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Multicentre validation of a patient-reported outcome measure for functional movement disorders

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ABSTRACT

Background No disorder-specific patient-reported outcome measure (PROM) has yet been validated for functional movement disorders (FMDs), leaving a critical gap in clinical care and research.

Objective To validate the FMD questionnaire (FMDQ) in a prospectively recruited sample through a multicentre study.

Methods Confirmatory factorial analysis (CFA) tested the assumed structure of the questionnaire with factors reflecting severity of motor symptoms, impairment of everyday activities, impact of non-motor symptoms and impairment of social functioning. Internal consistency and floor/ceiling effects were examined. The 36-item short form health survey (SF-36), patient health questionnaire-15 (PHQ-15), the fatigue assessment scale (FAS) and a clinician-rated scale corresponding to motor symptom items of the FMDQ (FMDQ-CR) were used to test criterion and construct validity. The minimally clinically important difference (MCID) was assessed through distribution-based and anchor-based methods in a convenience sample of patients with follow-up assessments.

Results Complete datasets from 157 patients were analysed; follow-up assessments were available from 30 patients. CFA confirmed that a four-factor model provides a better fit to the data compared with a more restrictive one-factor model. Internal consistency was appropriate for all factors/subscales. No floor or ceiling effects were detected. Criterion and content validity were supported by significant correlations with respective SF-36 subscores, PHQ-15, FAS and FMDQ-CR. Anchor-based MCID was estimated at 8 to 20 points, with the central value aligning with the distribution-based MCID of 12 points (8% of the total score range).

Conclusions The FMDQ is a psychometrically robust PROM, making it a useful tool for clinical practice and treatment trials.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is a clear need for a patient-reported outcome measure (PROM) tailored to functional movement disorder (FMDs), to systematically capture patients' experiences of motor symptoms, related non-motor issues and the impact on daily life.

WHAT THIS STUDY ADDS

⇒ This study validates a new FMD-specific PROM (FMDQ), showing strong internal consistency, robust construct validity and responsiveness to clinically meaningful change.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The FMDQ's psychometric strengths support its use in clinical trials and routine care, offering a valuable tool to improve patient assessment and readiness for intervention studies.

INTRODUCTION

Functional movement disorders (FMDs) are characterised by recurrent or persistent alterations in voluntary motor control arising from abnormal sensorimotor expectancies. They typically develop following acute sensory discomfort or motor disability, often in the context of other neurological and psychiatric conditions.[1–3] The clinical spectrum is wide and includes tremor, dystonia, dyskinesia, hyperkinetic paroxysms, problems with coordination and balance, weakness and stiffness as well as composite presentations. Motor symptoms are driven by interlocking dysregulations of higher-order motor, affective and attentional control. Symptoms can therefore vary on all time-scales, from moment-to-moment variability to daily fluctuations and across years of illness. Anatomical distribution and symptom types can be similarly inconsistent.[4] Still, since motor abnormalities tend to be contingent on situational requirements and intentionality, distress and disability tend to be a relatively consistent feature of FMD.[5] FMD also typically comprises a range of non-motor symptoms such as fatigue, cognitive difficulties, pain and anxiety, which significantly affect quality of life. Currently, FMD is experiencing a long overdue renewal of clinical and scientific attention with efforts to improve diagnosis, advance understanding and develop effective treatments. At the intersection of these endeavours lies our ability to reliably assess FMD and quantify its severity. Whether for biomarker development, for quantifying brain-behaviour correlations, or for

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evaluating treatment effectiveness, developing an appropriate outcome measure for FMD is essential.[6–8]

An ideal measure of disorder-specific impairment should be able to capture the range of motor symptoms as well as motor disability in general, taking into account the effect of common non-motor symptoms. Classical rating scales used in movement disorder neurology typically produce only a momentary snapshot of deficits in predefined movements and activities.[9] In a disorder, whose clinical hallmark is situational variability, clinician-rated instruments are likely to introduce unknowable bias.[6 7] Therefore, patient-reported outcome measures (PROM) are urgently needed. Although many such instruments exist for different aspects of mobility, activity and non-motor symptoms, comprehensive core outcome measure batteries can be impractical for routine clinical use and may miss key disorder-specific features while overemphasising others. The call for an FMD-specific PROM from experts has recently been reiterated by healthcare providers from various professions, as well as patients and caregivers.[10]

Here, we present the Functional Movement Disorder Questionnaire (FMDQ) and its psychometric validation. The FMDQ is the first patient-reported questionnaire developed specifically for FMD, designed to quantify motor symptoms, associated non-motor problems and resulting limitations in daily living.[11] The FMDQ was designed to cover the full spectrum of FMD presentations as many patients exhibit a combination of motor symptoms that defy strict categorisation into single phenotypes. The original development of this tool followed an iterative process including a literature review, structured expert input and qualitative cognitive interviews with patients to ensure content validity and patient involvement.[11] Here, we evaluated the reliability, validity and responsiveness of the FMDQ in a large, diverse sample of FMD patients recruited in a multicentre study.

METHODS

Study design, setting and recruitment

Five German university hospitals (Bochum, Essen, Göttingen, Kiel and Lübeck) and one specialised hospital for movement disorders with a treatment programme for FMD (Beelitz-Heilstätten)[12] prospectively recruited adult inpatients and outpatients from January 2022 to July 2024, although some centres started recruiting later. Eligibility for participation was assessed by consultant neurologists with expertise in movement disorders, who made the clinically definite diagnosis of FMD, according to the established Gupta and Lang diagnostic classification criteria.[13] Participants were required to have sufficient knowledge of the German language to complete the questionnaires. Patients with factitious disorders, acute suicidality, acute psychotic symptoms or intellectual disability were not included. In cases when patients were seen twice within the recruitment period, either as part of routine care or as part of an ongoing treatment trial at two of the centres,[14] they were offered to participate again, creating a convenience sample for follow-up data.

Data collection

Recruiting clinicians provided basic demographic and clinical information including sex, current age, age at first onset of symptoms, age at diagnosis of FMD, diagnosis and pattern of FMD.

The FMDQ was designed to assess both anatomical and kinetic features of motor symptoms as well as functional limitations and impairments in movement-related everyday functioning.[11] Items are grouped into seven blocks, consisting of four to seven items each, resulting in a total of 38 items. Figure 1 shows how the items are grouped thematically. Responses are given on a 4 or 5-point Likert scale and relate to the patients' perceptions over the past 2 weeks. The FMDQ ranges from 31 to 181 points, as Likert scale responses are scored as 1–4 or 1–5 points, respectively, and seven items have an additional "not applicable" option, with higher scores indicating more severe impairment. The FMDQ has previously been iteratively evaluated by an expert panel for comprehensibility and relevance; the average Content Validity Index value was "excellent".[11] In addition, a participatory approach was implemented to explicitly incorporate patient feedback into the iterative development of the questionnaire by conducting "cognitive interviews" with a group of clinically and demographically diverse FMD patients (not part of this trial).[11]

A translation of the German original version (see online supplemental file 1) into English (see online supplemental file 2)

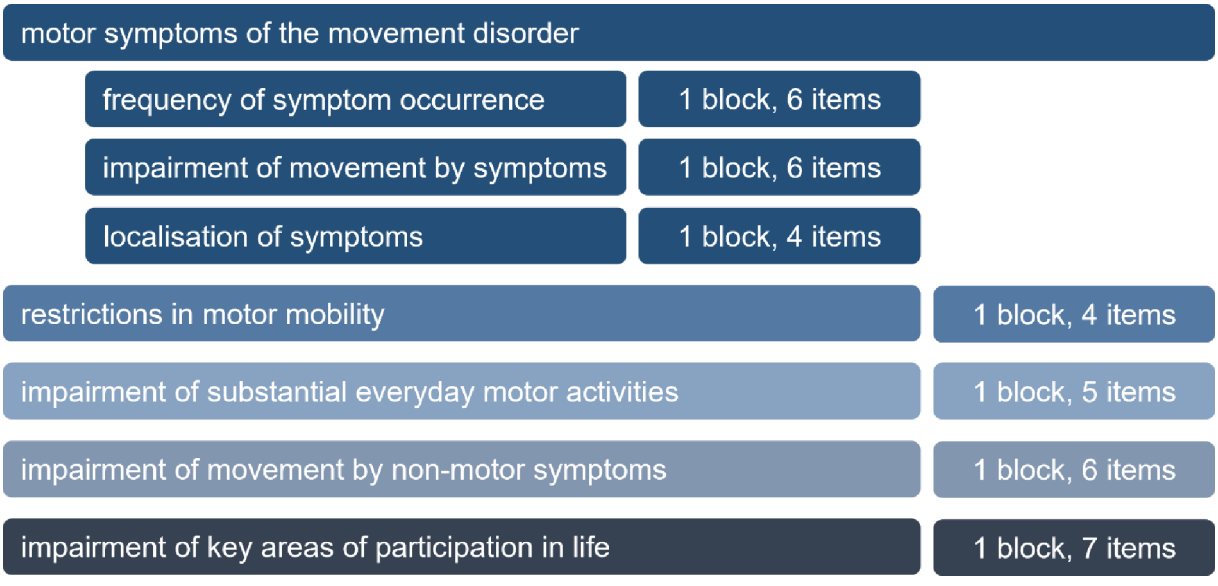

Figure 1 Thematic groups of the functional movement disorder questionnaire. The questionnaire is available in English and in German (online supplemental documents 1 and 2).

was performed using a multi-step process based on established best practices for cross-cultural adaptation of PROMs.[15 16] First, two bilingual FMD experts (KL, ACL) with work experience in the USA, UK and Australia independently translated the original into English. These versions were reconciled by two members of the original questionnaire development team (RM, SP) with clinical and academic work experience in the USA and UK into a single version.

To ensure comparability of patient-reported and clinician-rated (CR) scores, the diagnosing clinicians independently answered the 16 items from the three motor symptom blocks based on the history taken and the clinical examination, without seeing the patient's responses. This questionnaire was called FMDQ-CR and did not include any other items. The FMDQ-CR score ranges from 16 to 80 points.

Patients also completed the 36-item short form health survey (SF-36),[17] the patient health questionnaire-15 (PHQ-15)[18] and the fatigue assessment scale (FAS).[17] Further information regarding these questionnaires is provided in the online supplemental file 3.

As part of the protocol, clinicians checked returned questionnaires immediately for missing responses and asked patients to complete them, thus preventing missing data points. Patients attending follow-ups were only asked to complete the FMDQ and SF-36 again. Follow-up data was only used to calculate the minimally clinically important difference (MCID).

Data analysis

The design of this validation study is informed by the quality criteria for measurement properties of health status questionnaires by Terwee *et al*.[19] Statistical analyses were performed using RStudio.[20] We followed recommended sample size planning of >100 and at least four times the number of items,[19] suggesting a minimum of 4*38=152 subjects. The responsivity analysis was exploratory and no power estimation was performed for the follow-up convenience sample. Subjects with incomplete data were excluded from final analysis. To calculate the scores on the eight SF-36 dimensions and the MCS and PCS values, an evaluation scheme was used according to Ritvo *et al*. [21] Shapiro-Wilk tests were applied to check for normality. In most cases, the data were not normally distributed. Therefore, non-parametric testing procedures were used where possible. In addition to the basic descriptive statistical parameters of baseline and follow-up data sets, correlations between FMDQ items and other questionnaires and subscales were studied in the baseline sample using non-parametric Spearman correlations.

The blocks of our questionnaire provide a specific hypothesis about the factor structure across the 38 items.[11] Thus, a confirmatory factor analysis (CFA) was conducted to test for reliability, and different fit indices were calculated to evaluate the predefined factor structure. Subsequently, Cronbach's α was calculated for every factor to test for internal consistency. In addition to Cronbach's α, we evaluated item-total correlations and inter-item correlations to further examine the internal consistency and structural coherence of the questionnaire. Item-total correlations were calculated using corrected Pearson correlations, omitting each item from the total score. Correlations above 0.2 were satisfactory.[22] Inter-item correlations were assessed via a Pearson correlation matrix with correlations >0.8 considered a potential indication of redundancy.

Criterion validity regarding motor symptoms was tested by correlating patients' responses to items 1a to 3d of the FMDQ with the FMDQ-CR. Construct validity was assessed by performing correlation analyses between responses and respective validated measurement instruments.[19] The percentages of participants achieving the highest (ceiling effect) or lowest (floor effect) total scores were calculated to examine floor and ceiling effects. Non-parametric Wilcoxon signed-rank tests with continuity correction were performed to assess the differences between the measurement points of the outcome measures. A significance level of α=5% was assumed for all calculations.

MCID was determined by combining distribution-based and anchor-based methods as is recommended.[23] First, MCID was calculated using the distribution-based method of taking half of the SD of baseline total sum values of the FMDQ.[24] Next, the MCID was calculated based on the convenience sample of follow-up data using anchor-based methods. For this, scores/subscores from the SF-36 completed at baseline and follow-up were used. Suitable subscores were selected based on the degree of correlation between them and FMDQ scores. Since the interpretation of SF-36 subscores depends on the clinical condition and setting, appropriate MCID for SF-36 subscores was triangulated by considering distribution-based values from our own baseline data and from a large published treatment trial of FMD as well as previously published anchor-based MCIDs when available. All anchor-based calculations were performed on the relatively small convenience sample of patients with follow-up data and should be considered strictly exploratory in nature.

RESULTS

Patient characteristics

A baseline sample of 165 patients was recruited between January 2022 and July 2024. After the elimination of eight datasets due to incomplete data, fully completed datasets of 106 female and 51 male participants (n=157) were included in the final analysis. Table 1 provides an overview of age range and chronicity.

Most patients had exclusively hyperkinetic FMD symptoms (43%), with functional tremor as the most common symptom, while 13% of patients had exclusively hypokinetic FMD symptoms (mostly weakness). Twenty-six per cent of all patients had a mixed phenomenology (table 2).

Reliability

The following factors were expected in the CFA based on the structure of the questionnaire:

Factor 1: severity of functional motor symptoms (FMDQ items 1a–3d).

Factor 2: impairment of everyday activities (FMDQ items 4a–5e).

Factor 3: impact of non-motor symptoms (FMDQ items 6a–6f).

Factor 4: impairment of social functioning (FMDQ items 7a–7g).

Table 1 Characteristics of patient sample

Variable	Median (range)
Age*	53 (18–82) years
Age at first onset of symptoms†	46 (6–80) years
Age at FMD diagnosis*	52 (16–82) years
Latency between onset and diagnosis†	2 (0–40) years
Symptom duration†	3 (0–59) years

*n=157.
†n=154.
FMD, functional movement disorder.

Table 2 Frequency of functional movement disorder patterns

Symptom	Grouping	N	%
Functional Tremor	Hyperkinetic	50	32
Functional Dystonia	Hyperkinetic	23	15
Functional Myoclonus	Hyperkinetic	11	7
Functional Tic-like behaviour	Hyperkinetic	4	3
Functional Chorea and Dyskinesia	Hyperkinetic	10	6
Functional weakness	Hypokinetic	35	22
Functional Parkinsonism	Hypokinetic	6	4
Functional gait disorder	Gait	64	41

The sum of the frequencies is more than 100% because many patients suffered from more than one symptom pattern, n=157. Hyperkinetic symptoms: Functional Tremor, Functional Dystonia, Functional Myoclonus, Functional Tics, Functional Chorea and Dyskinesia; Hypokinetic symptoms: Functional Weakness, Functional Parkinsonism, Gait: Functional gait disorder.

The CFA evaluated how closely the observed data fit this hypothesised structure of the questionnaire—that is, whether items cluster into four meaningful domains representing different aspects of functional impairment. Lower RMSEA and SRMR values and higher CFI and TLI values indicate better fit. In the present analysis, a restrictive single-factor model (representing the overall questionnaire as a single dimension) was compared with a more complex four-factor model, which encompasses distinct but related domains of impairment (motor symptoms, daily activities, non-motor symptoms and social functioning). The CFA confirmed that the four-factor model provides a better fit to the data compared with a more restrictive one-factor model, also indicated by the significant $\chi 2$ difference test ($p<0.001$) (table 3). This superior fit of the complex model supports the multidimensional structure of the FMDQ.

Cronbach's α of the FMDQ subscales and the FMDQ-CR was in the expected range of $\alpha=0.70$ to 0.95, as shown in table 4.

The corrected item-total correlation analysis revealed that 95% of items were above the recommended minimum of 0.2 (see online supplemental table 1). The two items below this threshold—(frequency of tremors or muscle twitches ($r=0.19$) and impact on work or school (0.18)—were deemed essential from a conceptual point of view.

The inter-item correlations (online supplemental table 2) showed a consistent pattern of moderate positive associations between most item pairs, supporting the internal coherence of the scale. Less than 1% of pairwise correlations (6/703) showed excessive correlations ($r>0.80$). These were pairs of items reflecting the frequency and impact of movement abnormalities (items 1 and 7, 4 and 10, 5 and 11, 6 and 12), which was a conscious choice due to the nature of FMDQ. The other two item pairs with excessive correlations were items 18 and 19 (walking short distances (<10 m) and walking long distances (>100 m)) and items 24 and 25 (impairment in writing or typing and impairment in getting dressed). Although these seem like relevant items to include from a qualitative perspective, the high inter-item correlations could inform future abridgements of the questionnaire.

Table 3 Fit indices of the confirmatory factorial analysis

Fit indices	Cut-off for acceptance	Restrictive model	Complex model
χ^2–test	p<0.05	χ^2 (665)=2825.6, p<0.001	χ^2 (659)=2429.3, p<0.001
CFI	>0.95	0.385	0.496
TLI	>0.95	0.35	0.463
RMSEA	<0.10	0.144	0.131
SRMR	<0.10	0.124	0.124

Baseline data, n=157.
CFI, Comparative Fit Index; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardised Root Mean Square Residual; TLI, Tucker-Lewis-Index.

Table 4 Cronbach's α for all (sub-)scales

(sub-)scale	Cronbach's α
FMDQ subscale 1 (severity of functional motor symptoms)	0.85
FMDQ subscale 2 (impairment of everyday activities)	0.82
FMDQ subscale 3 (impact of non-motor symptoms)	0.75
FMDQ subscale 4 (impairment of social functioning)	0.80
FMDQ-CR	0.76

Baseline data, n=157.
CR, clinician-rated; FMDQ, functional movement disorder questionnaire.

Criterion validity

Spearman correlation confirmed a strong correlation between the FMDQ items 1a to 3d and the FMDQ-CR (Spearman $\rho=0.602$, $p<0.001$).

Construct validity

The construct validity hypothesis assumed high correlations between FMDQ items and other measured questionnaires or their subscales. The polarity of each result scale must be considered when interpreting these results. Higher FMDQ, FAS and PHQ-15 scores indicate greater health impairment and symptom severity. In contrast, higher scores on the SF-36 dimensions reflect a subjectively better health-related quality of life, so greater health impairments are reflected in lower scores. The median, minimum and maximum scores of all measures and their subscales are shown in online supplemental table 3 . As expected, the Spearman correlation indicated a strong negative relationship between FMDQ item 6b ("pain") and the SF-36 subscale "bodily pain" (Spearman $\rho=-0.673$, $p<0.001$), meaning that higher FMDQ impairment rates due to pain are associated with lower subjective quality of life due to pain in the SF-36. The Spearman correlation between FMDQ item 6d ("fatigue") and the SF-36 subscale "energy/fatigue" is also strongly negative (Spearman $\rho=-0.626$, $p<0.001$). In contrast, FMDQ item 6d ("fatigue") and the total FAS score correlate strongly positively (Spearman $\rho=0.637$, $p<0.001$). Therefore, more severe fatigue impairment in the FMDQ is associated with more severe fatigue symptoms in the FAS and lower health-related quality of life due to fatigue symptoms in the SF-36. The Spearman correlation also confirmed a strong relationship between FMDQ items 4a-5e and the SF-36 "physical functioning" subscale (Spearman $\rho=-0.76$, $p<0.001$), meaning that greater impairment of everyday activities as measured by the FMDQ is associated with lower perceived "physical functioning" in the SF-36. A higher impairment of movement due to non-motor symptoms, such as dizziness or sensory disturbances, is also associated with a lower "physical functioning" score in the SF-36, as indicated by the strong negative correlation between FMDQ items 6a–6f and the SF-36 subscale "physical functioning" (Spearman $\rho=-0.638$, $p<0.001$). In addition, impairment of movement due to non-motor symptoms in the FMDQ correlates strongly positively with the total PHQ-15 score, which also measures health impairment due to non-motor symptoms (Spearman $\rho=0.649$, $p<0.001$), meaning that higher impairment rates in the FMDQ are associated with greater impairment in the PHQ-15. Also, the correlations examined between FMDQ items 7a–7g and the SF-36

subscales "role limitations due to physical health problems" and "social functioning" subscales each show a strong correlation (Spearman $\rho=-0.554$, $p<0.001$ for "role limitations due to physical health problems" and Spearman $\rho=-0.531$, $p<0.001$ for "social functioning"). These correlations indicate that greater impairment in social functioning measured by the FMDQ is associated with greater role limitations due to physical health problems and decreased social functioning assessed by the SF-36.

Floor and ceiling effects

No floor or ceiling effects were observed in the baseline and follow-up samples. In both samples, no patient scored the lowest or highest possible value.

Responsiveness

The MCID of the FMDQ, calculated from the baseline total summed scores using the distribution-based method, was SD/2=23.85/2=11.93 points.

To calculate the anchor-based MCID for the FMDQ, first, the SF-36 subscores with the highest significant correlation with the FMDQ scores were determined. The correlation matrix revealed that these were the physical functioning (PF) subscore ($r=-0.73$, $p<0.00001$) and the physical component summary (PCS) subscore ($r=-0.71$, $pp<0.00001$). For the SF-36 PF subscale, published anchor-based MCID is 10.4 points.[25] Distribution-based MCID of PF from the largest treatment trial of FMD (n=246) is SD/2=23.1/2=11.55 points.[26] In our own baseline data, distribution-based MCID of PF was SD/2=30.26/2=15.13 points. Anchor-based calculation of the MCID of the FMDQ based on these two different anchors (11.55 and 15.13 points on the PF SF-36 subscale) both yielded an MCID of 19.5 points. For the PSC subscale, our distribution-based MCID would be SD/2=11.7/2=5.85, in line with published anchor-based MCID of 5.5 points for dystonia;[27] taking the latter as an anchor, an MCID for the FMDQ of 8.15 can be calculated. Collectively, anchor-based calculations suggest a MCID of the FMDQ ranging from 8 to 20 points, with the central value approximately aligning with the distribution-based MCID of 12 points. This MCID corresponds to 8% of the questionnaire's points range (minimum score: 31; maximum score: 181 points), indicating good overall responsivity of the FMDQ.

DISCUSSION

The present multi-centre study provides evidence that the newly developed FMDQ is a psychometrically robust PROM, showing strong internal consistency, good construct validity and sensitivity to clinically meaningful change. The questionnaire showed high internal consistency (Cronbach's α coefficients were strong for the total score and subcomponents), and no floor or ceiling effects.

Our study sample reflects the known predominance of females in FMD populations (approximately 2:1 female-to-male in our study).[28] The clinical features of this study's cohort are comparable to the characterisation of the cohort in the largest intervention study to date.[26] The range of symptom duration, for example, shows that both highly chronic cases and patients with acute symptom onset were included. In addition, a broad spectrum of motor symptoms is represented. Despite this heterogeneous case mix, no floor or ceiling effects were observed, indicating that this questionnaire can discriminate a wide range of heterogeneity among patients.

Importantly, the FMDQ exhibited strong convergent validity with external measures. For example, patient ratings of pain and fatigue on the FMDQ were strongly associated with the SF-36 "Bodily Pain" and "Energy/Fatigue" subscales, respectively, and with an independent measure of fatigue severity, indicating that the FMDQ effectively quantifies these non-motor symptoms consistent with established instruments. Likewise, the degree of activity limitation captured by the FMDQ showed a robust inverse correlation with the SF-36 PF domain, underscoring that our questionnaire's disability items meaningfully reflect objective functional status. Subscores of items capturing severity of specific motor deficits correlated well with respective clinician-rated assessments. These results support the notion that the FMDQ is measuring relevant constructs of health-related quality of life in FMD patients.

Notably, the FMDQ has a distribution-based MCID of 12 points, which falls within the range of anchor-based estimation of MCID of eight to 20 points, and corresponds to 8% of the total score range. This level of responsiveness qualifies the FMDQ as an adequate PROM for future FMD research as well as routine clinical use, especially in combination with clinician-rated instruments such as the Simplified Psychogenic Movement Disorders Rating Scale (S-FMDRS)[9] for motor symptoms, the Rating Scale for Psychogenic Movement Disorders (PMD)[29] or a Clinical Global Impression scale for more general assessment.

In practical terms, the FMDQ can be easily administered and scored, making it feasible for routine clinical use. By capturing the severity of motor symptoms along with the impact of fatigue, pain and other factors on daily activities, the FMDQ can help clinicians gain a holistic view of a patient's condition at baseline and track progress over time. Incorporating this PROM into care may facilitate more patient-centred discussions and tailored interventions, aligning treatment goals with what matters most to patients. At the same time, combining the self-assessment of symptom severity and impact on function in one questionnaire involves a controversial assumption: the questionnaire's first section assumes that a larger number of symptom types reflects a higher severity of the disorder. However, in FMD, variability and functional consequences may be more relevant than the number of phenotypes. This may affect the instrument's ability to compare severity between different individuals and highlights the need for further research to clarify the relationship between illness severity and motor symptom severity in FMD. Future statistical work could also explore alternative weightings or scoring approaches to accommodate these findings and further improve psychometric performance.

The FMDQ assesses the impact of common non-motor features such as pain, dizziness, fatigue, sensory symptoms, concentration problems and fear of falling or injury. However, it does not capture the full range and complexity of all non-motor symptoms reported by individuals with FMD, nor does it assess other functional neurological symptoms such as seizures. As in any disorder-specific PROM, this reflects a trade-off between breadth and specificity. Our findings demonstrate that a focus on FMD as a distinct subtype of FND in general can yield a psychometrically robust and clinically useful instrument. More broadly, this supports the feasibility of developing reliable PROMs for other specific subtypes within the wide spectrum of functional disorders. While nosological boundaries between subtypes (eg, FMD, functional/dissociative seizures, functional dizziness, etc) remain fluid, PROMs can be successfully tailored to capture core symptom domains and disability profiles that are meaningful within a given phenotype. At the same time, combining symptom-specific items with measures of overall functioning and disability, as demonstrated here, may offer a useful framework for future PROM development across FND subtypes. The above-mentioned heterogeneity of presentations even within the subtype of FMD requires

a relatively high number of different items, which in turn necessitate a very large sample size for ideal validation conditions. Herein lies a potential limitation of our study, which had to account for the practical limits of patient recruitment. Although our sample size with a 4:1 patients-to-items ratio formally satisfies published guidance for CFA,[19] it is on the lower end of current practice.[30] This may have affected the stability of parameter estimates and contributed to suboptimal model fit indices, which partly fell short of conventional benchmarks.

Another limitation is that the convenience sample of follow-up data used to estimate the MCID only allows for exploratory analyses. The fact that the anchor-based MCID values were close to the distribution-based values suggests that the sample size may have been sufficient for this preliminary assessment, but replication is needed. This study had no formalised documentation system for patient screening, meaning that the reasons for not recruiting some FMD patients were not systematically tracked and respective potential biases will remain unknown. Lastly, test–retest reliability was not studied in a stable subset. Thus, the measure's short-term stability in the absence of change is assumed but not formally quantified. These limitations highlight areas for future investigation to further establish the FMDQ's utility. An English translation of the FMDQ was prepared according to best practice guidelines in service of linguistic equivalence. Future studies should ideally include separate psychometric validation in English-speaking populations.[31]

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Contributors RM and SP conceived the study and designed the methodology. LH performed the statistical analyses. KL and ACL made a substantial contribution to the development and linguistic validation of the English version of the questionnaire. Data collection was conducted by: AW, CR, KEZ, TS, CB, FB, ML, CG, AR, DS, RM and SP drafted the manuscript; RM is the guarantor. All authors revised the manuscript critically for important intellectual content and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not applicable.

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