To describe the diagnosis status and outcome of patients diagnosed with fibromyalgia (FM) by US rheumatologists. We assessed 1555 patients with FM with detailed outcome questionnaires during 11,006 semiannual observations for up to 11 years. At entry, all patients satisfied American College of Rheumatology preliminary 2010 FM criteria modified for survey research. We determined diagnosis status, rates of improvement, responder subgroups, and standardized mean differences (effect sizes) between start and study completion scores of global well-being, pain, sleep problems, and health related quality of life (QOL). Results: The 5-year improvement rates were pain 0.4 (95% CI 0.2, 0.5), fatigue 0.4 (95% CI 0.2, 0.05), and global 0.0 (95% CI -0.1, 0.1). The standardized mean differences were patient global 0.03 (95% CI -0.02, 0.08), pain 0.22 (95% CI 0.16, 0.28), sleep problems 0.20 (95% CI 0.14, 0.25), physical component summary of the Short-form 36 (SF-36) 0.11 (95% CI -0.14, -0.07), and SF-36 mental component summary 0.03 (95% CI -0.07, 0.02). Patients switched between criteria-positive and criteria-negative states, with 716 patients (44.0%) failing to meet criteria at least once during 4228.5 patient-years (7448 observations). About 10% of patients had substantial improvement and about 15% had moderate improvement of pain. Overall, FM severity worsened in 35.9% and pain in 38.6%. Although we found no average clinically meaningful
improvement in symptom severity overall, 25% had at least moderate improvement of pain over time. The result that emerged from this longitudinal study was one of generally continuing high levels of self-reported symptoms and distress for most patients, but a slight trend toward improvement.