

Impact of subcutaneous levodopa infusion with ND0612 on patient reported outcomes

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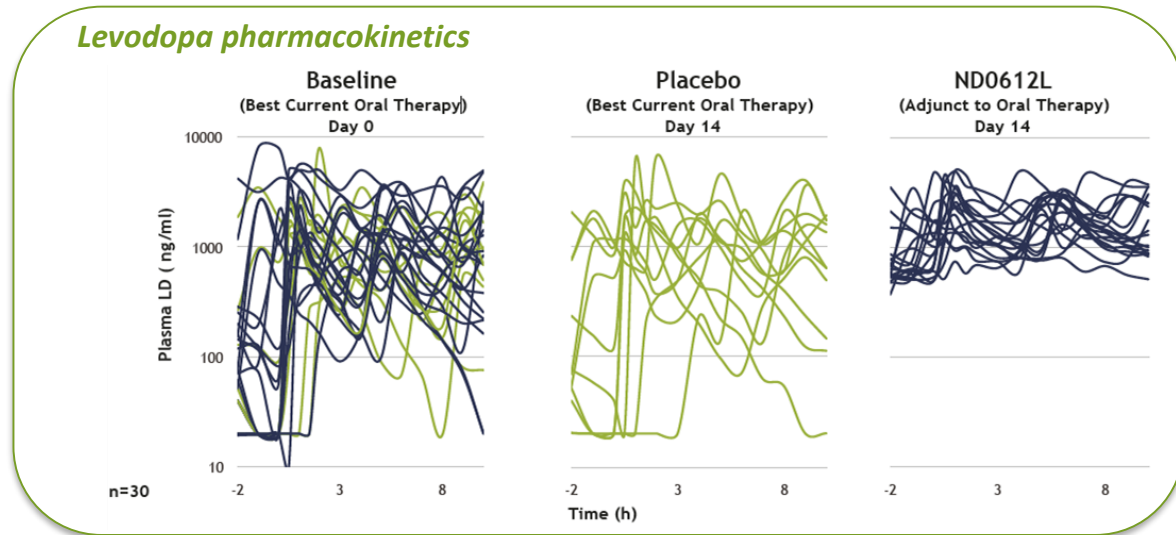
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*Aaron Ellenbogen reports fees for consultancy from **NeuroDerm**.*

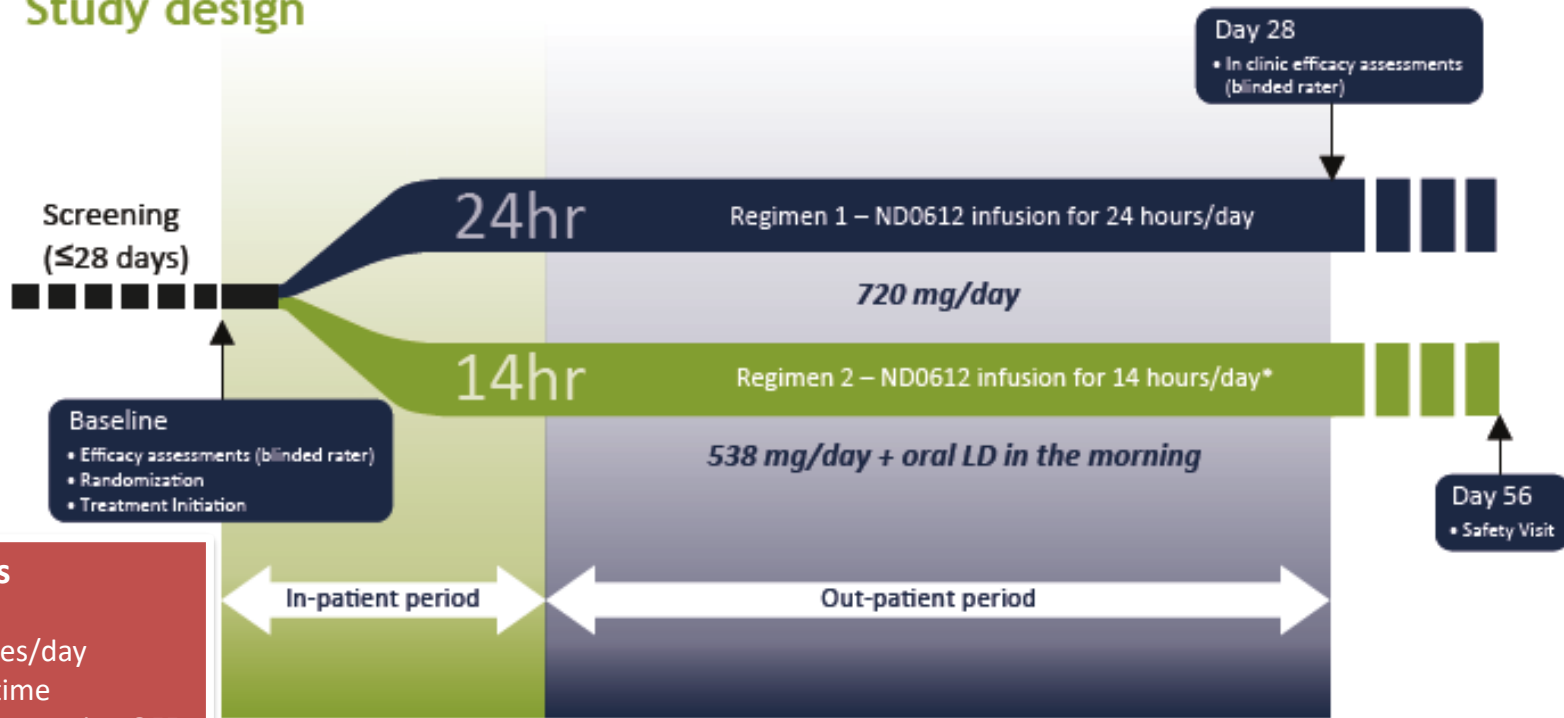
Background

- ND0612 is a drug-device combination designed to continuously deliver liquid levodopa/carbidopa (60/7.5 mg/mL) by continuous subcutaneous infusion
- Early Phase 2 studies vs. oral levodopa demonstrated:¹
 - Stable levodopa plasma levels with reduced fluctuations
 - Reduced OFF time



ND0612 Methods

Study design

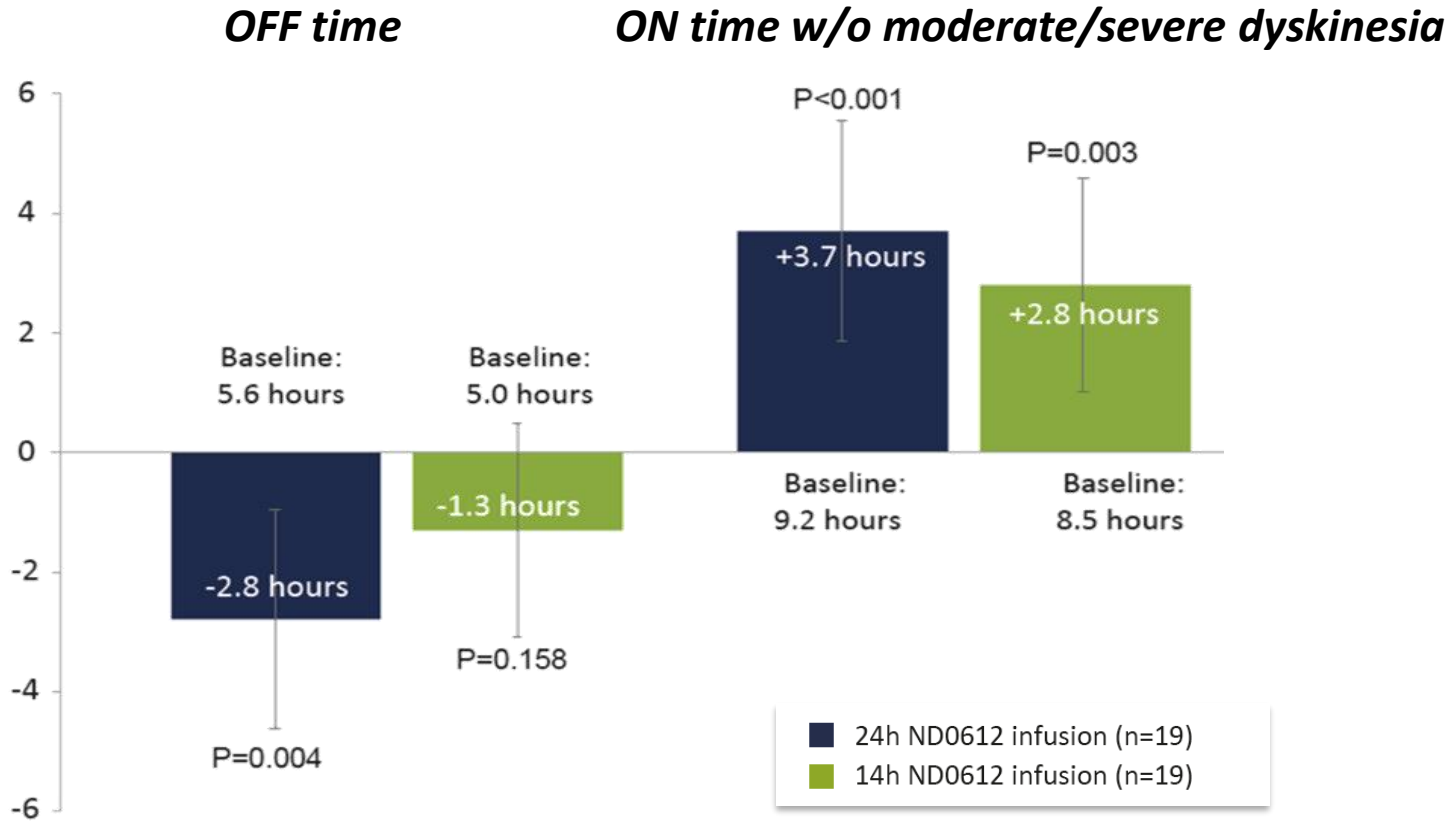


N=38 PD patients

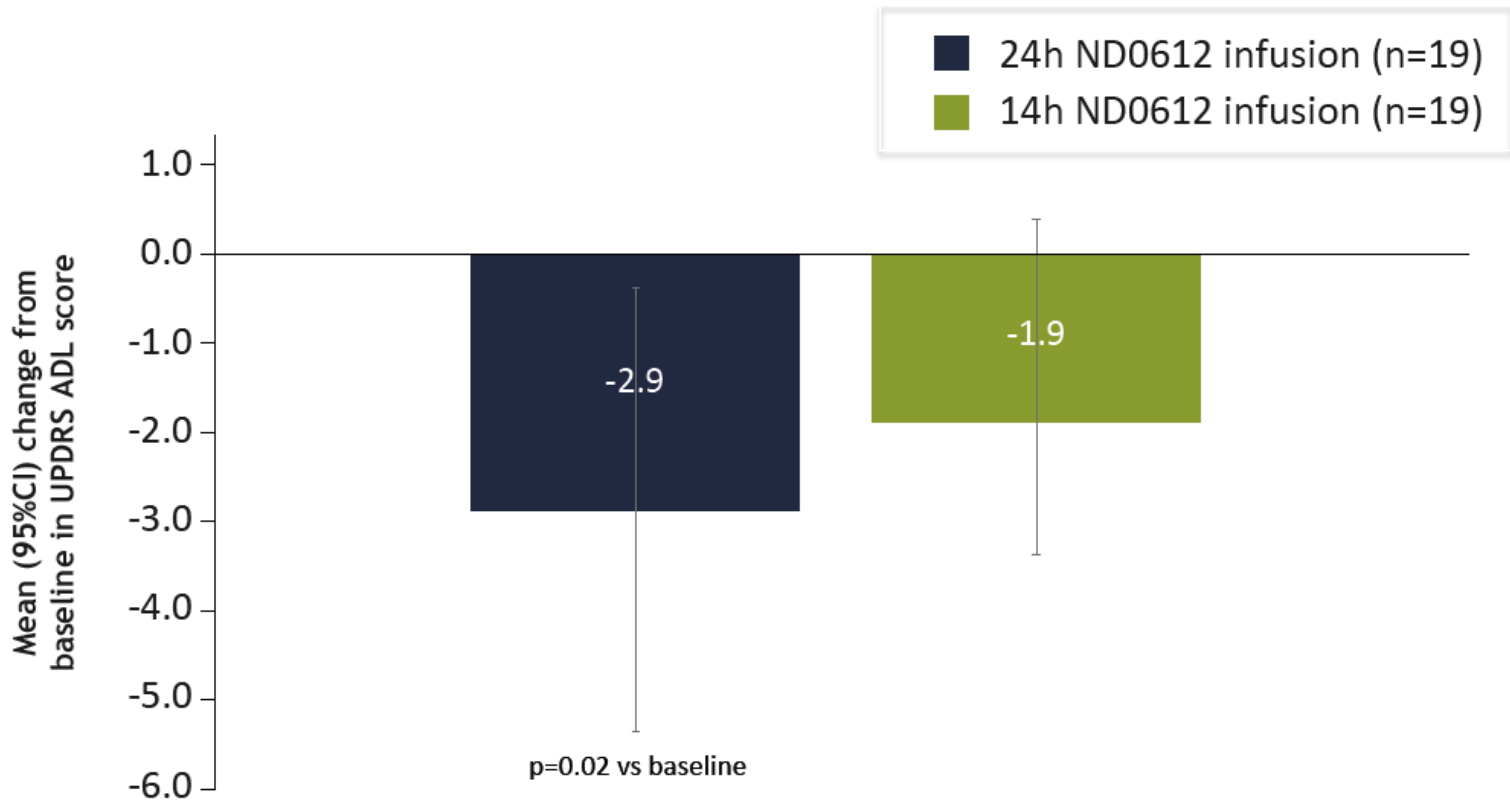
- H&Y ≤3 (ON)
- ≥4 levodopa doses/day
- ≥ 2.5h/day OFF time
- Predictable early morning OFF

* Patients who have discontinued LCIG treatment ≥6 months prior & have had closed stoma surgery may be included

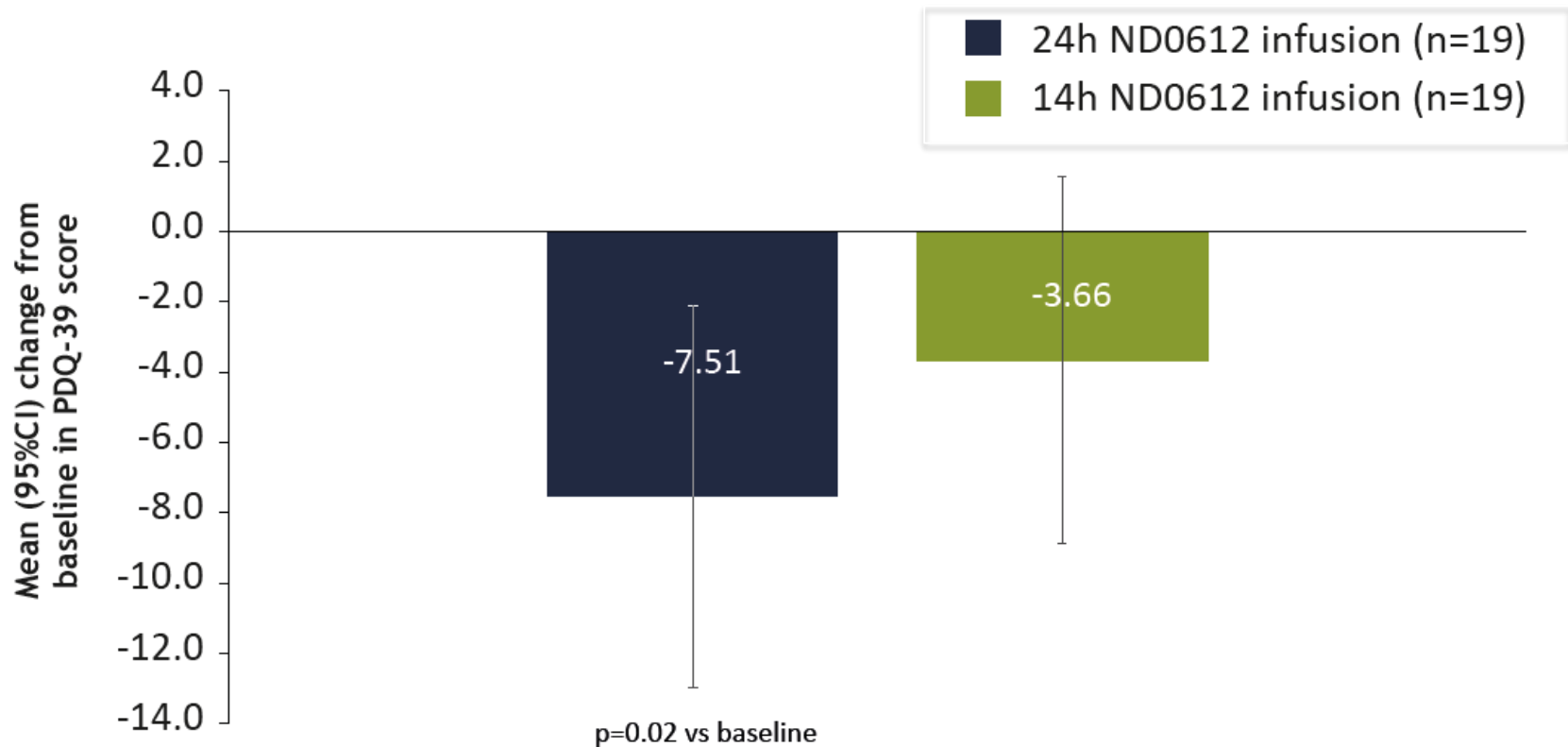
The 24h regimen significantly reduced OFF time (primary endpoint) and increased ON time without moderate-severe dyskinesia



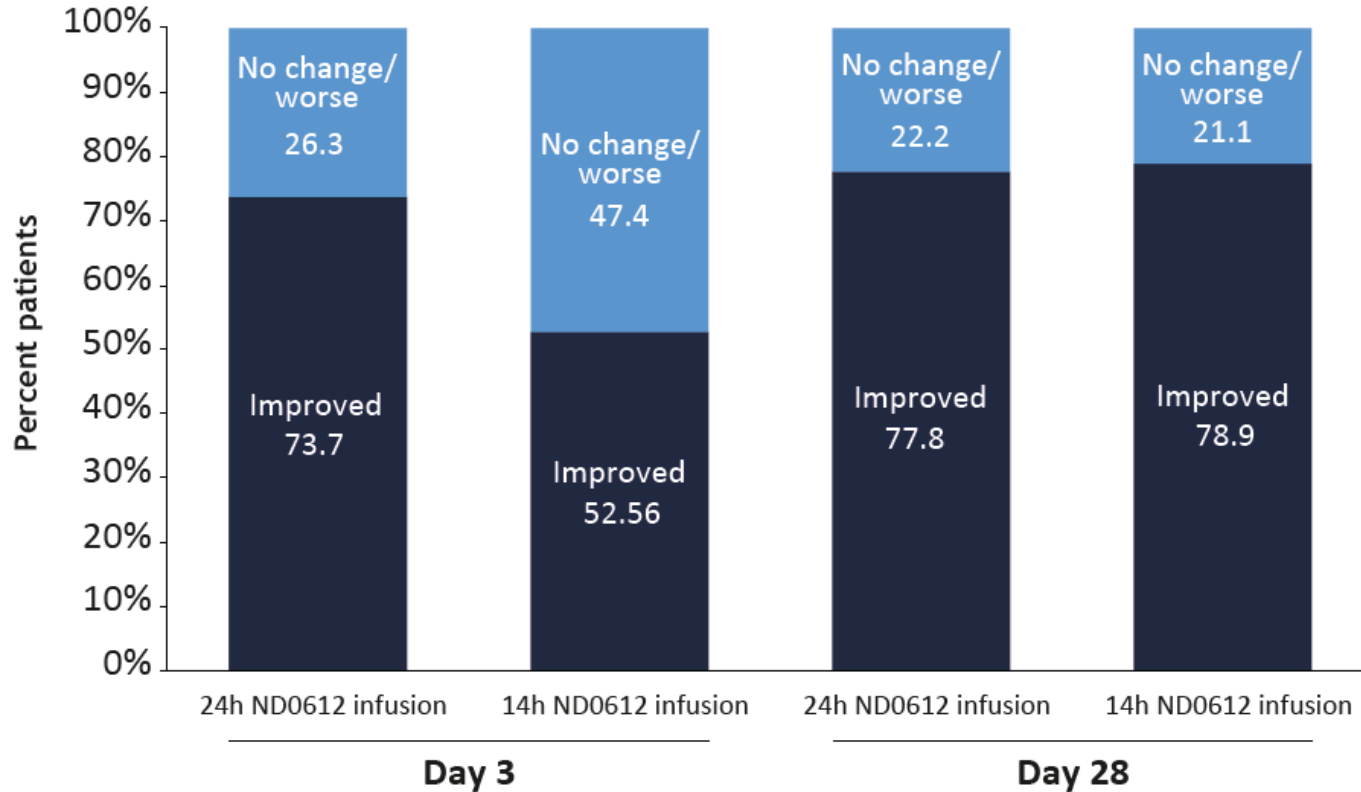
Statistically significant improvements ($p=0.02$) in activities of daily living were seen with the 24h ND0612 regimen



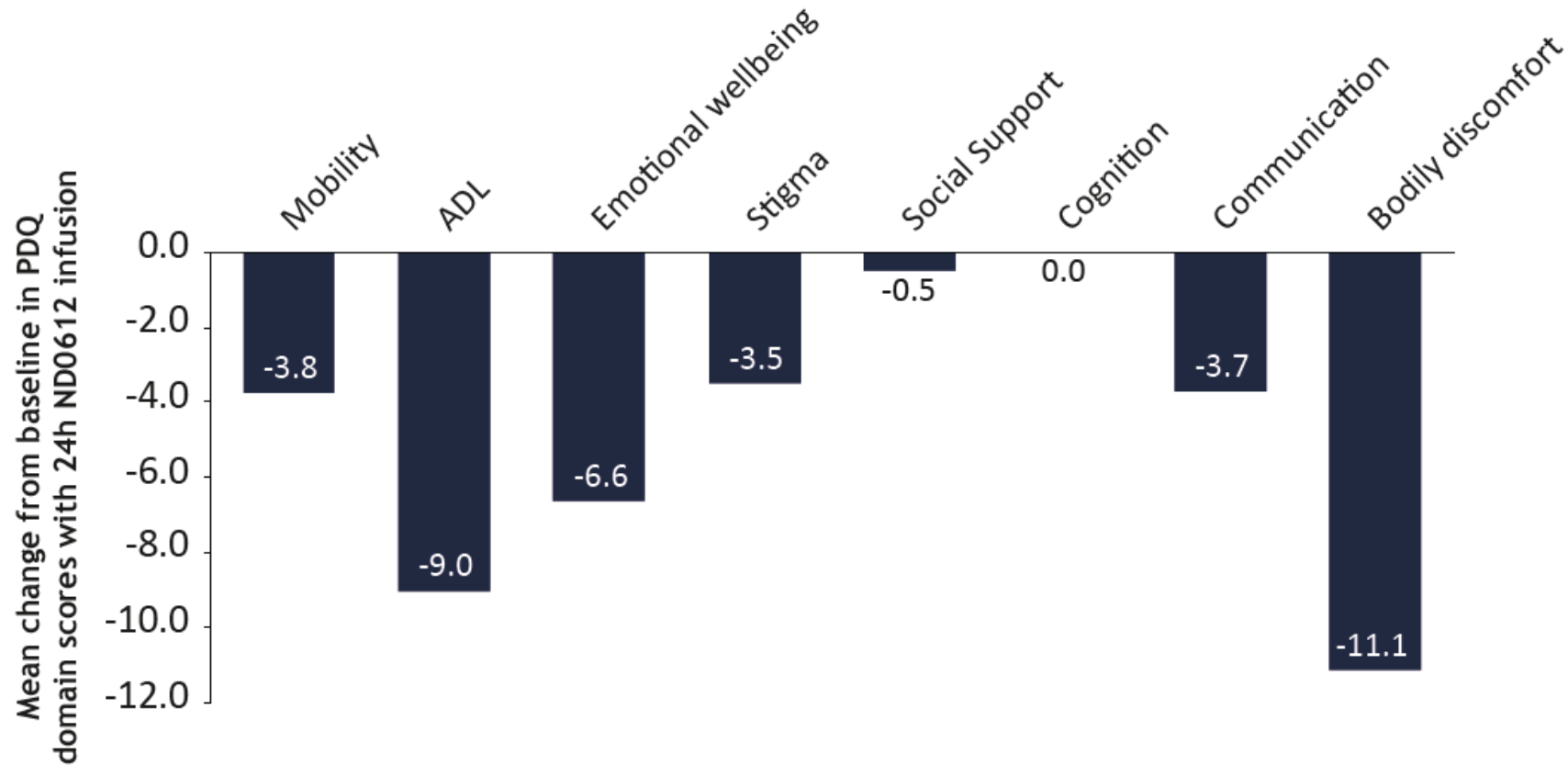
Statistically significant ($p=0.02$) improvement in quality of life with 24h ND0612 infusion



Over 70% of patients treated with 24h ND0612 infusion self-reported improvements in their clinical status already at Day 3



6 out of 8 PDQ-39 QoL domains showed improvement following 24h ND0612 infusion



Conclusions

- 24 hour, 'round-the-clock' levodopa sc infusion with ND0612:
 - reduced daily OFF time and morning akinesia and increased ON time
 - improved patient ratings of activities of daily living
 - improved patient quality of life and overall clinical status
- ND0612 may provide a minimally invasive treatment option for continuous levodopa delivery in patients with PD experiencing motor fluctuations.