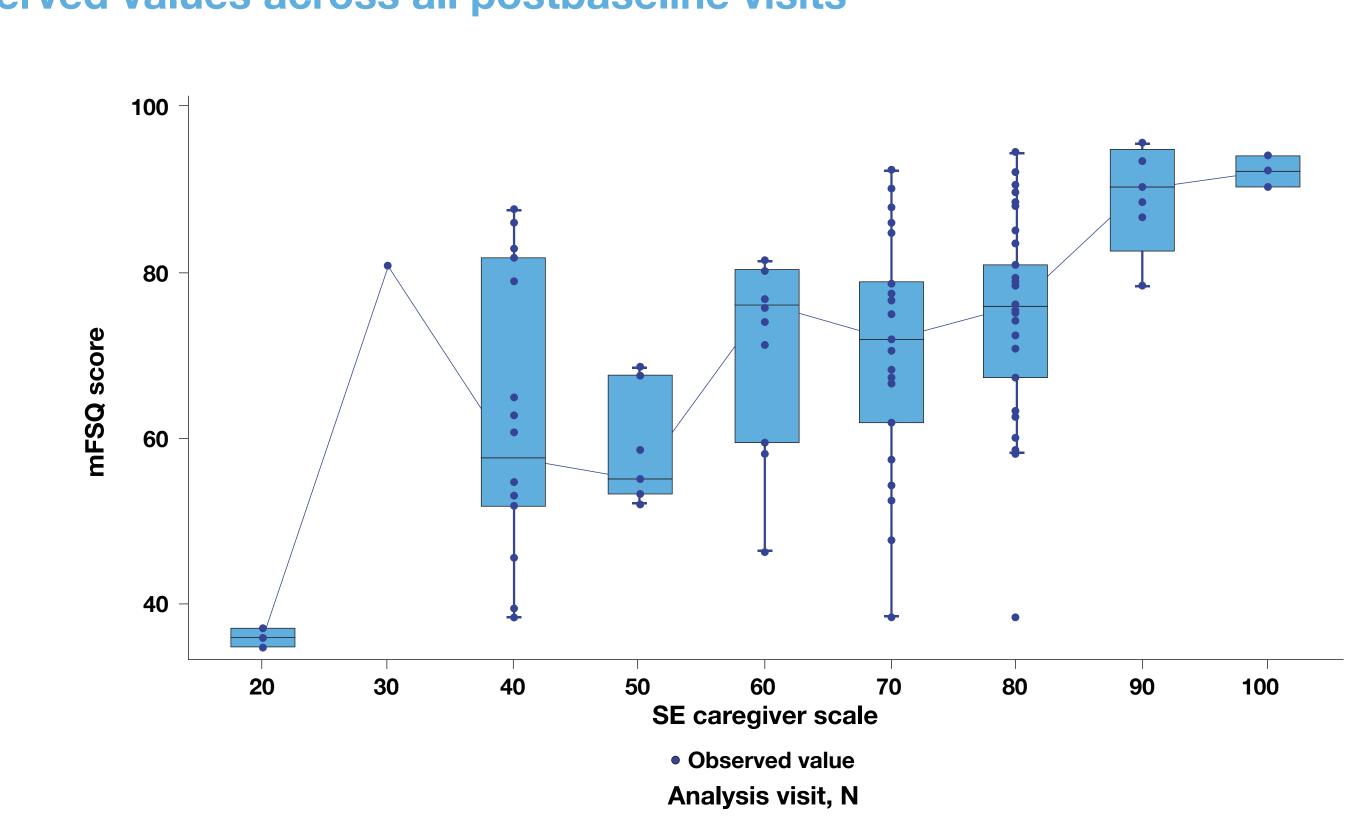
ADL, activities of daily living; Bsln, baseline; mFSQ, Modified Functional Status Questionnaire; W, week.

Figure 3. Correlation of Schwab & England ADL patient scale and mFSQ observed values across all postbaseline visits



mFSQ, Modified Functional Status Questionnaire; SE, Schwab & England ADL scale.

Figure 4. Correlation of Schwab & England ADL caregiver scale and mFSQ observed values across all postbaseline visits



mFSQ, Modified Functional Status Questionnaire; SE, Schwab & England ADL scale.

CONCLUSIONS

- In this small, open-label clinical trial, the first to utilize the mFSQ in patients with PDP, treatment with pimavanserin was associated with improvement across all mFSQ domains; the greatest improvement was seen in social activity
- Additionally, in this proof-of-concept study, the mFSQ was significantly correlated with the Schwab & England ADL, highlighting the mFSQ as a promising scale deserving of further evaluation in clinical studies testing for the reliability and validity of the scale.

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DISCLOSU

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All authors contributed to the conceptualization, design, analysis, and interpretation of this work, as well as the ctritical review of the abstract and poster.

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