

Title: Characterizing the positive experience reported by natalizumab-treated patients with relapsing multiple sclerosis

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Introduction: Natalizumab's efficacy in relapsing multiple sclerosis (RMS) has been demonstrated with traditional outcome measures. Some patients have anecdotally reported a "Feel Good" (FG) experience on natalizumab. Whether this FG experience is adequately captured by quality of life (QoL) surveys used in clinical research is not currently known.

Objective: To identify concepts that may contribute to a natalizumab-associated FG experience.

Methods: A previously published qualitative interview strategy was used for concept elicitation in RMS patients currently or previously on natalizumab for ≥ 6 months who described a FG experience to their clinician. Interview transcripts were evaluated to identify concepts associated with the natalizumab experience. Patients were asked to rank the most relevant concepts and QoL surveys.

Results: In April/May 2019, interviews were completed for 23 patients from US clinical sites, 21 of whom were currently receiving natalizumab. Median age was 45 years. Median time on natalizumab was 38 months. A mean of 13.2 concepts per patient were identified from the qualitative interview. Nearly all (n=21; 91%) indicated improved physical functioning compared with pre-natalizumab; improved energy was identified

most commonly (n=17; 74%). Reported emotional functioning improvements (n=18; 78%) were primarily characterized by feeling happier and feeling “like self” again. Patient-reported cognitive function improvements were mentioned (n=10; 43%), with improved thinking/focus noted most frequently (n=9; 39%). Of 33 key concepts from QoL surveys, patients identified having energy (n=15; 88%), hopefulness (n=14; 82%), and happiness/cheerfulness (n=11; 65%) as most affected by natalizumab. QoL surveys identified as most relevant measured fatigue, positive affect, and cognition.

Conclusions: Interview-based concept elicitation identified improved energy as most commonly associated with the natalizumab FG experience. Similarly, rankings of concepts and QoL measures highlighted reductions in fatigue and positive affect. These exploratory results provide concepts to be considered when investigating components of the FG experience reported by some natalizumab-treated patients.

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