

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

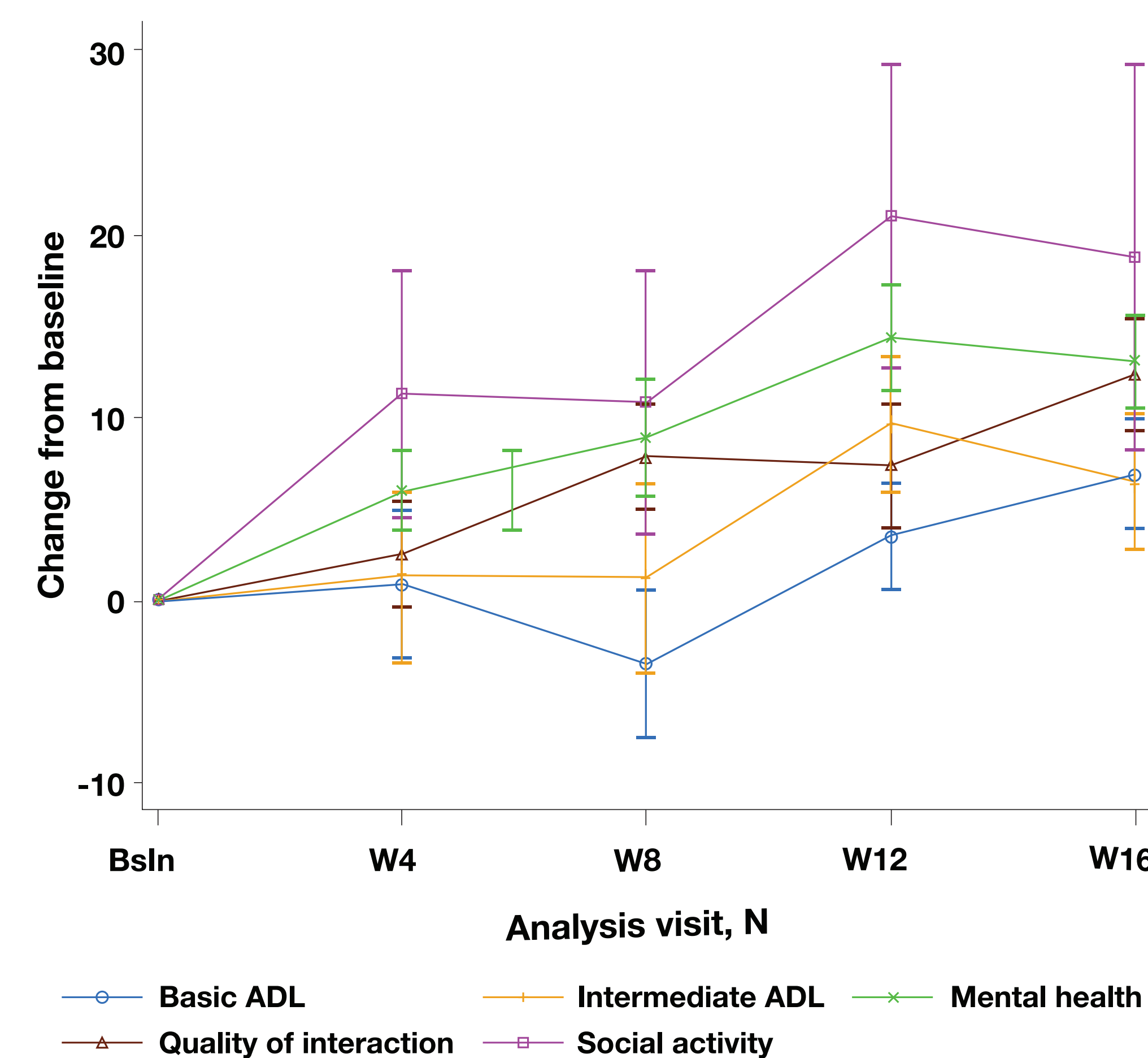
- A total of 29 patients were included in the analysis; the mean patient age was 70.2 years, 62.1% were male, 75.9% were not Hispanic or Latino, 51.7% had a spouse or partner as their primary caregiver, and 96.6% were living at home
- Patients' PDP were considered moderately severe at baseline; full 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)	74.3 (3.14)

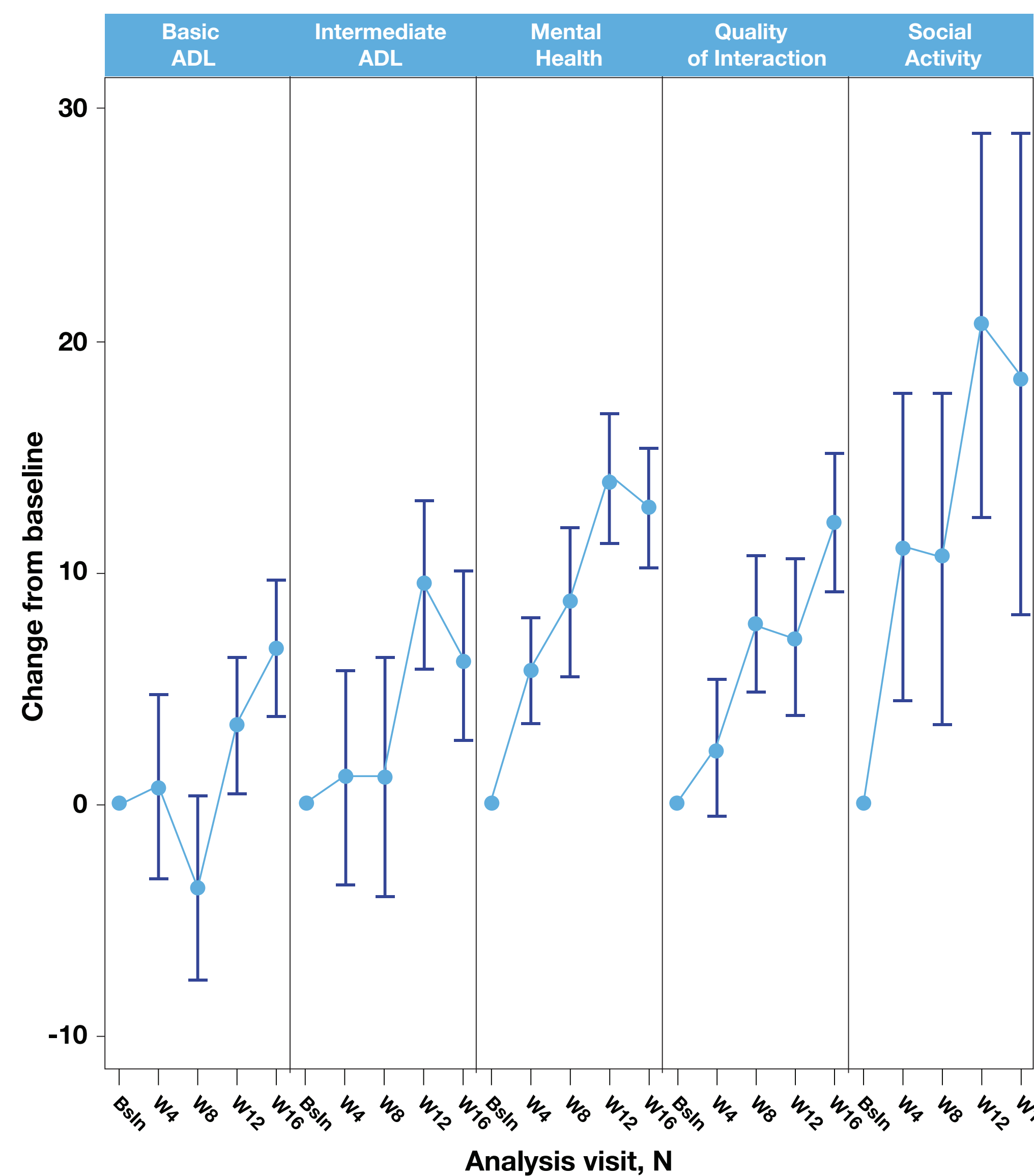
ADL, activities of daily living; CGI-S, Clinical Global Impression–Severity of Illness; GDS, Geriatric Depression Scale; MDS-UPDRS, Movement Disorders Society–modified Unified Parkinson's Disease Rating Scale; mFSQ, Modified Functional Status Questionnaire; MMSE, Mini-Mental Status Examination; NPI, Neuropsychiatric Inventory.

Figure 1. Mean mFSQ subscale change from baseline



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

Figure 2. Mean mFSQ subscale change from baseline by subscale

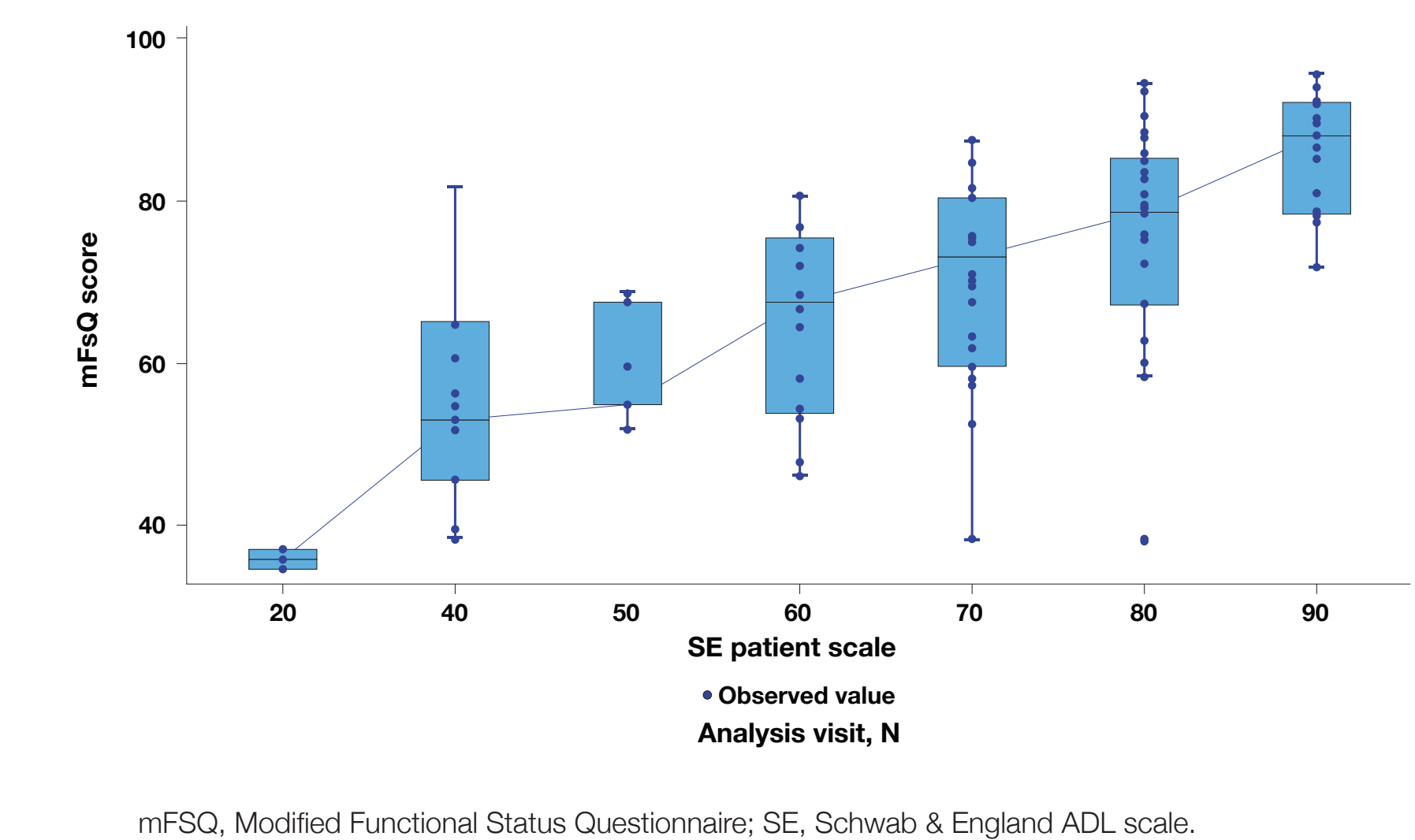


ADL, activities of daily living; Bsl, baseline; mFSQ, Modified Functional Status Questionnaire; W, week.

CONCLUSIONS

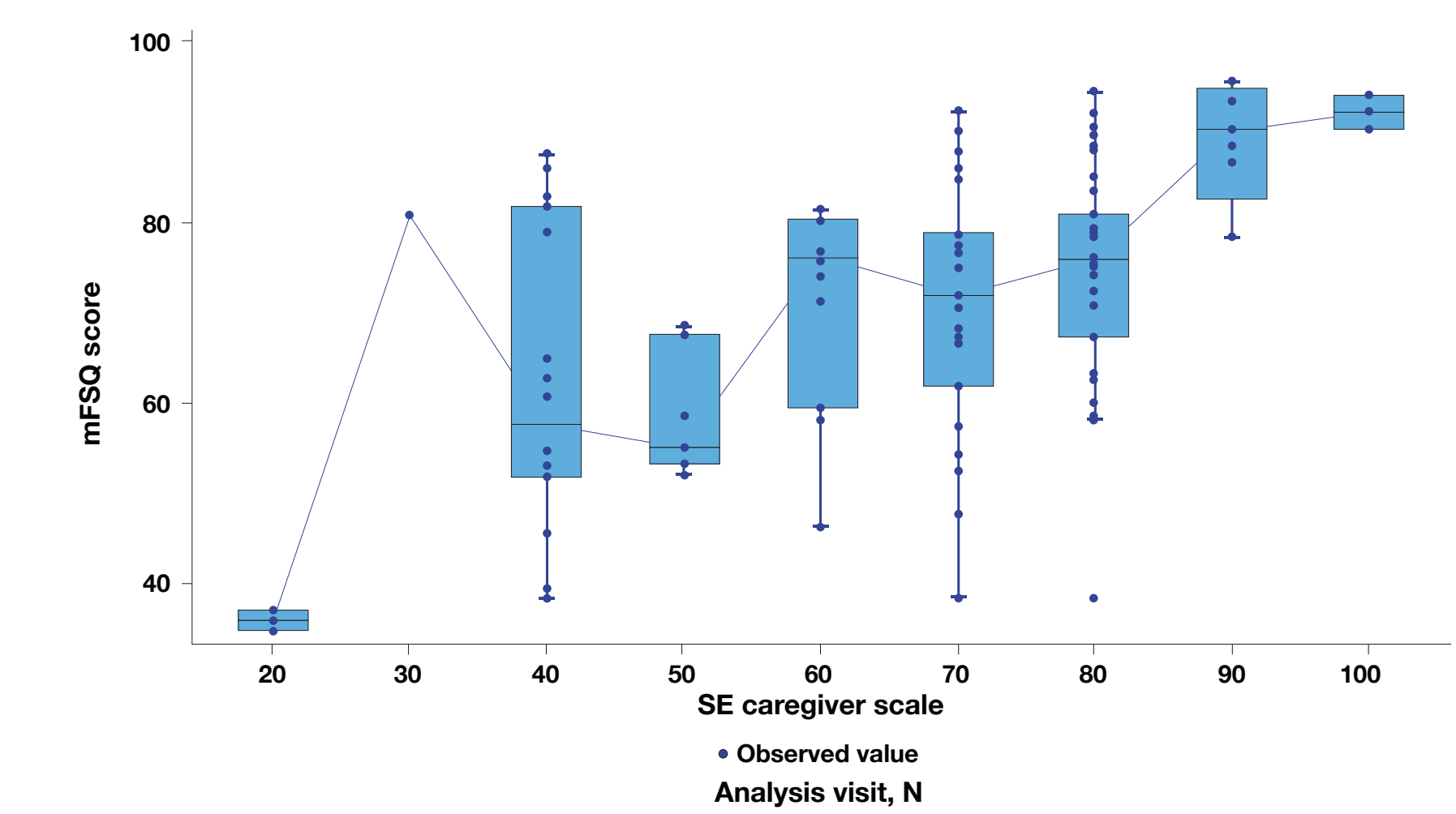
- In this small, open-label clinical trial, the first to utilize the mFSQ in patients with PDP, treatment with pimavanserin was associated with improvement across all mFSQ domains; the greatest improvement was seen in social activity
- Additionally, in this proof-of-concept study, the mFSQ was significantly 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

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.

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DISCLOSURES

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KEY CONTRIBUTORS

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

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