



Figure 22.1 Physical Component Summary in the Rudick study. Change in Physical Component Summary (PCS) scale with administration of natalizumab (solid line) or placebo (dashes)

(14) Functional Assessment of Multiple Sclerosis (FAMS), the Fatigue Impact Scale (15) and visual analogue scales (16).

a. The Rudick study

The following clinical trial on multiple sclerosis compared outcome, where subjects were administered an antibody (natalizumab; Tysabri[®]) or a placebo. Rudick et al. (17) evaluated the relationship between HRQoL scores and clinical measures of multiple sclerosis. Subjects received either natalizumab (627 subjects) or placebo (315 subjects). All subjects had a form of the disease known as relapsing remitting multiple sclerosis (RRMS).

SF-36 was used to calculate the Physical Component Summary (Fig. 22.1) and the Mental Component Summary (Fig. 22.2). When comparing the study drug with placebo, improvements were found with the study drug, where the improvements were sustained over the entire 104-week duration of the clinical study.

Of practical use to future patients is that these results justify counseling patients that they may expect improvements in HRQoL by 24 weeks of therapy with the antibody. In other words, because of the Rudick study, physicians may be justified in stating, “You should expect to feel somewhat better by or before 24 weeks of treatment.”

In the Rudick study, clinical endpoints were measured by the EDSS score and also the volume of brain lesions, where brain lesions were measured by magnetic resonance

¹⁴ Fischer JS, LaRocca NG, Miller DM, Ritvo PG, Andrews H, Paty D. Recent developments in the assessment of quality of life in multiple sclerosis (MS). *Mult Scler.* 1999;5:251–259.

¹⁵ Melanson M, Grossberndt A, Klowak M, et al. Fatigue and cognition in patients with relapsing multiple sclerosis treated with interferon beta. *Int J Neurosci.* 2010;120:631–640.

¹⁶ Kos D, Nagels G, D’Hooghe MB, Dupontail M, Kerckhofs E. A rapid screening tool for fatigue impact in multiple sclerosis. *BMC Neurol.* 2006;6:27.

¹⁷ Rudick RA, Miller D, Hass S, et al. Health-related quality of life in multiple sclerosis: effects of natalizumab. *Ann Neurol.* 2007;62:335–346.