A QUALITATIVE STUDY OF THE INDIVIDUALISED IMPACT OF RESTLESS LEGS SYNDROME (RLS) ON QUALITY OF LIFE
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OBJECTIVES: Restless Legs Syndrome (RLS) is a neurological movement disorder characterised by uncomfortable leg sensations when at rest, exacerbated in the evening/at night, and alleviated by movement. A systematic literature review demonstrated the need for a new RLS-specific QoL instrument. This interview study forms the second step in instrument development. METHODS: The Schedule for the Evaluation of Individual Quality of Life (SEIQoL) was used to identify aspects of life that are most important for individuals’ QoL, rank their relative importance and then rate them in terms of impact by RLS. We adapted the SEIQoL to be RLS-specific and suitable for telephone administration. Twenty-six participants (mean age 61 years (range 32–83 years); 58% female) were recruited from the Ekbom Society, the UK’s RLS patient support group. Telephone interviews (mean duration 54 mins (range 31–83 mins)) included the adapted SEIQoL and semi-structured questions about experience of RLS and its treatment. RESULTS: The adapted SEIQoL was acceptable to participants and facilitated an individualised investigation of the impact of RLS on QoL. On average, participants had experienced RLS symptoms for 22 years (range: 6 months to 65 years), though 35% had never received a diagnosis from their doctor. Most participants described their symptoms as severe (73%) and occurring daily (88%). General aspects of life impacted by RLS included family, health, hobbies, spirituality and social life, as well as some areas that may be more specific to living with RLS (physical ability, stress and sleep). CONCLUSION: RLS had an adverse impact on most aspects of life nominated by individuals as important for their QoL. This study supports our previous literature review, which indicated that QoL is impacted in many ways that are important to the individual and rarely assessed in existing measures. These results will be used to develop a comprehensive measure of the impact of RLS on QoL.

MEASURING THE IMPACT OF RESTLESS LEGS SYNDROME (RLS) ON QUALITY OF LIFE: A SYSTEMATIC REVIEW
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OBJECTIVES: Restless Legs Syndrome (RLS) is a neurological movement disorder affecting 5–15% of the general population. Given its subjective nature, it is important to assess the impact of RLS from the patient’s perspective. The objective of the literature review was to identify and assess the suitability of instruments used to measure the impact of RLS on quality of life (QoL).

METHODS: Systematic searches of Medline and PsychINFO were conducted using terms synonymous with “RLS” in combination with terms associated with measuring “QoL”. RESULTS: Two hundred and six abstracts were identified and screened. Of these, 21 reported quantitative studies using a variety of measures (i.e., generic health status, RLS-specific health status, symptoms and emotional well-being, anxiety/depression and fatigue/sleep), despite almost all abstracts referring to the measurement of “QoL”. Generic measures, such as the SF-36 can be useful when making comparisons with other medical conditions but have limited value for assessing the full impact of RLS because they include irrelevant items (e.g., mobility, which is likely to relieve symptoms) and exclude relevant issues (e.g., impact on sleep, working life). The RLS-specific symptom measure (the IRLS) is often misinterpreted as measuring QoL rather than symptoms. Recently, the RLSQOL and RLSQLI have been developed to measure the impact of RLS on QoL. Despite displaying adequate psychometric properties and assessing some facets of QoL impacted by RLS, these also do not assess the full range of aspects of life affected by RLS. CONCLUSION: This review concludes that existing generic and RLS-specific measures are likely to underestimate the full impact of RLS on QoL and, therefore, underestimate the full potential benefits of new treatments. In addition, they rarely offer opportunities for patients to indicate any perceived benefits of the condition. A new questionnaire is needed to assess the full impact (both positive and negative) of RLS on QoL.

FIT OF THE MIGRAINE PREVENTION ASSESSMENT CLINICAL TOOL (M-PACT) WITH QUALITATIVE DEVELOPMENT
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OBJECTIVES: Guidance from European and U.S. regulatory agencies regarding Patient Reported Outcomes (PROs) has afforded greater clarity on various aspects of instrument development. As no current measures of migraine Quality of Life (QoL) impact have addressed issues related to prophylactic treatment, the M-PACT was developed as a PRO tool to evaluate this aspect of migraine-impaired QoL. The current abstract provides details on the fit of the M-PACT with qualitative development guidelines.

METHODS: An exhaustive review of the literature was first conducted to identify pertinent PRO instruments or items. Experts in migraine were gathered for additional input on the domains and format of the PRO. Next, patient (i.e., migraineurs) focus groups were held to understand the patient-perceived applicability of domains as well as to generate item language. With the introduction of EULA and FDA guidance documents during development of the M-PACT, item anchors and test instructions were refined. The final format of the M-PACT was evaluated by experts in migraine and with migraine and headache sufferers through cognitive interviews. RESULTS: The multiple modalities of conceptual framework development yielded a total of 21 items covering 4 related domains (daily activities, emotional stability, concentration, and social interaction), all subsumed under a single factor of migraine-related QoL impact. An overabundance of items was specifically sought to allow for selection of the best items during quantitative analysis of M-PACT. Feedback from the cognitive interviews confirmed these questions as relevant and easy to understand CONCLUSION: The M-PACT questionnaire was developed following a sequential, multistep, multisource approach for questionnaire development. Given the strong synergy between key opinion leaders, migraineurs, and the literature, the M-PACT PRO is expected to be an effective measure to assess QoL impact on migraineurs undergoing prophylactic treatment. Quantitative validation of the M-PACT is underway. Overall, the M-PACT fits well with qualitative development guidelines.

A REVIEW OF PATIENT-REPORTED OUTCOMES THAT COMPLEMENT ASSESSMENTS OF SEIZURE REDUCTION IN ADULT EPILEPSY DRUG TRIALS
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OBJECTIVES: 1) To identify patient-reported outcomes used to complement assessments of seizure reduction in adult epilepsy