

Activity Goals Outcomes as Complementary Measures of Treatment Success for SCS Patients at 12 Months

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OBJECTIVE

Multiple studies have demonstrated the benefits of spinal cord stimulation (SCS) for the treatment of a number of painful conditions¹. While pain scores are traditionally utilized as the primary metric to provide insight into the effectiveness of SCS therapy, their ability to capture its full benefit for patients is limited. Establishing a holistic view of patient well-being in the real world and understanding how improvements in pain positively impact multiple facets of the patient's life provides a more complete picture of the benefits of SCS therapy.

SENSE SCS (Study to Evaluate Neuromodulation Subject Experience with Contemporary Spinal Cord Stimulation; NCT05775510) balances traditional in-clinic visits with remote data collection via a custom-built mobile application to capture electronic patient-reported outcomes². Collection of real-world outcome data provides an opportunity to explore Quality of Life (QoL) and functional metrics as a means to understand the outcomes that are most meaningful to patients. Activity Goals, in particular, offer unique insight into holistic patient experiences with SCS therapy.

Here, patient-reported QoL outcomes, including Activity Goals, are presented at 12 months following SCS device activation. Understanding the full spectrum of the patient experience with SCS therapy represents an opportunity to move beyond traditional pain scores to evaluate therapy success through individualized, patient-centered outcomes.

RESULTS

Table 2. Baseline Demographics in Enrolled Subjects (N=91, Unless Otherwise Indicated)

Subject Characteristics	Enrolled Mean (SD) or N (%)
Age (Years)	63 (10)
Male	47 (51.6%)
White	82 (90.1%)
Primary Indication: Failed Back Surgery Syndrome (PSPS-T2)	42 (46.2%)
Year Since Onset of Chronic, Intractable Pain (n=64)	12 (11)
Pain Intensity, 0-10 (n=85)	7.2 (1.8)

Figure 2. EQ-5D-5L Index Scores at Baseline and 12-Month (N=30)

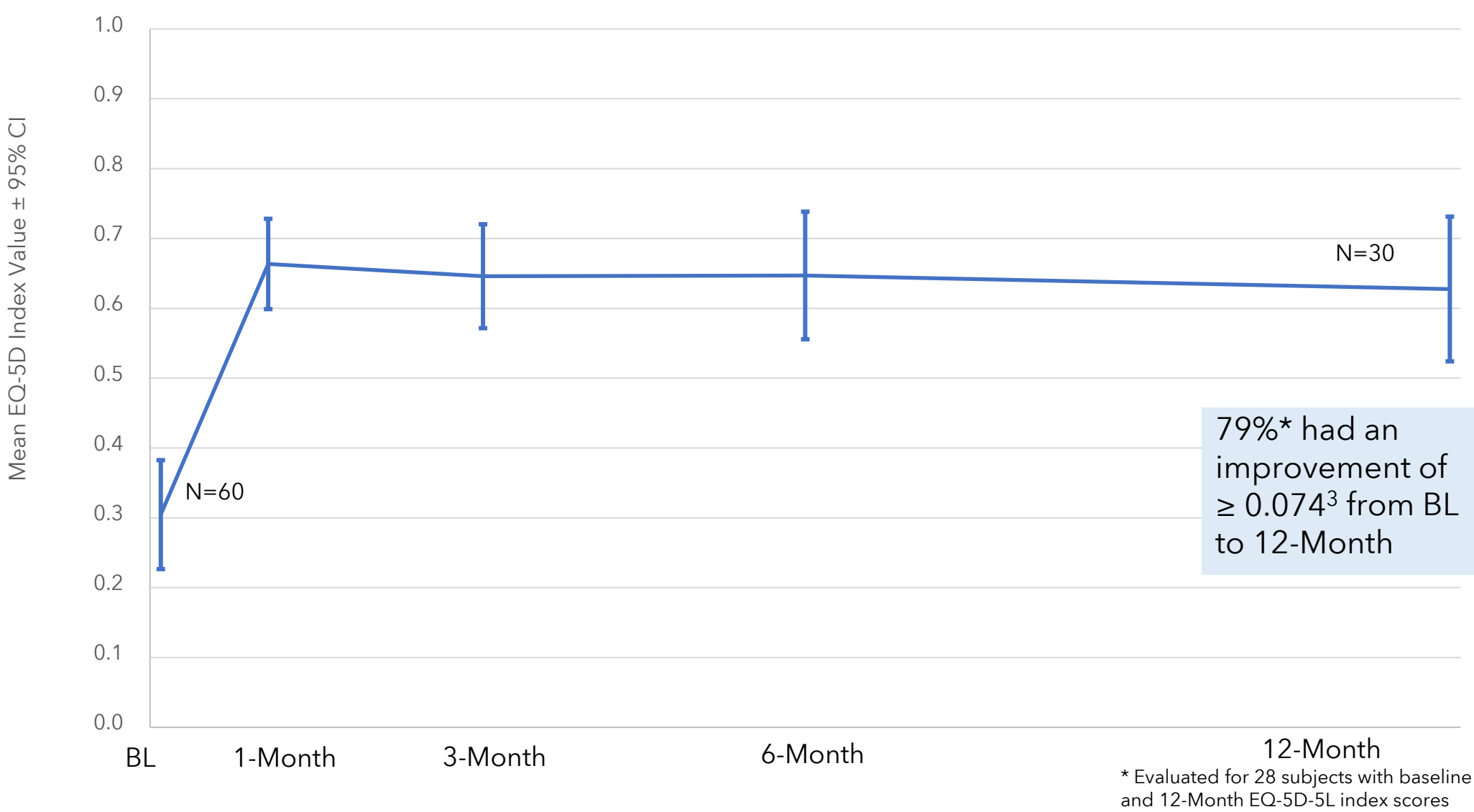


Figure 1. Percent of Patients with Normal or Mildly Impaired PROMIS-29 Domain Scores at Baseline and 12-Month (N=29)

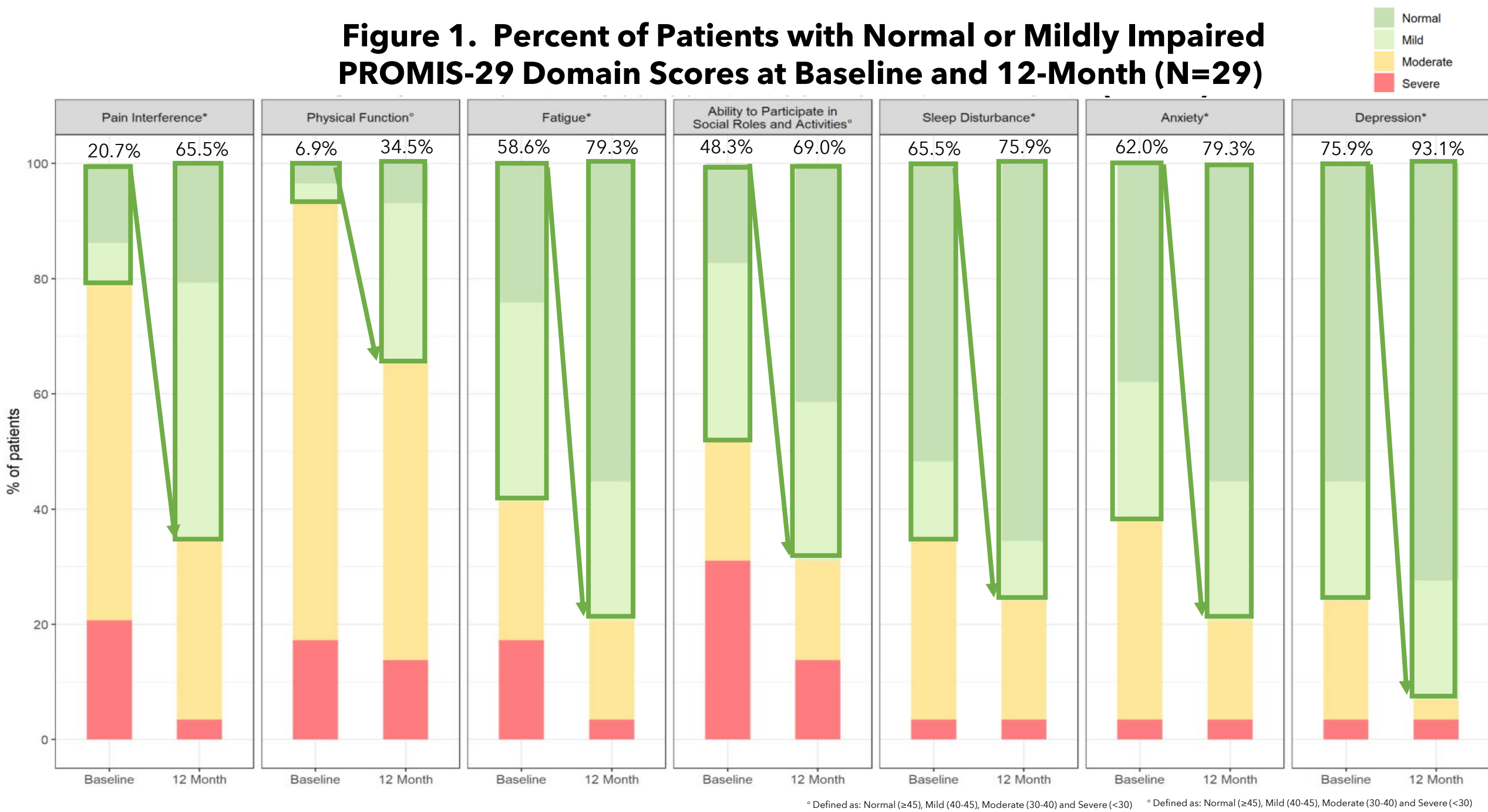
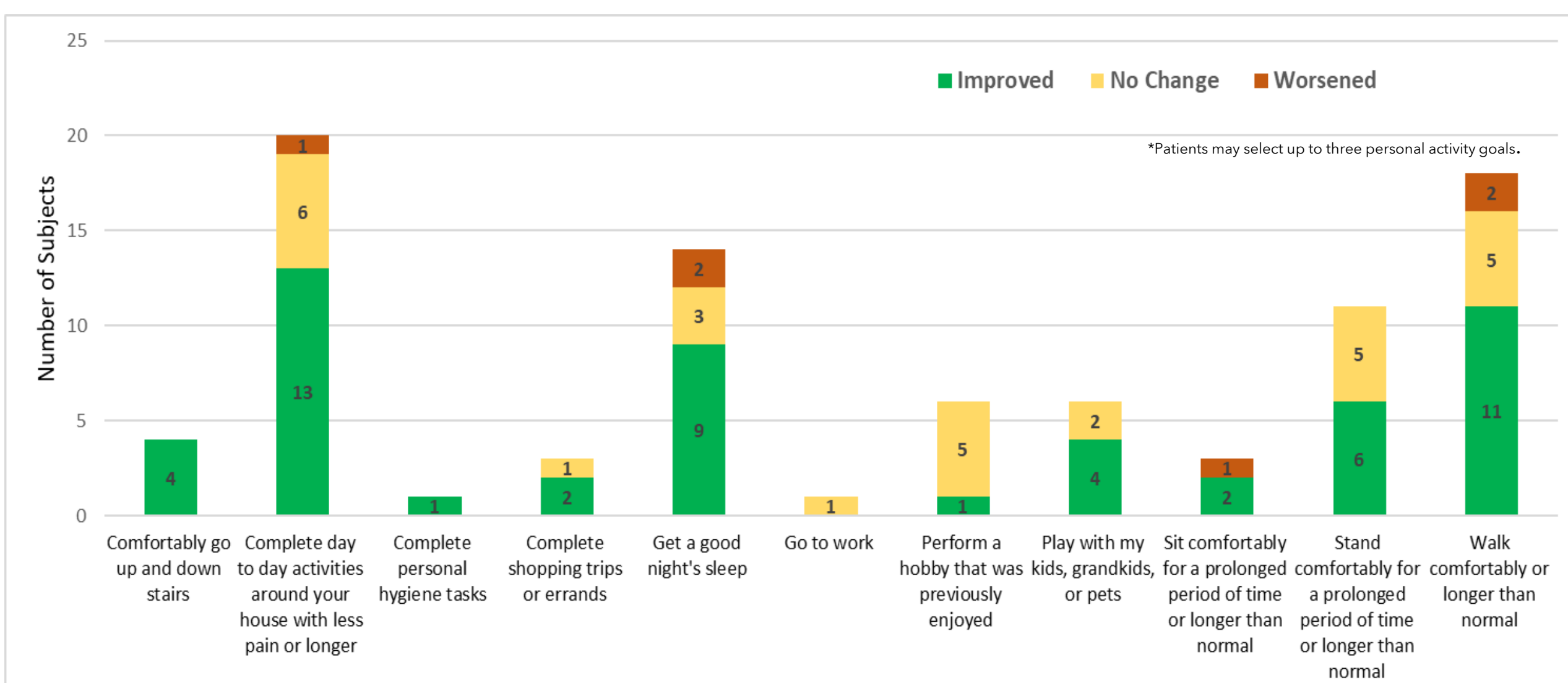


Figure 3. Activity Goals* at 12-Month (N=29)



DESIGN

SENSE SCS - Study to Evaluate Neuromodulation Subject Experience with Contemporary Spinal Cord Stimulation Modalities for Chronic Pain

Design:

- Prospective, post-market, non-randomized, observational study
- IRB approved study, registered on clinicaltrials.gov (NCT05775510)
- Hybrid decentralized model of execution
- Subjects with an on-label SCS indication eligible to enroll
- Enrolled at 8 sites across the United States

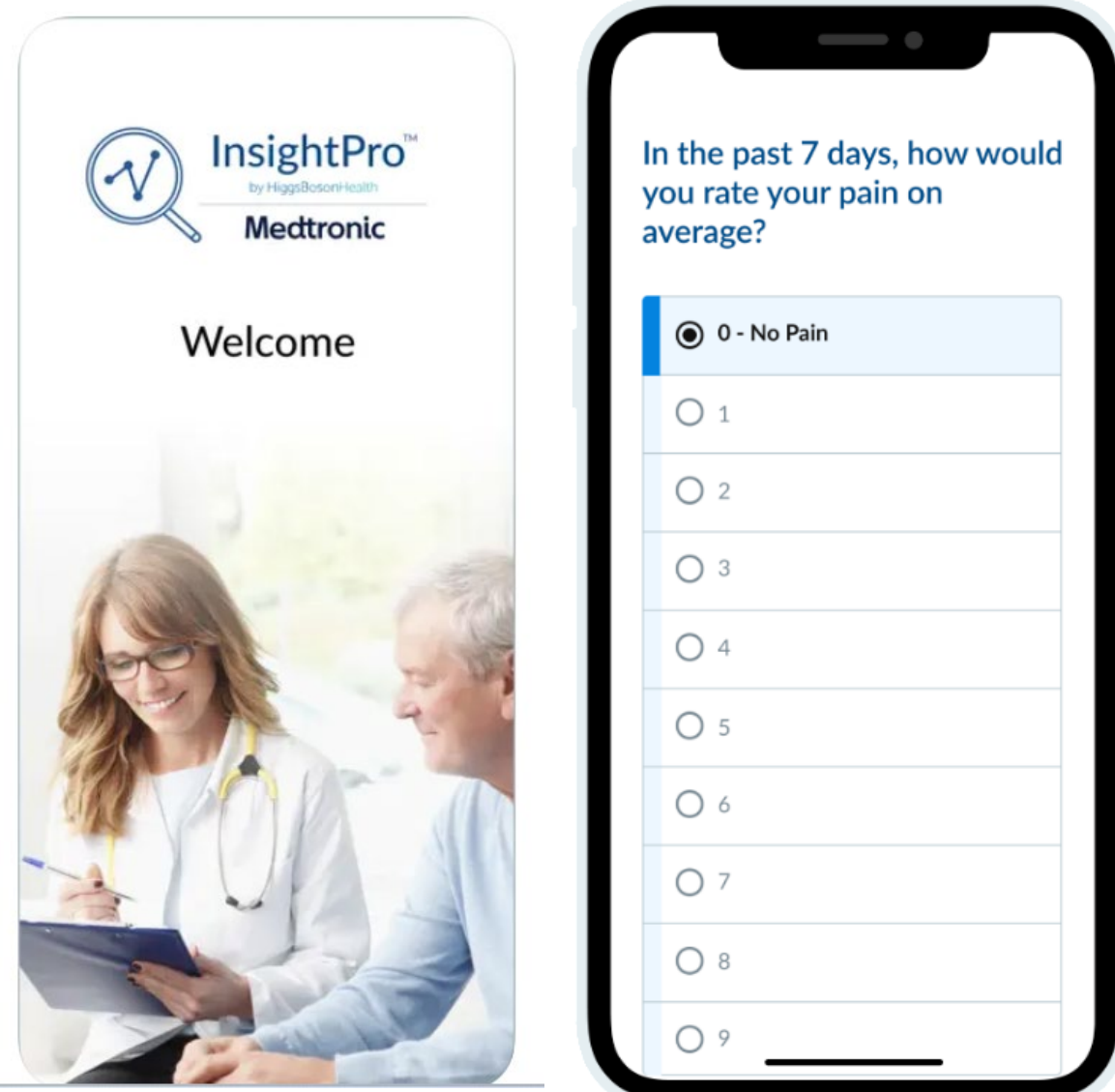
Purpose:

Evaluate workflow of a mobile clinical trial application for collection of patient-reported outcomes and to characterize outcomes on patient experience with commercially available Medtronic SCS devices.

- Subjects electronically consented using a custom-made mobile application, InsightPro™ clinical trial app
- Subjects were trialed and implanted with a commercially available Medtronic SCS system (Vanta™, Intellis™ or Inceptiv™).
- Patient-reported outcomes collected electronically using InsightPro™ at baseline, SCS trial, and after permanent SCS implantation through 12 months
- Data collected include EQ-5D-5L, PROMIS-29 (Patient-Reported Outcomes Measurement Information System®), and Activity Goals

Table 1. Key Inclusion / Exclusion Criteria

Pilot Phase Key Inclusion Criteria
- Candidate with an on-label SCS indication for a commercially available Medtronic SCS system. - Willing and able to use a personal smart phone for study surveys.
Pilot Phase Key Exclusion Criteria
Any active implantable neuromodulation device



RESULTS AND CONCLUSION

Results: Ninety-one subjects were enrolled; Baseline demographics are presented in Table 2. The mean age for enrolled subjects was 63 years (SD 10), 51.6% were male, and the majority were white (90.1%). Persistent Spinal Pain Syndrome: Type 2 (PSPS-T2) was the most common indication (46.2%). Of the 91 enrolled subjects, 65 were implanted, and 37 completed the in-clinic 12-Month visit.; 15 of the 28 early exits were due to study closure. Differences in the number of subjects with a 12-Month visit and those with 12-Month data are due to subjects not completing the electronic questionnaires. PROMIS-29 demonstrated improvement across all seven health domains at 12-Month (Figure 1). Pain Interference, Physical Function, and Ability to Participate in Social Roles and Activities domains showed the largest increases in the percentage of subjects in the Normal/Mild range from Baseline to 12-Month (21% to 66%, 7% to 35%, and 48% to 69%, respectively). At 12-Month, 79% of subjects (22/28) experienced a clinically meaningful improvement ($\geq 0.074^3$) in QoL from Baseline as measured by EQ-5D-5L (Figure 2), with an average (SD) improvement of 0.306 (0.355). The most common Activity Goals at Baseline (N=84) were to “walk comfortably or longer than normal” (71.4%) and “complete day to day activities around your house with less pain or longer” (57.1%). At 12-Month 61% (11/18) and 65% (13/20) of subjects reported improvement in these specific goals, respectively (Figure 3, N=29).

Conclusion: Activity Goals for patients undergoing SCS therapy offer unique insights into individualized therapy success, reflecting outcomes that are meaningful and aligned with each patient's functional aspirations. Incorporating Activity Goals alongside other multidimensional measures, allows for a more comprehensive understanding of the impacts pain has had on patients' lives prior to the SCS therapy and how their daily functioning improves over time. This approach enables a patient-centric evaluation of SCS therapy effectiveness.

References

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