



Figure 22.2 Mental Component Summary scale in the Rudick study. Change in Mental Component Summary (MCS) scale with administration of natalizumab (solid line) or placebo (dashes)

imaging (MRI). The authors found that subjects who experienced sustained worsening of EDSS score also had worsened PCS scores and MCS scores. Moreover, subjects with a greater relapse rate correlated with worse HRQoL scores. Additionally, the study found that subjects with a more serious lesion, according to magnetic resonance imaging (MRI), also had worse HRQoL scores. Twork et al. (18) compared the EDSS instrument with the HRQoL instrument, as described below.

b. EDSS score versus HRQoL score

EDSS scale is described in the chapter on endpoints for multiple sclerosis. Note that although the EDSS score is acquired by way of a questionnaire, it does not assess HRQoL. Twork et al. (19) conducted a side-by-side comparison of the goals of an HRQoL instrument specific for multiple sclerosis (MSQOL-54) and the EDSS questionnaire. The EDSS instrument is a questionnaire used for multiple sclerosis, but it is not an HRQoL instrument. These authors found that there was some overlap between these two types of instrument, and that there is a moderate correlation between results from use of the first instrument and the second instrument.

c. Interferon-alpha-2a – the Nortvedt study

In a clinical trial of 97 subjects, Nortvedt et al. (20) administered low-dose interferon alpha-2a, high dose interferon alpha-2a, or placebo. Study drugs and placebo were

¹⁸ Twork S, Wiesmeth S, Spindler M, et al. Disability status and quality of life in multiple sclerosis: non-linearity of the Expanded Disability Status Scale (EDSS). *Health Qual Life Outcomes*. 2010;8:55.

¹⁹ Twork S, Wiesmeth S, Spindler M, et al. Disability status and quality of life in multiple sclerosis: non-linearity of the Expanded Disability Status Scale (EDSS). *Health Qual Life Outcomes*. 2010;8:55.

²⁰ Nortvedt MW, Riise T, Myhr KM, Nyland HI, Hanestad BR. Type I interferons and the quality of life of multiple sclerosis patients. Results from a clinical trial on interferon alfa-2a. *Mult Scler*. 1999;5:317–322.