measurement experts to generate items, responses, and instructions for the new scale. Cognitive interviews were conducted with an additional 15 idiopathic RLS patients (aged 25–68) to understand the new measure, and to identify any necessary revisions to the items and conceptual framework. RESULTS: Two added items were generated from patient quotes obtained during the concept elicitation interviews. Impacts on next day functioning spontaneously attributed to disturbed sleep due to RLS symptoms included: activities of daily living (i.e., work, household chores), cognitive functioning (i.e., concentration, forgetfulness, mental fatigue), motor weakness, emotional functioning (i.e., irritability, depression), physical functioning (i.e., physical tiredness, active leisure activities), energy, daytime sleepiness, and social functioning (i.e., relationships, social activities/situations). Concept saturation was achieved. Modifications to questions and responses were based on patient input provided during cognitive interviews. The final measure included 12 items assessed “today” and rated on a severity numeric rating scale. CONCLUSIONS: The RLS-NDI is an evaluative tool with demonstrated content validity to assess the impact of disturbed sleep due to RLS symptoms on RLS patients’ next day functioning.

REFINING THE MEASUREMENT OF MOTOR AND NON-MOTOR SYMPTOMS IN PARKINSON’S DISEASE PATIENTS WITH FLUCTUATING SYMPTOMS

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OBJECTIVES: Parkinson’s disease (PD) is the second most prevalent neurodegenerative disorder in the US. The Scales for Outcomes in Patients with Parkinson’s disease—Diary Card (SCOPA-DC) is a daily diary designed to measure motor impairment in PD patients with fluctuating symptoms. Consistent with the FDA’s final guidance on patient-reported outcome measures, this study aimed to evaluate the content validity of the SCOPA-DC in the US and determine the feasibility of adding items that measure non-motor symptoms using qualitative techniques. METHODS: A literature review identified the most dominant non-motor symptoms experienced by PD patients with fluctuating symptoms. Three focus groups were conducted with PD patients (n = 24) to identify themes that specifically addressed the study objectives. The original SCOPA-DC was modified based on findings from the literature review and patient input. A fourth focus group (n = 9) consisted of a cognitive debriefing of the revised SCOPA-DC that included additional items and modified structure based on the previous results. RESULTS: Findings from the focus groups demonstrated support for the content of the original SCOPA-DC, generally finding it to be clear and intuitive, despite difficulties with some item definitions, time frames, and response labels. With respect to non-motor symptoms, seven domains were consistently mentioned: fatigue, concentration/memory, anxiety, pain, difficulty swallowing, frequent urination, and sweating. The cognitive debriefing focus group reported that the revised SCOPA-DC format was easier to use, provided better focus on the items and time frames, and more adequately captured experiences throughout the day as compared to the original. CONCLUSIONS: Non-motor symptoms occur frequently in PD patients with fluctuating symptoms and have a significant impact on health-related quality of life. A reliable and validated patient-reported daily diary may improve the ability to describe symptoms and have a significant impact on health-related quality of life. A reliable and validated patient-reported daily diary may improve the ability to describe symptoms and have a significant impact on health-related quality of life.

VALIDATING USE OF THE MIGRAINE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE VERSION 2.1 (MSQ) ACROSS MIGRAINE DISORDERS

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OBJECTIVES: The Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ) is a 14-item health-related quality of life instrument that measures the functional impact of migraine across three domains: Role Function-Restrictive (RF), Role Function-Restrictive (RR), and Emotional Functioning (EF). This study evaluated the factor structure and cross-cultural comparability of the MSQ in Chronic Migraine (CM) sufferers. METHODS: Cross-sectional data were collected via web-based survey, across eight countries. Respondents were classified as having CM per ICHD-2 criteria with ≥15 headache days/month (n = 499). Confirmatory factor analysis (CFA) of the 3-factor model was conducted using the robust maximum likelihood estimator (MLR) assuming multivariate normality. Goodness-of-fit was assessed by the comparative fit index (CFI), Tucker-Lewis Index (TLI), and root mean square error of approximation (RMSEA). Differential item functioning (DIF) was tested using ordinal logistic regression of MSQ item scores on group membership variables (i.e., language). RESULTS: The 3-factor model demonstrated good fit (CFI = 0.97; TFI = 0.96; RMSEA = 0.07) among CM sufferers. Factor loadings ranged between 0.72 and 0.89, and had similar values across the three factors. Most MSQ items showed absence of DIF. Non-uniform DIF (significant interaction term between group membership and trait level) was identified for six items (inability to concentrate; p = 0.028) and 12 (fed up or frustrated; p = 0.037). Item 12 also presented non-uniform DIF related to language (p = 0.010). CONCLUSIONS: Among Chronic Migraineurs, the MSQ provides a valid measure of RP, RR, and EF, yielding domain scores that can be reliably compared across languages and countries.

AN ASSESSMENT OF DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS RELATING TO BLADDER DYSFUNCTION USED IN PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: Bladder dysfunction is a common symptom in patients with multiple sclerosis (MS). This study assessed the current literature regarding instruments that have been used to measure the health-related quality of life (HRQOL) impact of this chronic illness, and to what extent bladder dysfunction affects HRQOL in this population. METHODS: Two searches using MEDLINE/PubMed’s MeSH database were made. Quality of life was isolated by checking the psychology subheading within the

PDQ-4 (r = −0.28 to −0.47), MIDAS (r = −0.42 to −0.58), and HIT-6 (r = −0.55 to −0.71). Known groups validity indicated significant differences (p < 0.0001) in the hypothesized direction between CM, HEM, and LEM for RP (F = 58.74), RR (F = 91.78), and EF (F = 153.38). CONCLUSIONS: The MSQ is a reliable and valid questionnaire that can differentiate the functional impact between CM, HEM, and LEM.