



Title	Improving the Evaluation of Therapeutic Interventions in Multiple Sclerosis: Development of a Patient-Based Measure of Outcome
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Reference	Health Technol Assess 2004;8(09). Feb 2004. www.ncchta.org/execsumm/summ809.htm

Aim

To develop a patient-based, disease-specific measure of the health impact of MS that is clinically useful, scientifically sound, and suitable as an outcome measure in clinical trials and routine clinical practice to monitor the progress of MS patients.

Conclusions and results

Stage 1: A pool of 129 items was generated.

Stage 2: From this item pool we developed a 29-item measure of the physical (20 items) and psychological (9 items) impact of MS – the Multiple Sclerosis Impact Scale (MSIS-29).

Stage 3: The MSIS-29 satisfied recommended psychometric criteria for rigorous measurement. Data quality was excellent: missing data were low, item level test-retest reliability was high, and scale scores could be generated for >98% of respondents. Item descriptive statistics, item convergent and discriminant validity, and factor analysis supported summing items to produce two summary scores. MSIS-29 physical and psychological scale scores showed good variability, low floor and ceiling effects, good internal consistency, and test-retest reliability. Correlations with other measures and confirmation of hypotheses about group differences provided evidence for the validity of the MSIS-29 as a measure of the physical and psychological impact of multiple sclerosis. Effect sizes (physical scale = 0.82, psychological scale = 0.66) provided preliminary evidence for responsiveness.

Recommendations

The 29-item MSIS-29 is a new measure of the physical and psychological impact of MS that satisfied traditional psychometric criteria for reliable and valid measurement. There is preliminary evidence of responsiveness. The MSIS-29 is particularly appropriate in clinical trials to evaluate therapeutic effectiveness from the patient's perspective.

Methods

Standard traditional psychometric methods were used to develop the MSIS-29 in three stages. See monograph for details.

Further research/reviews required

1. Further evaluations of the MSIS-29 in different samples and settings will help clarify its strengths and weaknesses and further define its role in clinical practice and research.
2. Head-to-head comparisons of the full spectrum of psychometric properties of the MSIS-29 and existing MS outcome measures should be undertaken to determine the advantages and disadvantages of different instruments and how they complement each other.
3. Further evaluations of the MSIS-29 using newer psychometric methods, eg, Rasch item analyses and Item Response Theory.
4. The specificity of the MSIS-29 to MS and applicability to other neurological conditions should be tested.
5. A larger followup interview survey would be useful for feedback, especially in questions deemed irrelevant by subgroups (ie, ethnic minority groups, older people).
6. Validation of the MSIS-29 in other languages.