

# Association of Health-related Quality of Life and Relapse in the Previous Year among Multiple Sclerosis Patients: Baseline Data from ROBUST



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## Background

- Previous research has shown that Health-related Quality of Life (HRQoL) is impaired with relapses in Multiple Sclerosis (MS) patients; this impairment directly correlates with the severity of disease.
- This analysis examines the association of HRQoL and relapses that occurred in the previous year among MS patients, using data from the Real-World Betaseron® Outcomes Study (ROBUST); ROBUST is a 12-month, US, prospective, observational, open-label, single-arm, multi-center outcomes study of interferon beta-1b given every other day for MS.

## Methods

- A total of 226 patients were registered across 52 sites, and 193 patients completed the baseline survey.
- Patient outcomes including relapse history, were reported independently by both patients and physicians via a web-based data capture tool.
- Analysis of Variance (ANOVA) methods were used to explore the association of HRQoL via the SF-12 Health Survey (SF-12) and pre-baseline relapse descriptors (relapse status, frequency, severity of typical and worst relapse).
- SF-12 results were summarized by Physical Component Score (PCS-12) and Mental Component Score (MCS-12), which are computed using the scores of twelve questions, and range from 0 to 100, where a zero score indicates the lowest level of health measured by the scales, and 100 indicates the highest level of health.
- Typical relapses were rated on a scale from 0 to 10 using the question: 'On a scale from 0 to 10, where 0 is least and 10 is most severe, how would you rate the typical severity of this patient's relapses during the past year?'
- Severe relapses were rated on a scale from 0 to 10 using the question: 'On a scale from 0 to 10, where 0 is least and 10 is most severe, how would you rate this patient's worst relapse during the past year?'

## Results

- Both physical and mental scores were lower among those patients reporting to be in relapse at baseline (N=78) than among those reporting to be relapse-free at baseline (N=115); however, the difference was statistically significant only on the MCS-12 (43.9 vs. 40.5; p=0.045).
- Reduction of both PCS-12 and MCS-12 were strongly associated with increasing frequency of patient-reported relapses (p=0.001 for both) as shown in Table 1; there was no association between SF-12 and physician-reported frequency of relapses.
- Figure 1 and Figure 2 show the association of SF-12 scores with baseline physician-assessed severity of typical relapses and worst relapses, respectively.
- PCS-12 was significantly associated with physician-assessed severity of relapse (p=0.002 for typical; p<0.001 for worst relapse).
- Figure 3 and Figure 4 show the association of SF-12 scores with baseline patient-reported severity of typical relapses and worst relapses, respectively.
- PCS-12 was significantly associated with patient-reported severity of relapse (p<0.001 for typical relapse; p<0.001 for worst relapse).
- MCS-12, however, was not significantly associated with physician-assessed or patient-reported relapse severity.

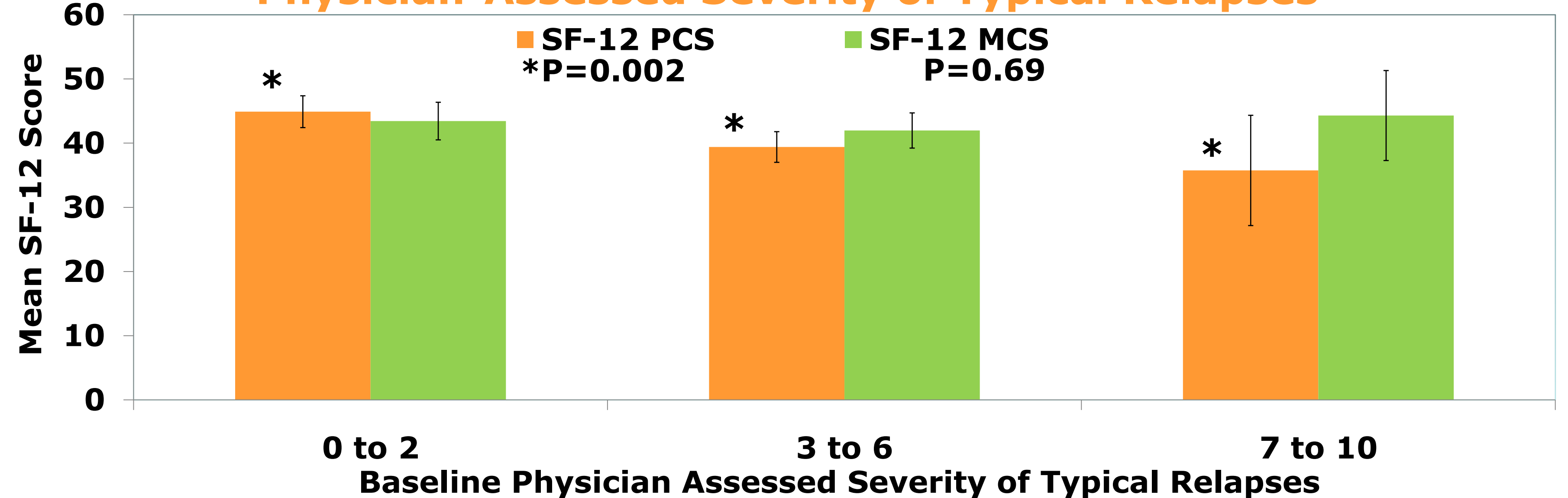
**Table 1. Baseline Health-related Quality of Life by Patient-Reported Number of Relapses at Baseline**

	No Relapse N=27	One Relapse N=70	Two Relapses N=58	Three + Relapses N=38	P-value
SF-12 PCS Mean (SD)	43.00 (10.92)	43.67 (10.76)	39.42 (10.39)	35.38 (11.49)	0.001
SF-12 MCS Mean (SD)	45.84 (10.29)	44.89 (11.34)	42.11 (11.01)	36.70 (11.10)	0.001

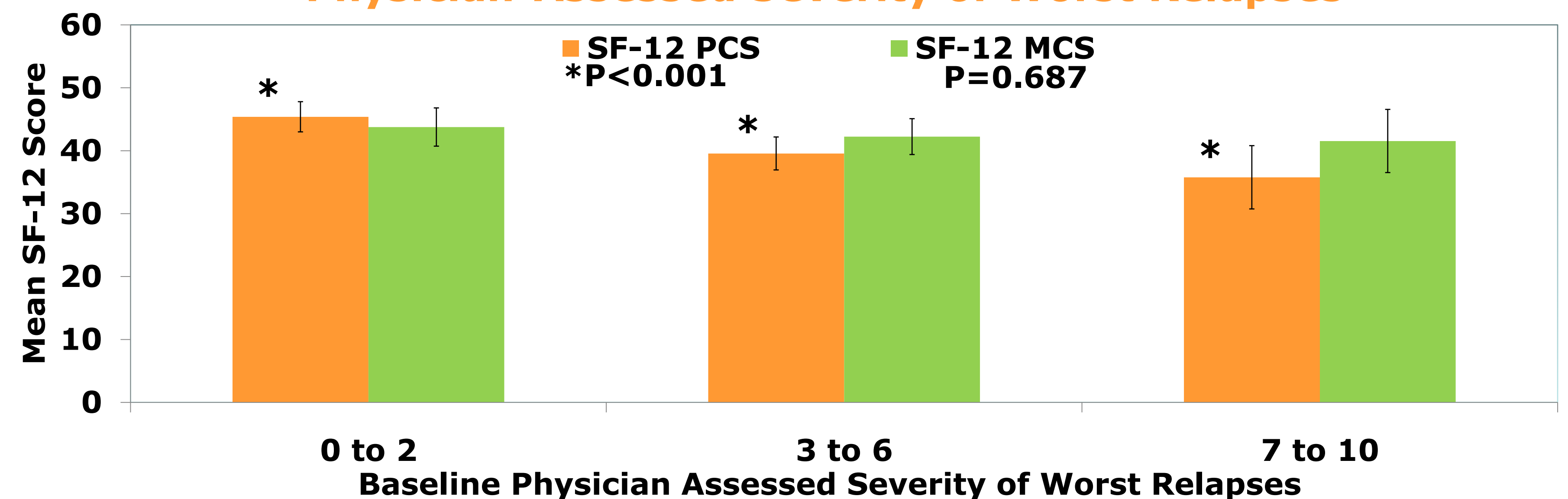
**Table 2. Baseline Health-related Quality of Life by Physician-Assessed Number of Relapses at Baseline**

	No Relapse N=37	One Relapse N=109	Two Relapses N=31	Three + Relapses N=13	P-value
SF-12 PCS Mean (SD)	38.07 (11.56)	42.40 (10.96)	36.55 (10.32)	42.22 (11.33)	0.027
SF-12 MCS Mean (SD)	42.06 (9.71)	44.74 (11.42)	38.13 (11.56)	36.55 (11.83)	0.0059

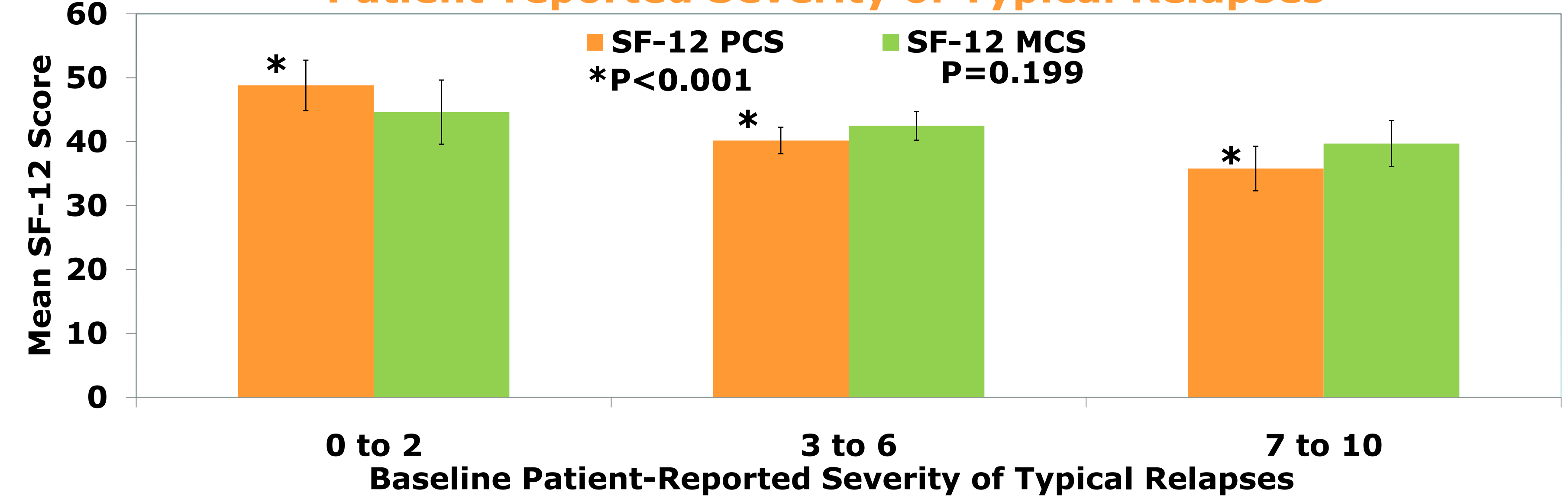
**Figure 1. Association of SF-12 Scores with Baseline Physician-Assessed Severity of Typical Relapses**



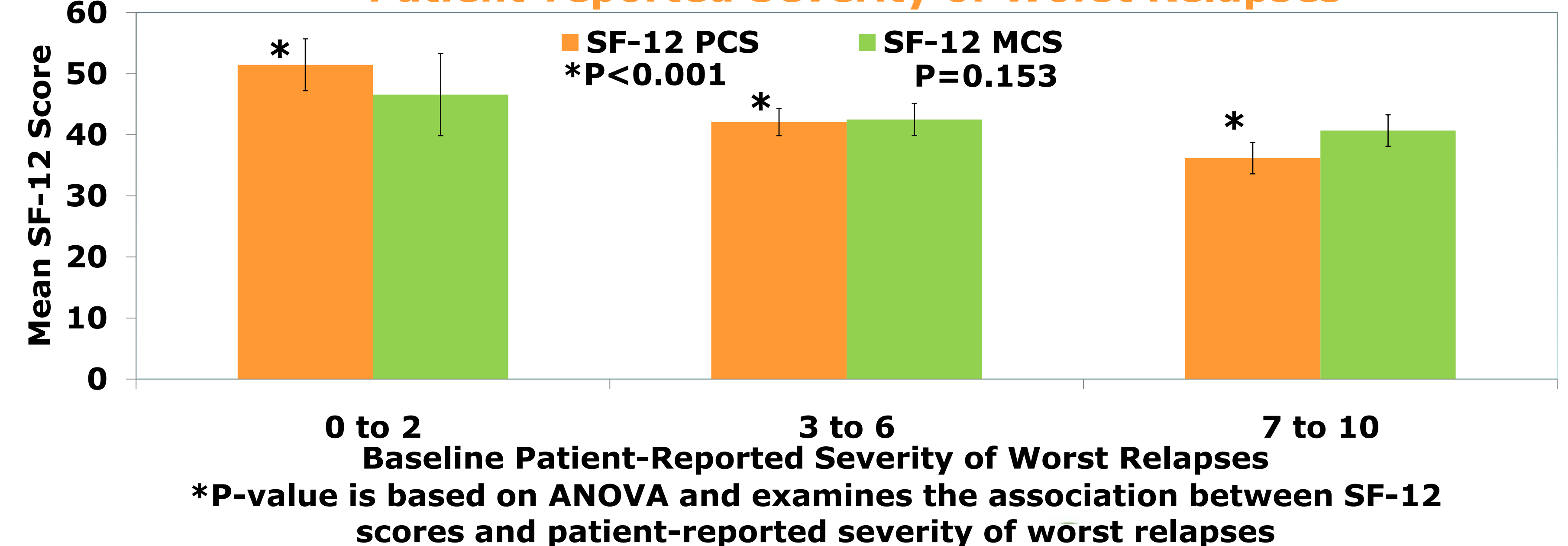
**Figure 2. Association of SF-12 Scores with Baseline Physician-Assessed Severity of Worst Relapses**



**Figure 3. Association of SF-12 Scores with Baseline Patient-reported Severity of Typical Relapses**



**Figure 4. Association of SF-12 Scores with Baseline Patient-reported Severity of Worst Relapses**



## Conclusions

- As a generic HRQoL tool, the SF-12 was associated with relapses in an MS population. In patient-reported, as opposed to neurologist reported, frequency of relapses was associated with a lower HRQoL. Patient-reported and neurologist-assessed severity of relapses was linked to a lower physical QoL. These observations suggest that relapses, both in quantity and severity, have a negative impact on HRQoL as measured by the SF-12.

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