Supplementary information for

Validation of a Parkinson's Disease Questionnaire-39-based Functional Mobility Composite Score (FMCS) in people with Parkinson's disease.

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1 Supplementary informations

1.1 Theoretical construct of the FMCS and validity of the two subscales

The theoretical construct provided by Bouca-Machado, Duarte, Patriarca, Castro Caldas, Alarcao, Fernandes, Mestre, Matias and Ferreira [1], i.e., to move independently and safely in a variety of environments in order to accomplish functional activities or tasks and to participate in activities of daily living at home, work and in the community guided the development. Consequently, the composite score combines the items of the subscale mobility with the items of the subscale ADL of the Parkinson's Disease Questionnaire (PDQ-39) [2]. To ensure that all key concepts according to the definition of Bouca-Machado, Maetzler and Ferreira [3] were included, we compared the items of the subscales Mobility and Activities of Daily Living to the different characteristics of functional mobility according to their definition [3]. Consequently, we can confirm that the items of both subscales cover all relevant characteristics of functional mobility. As a previous factor analysis confirmed unidimensionality [4, 5] except for two items, we concluded that the items are mainly measuring one construct, i.e., the construct of functional mobility. Consequently, after summing up the items, we transformed the FMCS score to a 0 – 100 scale according to the "User Manual" of the "The Parkinson's Disease Questionnaire" [6] and inverted it by subtracting the individual score from the maximum score to enhance the interpretation of the results, i.e., a high score corresponds to good functional mobility.

$$\boldsymbol{FMCS\ Score = 100 - \left(\frac{Sum\ of\ 16\ items}{(4\ levels * 16\ items)} * 100\right)}$$

A spreadsheet calculator in form of an R-Shiny app [7] can be found under the following osf-webpage: https://tq9t3h-ahanff.shinyapps.io/FMCS_calculator/. According to Peto, Jenkinson and Fitzpatrick [8] mean change in the PDQ-39 subscore mobility of +3.2/100 (SD 13.26) and of +4.4/100 (SD 16.56) for the PDQ-39 subscore ADL corresponds to patients indicating feeling a little worse. The subscore mobility weights 62.5% (10/16) of the count based algorithm calculating the PDQ-39-based FMCS while the subscore ADL weights for 37.5% (6/16) of the score. Consequently, we weighted the change accordingly[1] resulting in a change of -3.65/100 indicating the patients experience worse functionally mobility.

The PDQ-39 is a thoroughly tested, translated, widely applied patient-reported quality of life assessment with adequate clinimetric characteristics. In particular, regarding content validity, questionnaire items were originally generated from in-depth interviews with PwP [2]. Consequently, the included items are also relevant for the target population, i.e., PwP. Both subscales show internal consistency according to the criteria of Prinsen, Mokkink, Bouter, Alonso, Patrick, de Vet and Terwee [9], i.e. a Cronbach's $\alpha \geq 0.70$ and ≤ 0.95 in almost all studies [2, 10-17]. In addition, Hagell and Nygren [4] reported corrected item-total correlations above the recommended criteria of 0.4 for all items. Regarding reliability, previous research showed test-retest-reliability, i.e. intraclass correlation coefficient (ICC) values above 0.70 for both subscales with test-retest

[1] (3.2 x 10) + (4.4 x 6) = 32 + 26.4 = 58.4/16 = 3.65

periods between three days and two weeks [2, 10, 11, 18]. While construct validity of each subscale was previously assessed by correlations with patient-reported motor symptoms (MDS-UPDRS II) [11] ($r > 0.70$), disease stage Hoehn and Yahr (H&Y) ($r > 0.60$) [11, 17, 19, 20], disability scores (Columbia University Rating Scales [17, 18], Barthel index [21], and Schwab and England Disability Score [17, 20] ($r > 0.55$)), clinician-assessed motor symptoms (MDS-UPDRS III) [17, 20] ($r > 0.50$), depression (Beck Depression Inventory [20] and Hospital Depression Scale [11]) ($r > 0.50$) and Levodopa duration [11] ($r > 0.40$), a construct validation with an instrument measuring functional mobility was never performed. Although, correlations are less clear regarding disease duration in years [11, 20] (r: 0.18 – 0.50) and cognition (Mini-mental score [20] or Short Portable Mental Status Questionnaire [11] (r: 0.23 – 0.39), both subscales discriminate PwP according to their disease stage [14, 15, 17, 19], perceived PD [16] and symptoms severity [2].

1.2 Hypotheses

We tested the following four directed hypotheses to assess convergent validity:

H0: Correlation of FMCS and TUG = 0

HA: Correlation of FMCS and TUG < 0

We expected an absolute correlation of > 0.40 as the objective TUG does not consider the subjective point of view of PwP. Recent research by [22] supports our assumption as they detected a similar absolute correlation (r_s = 0.46) between patient-reported mobility and spatiotemporal domain step velocity.

H0: Correlation of FMCS and PIGD Score = 0

HA: Correlation of FMCS and PIGD Score < 0

We expected an absolute correlation (r_s) of > 0.60 as the PIGD is a combination of clinician-assessed and patient-reported items about balance and gait. Consequently, it does consider the subjective point of view of PwP.

H0: Correlation of FMCS and MDS-UPDRS II = 0

HA: Correlation of FMCS and MDS-UPDRS II < 0

We expected an absolute correlation (r_s) of > 0.60 as the MDS-UPDRS II is a patient-reported outcome of motor symptoms. Consequently, it does consider the

subjective point of view of PwP and measures symptoms that are associated with functional mobility.

H0: Correlation of FMCS and MDS-UPDRS III = 0

HA: Correlation of FMCS and MDS-UPDRS III < 0

We expected an absolute correlation (r_s) of only > 0.40 as the MDS-UPDRS III is a clinician-assessed measure of motor symptoms compared to the PROM FMCS. Recent research by Zolfaghari, Thomann, Lewandowski, Trundell, Lipsmeier, Pagano, Taylor and Postuma [23] supports our expectation as they detected a correlation of the MDS-UPDRS III with the MDS-UPDRS II in two different datasets (r_s = 0.38 and r_s = 0.28).

Also, we tested the following four directed hypotheses to assess discriminative validity:

H0: FMCS in early disease stages = FMCS in advanced disease stages

HA: FMCS in early disease stages > FMCS in advanced disease stages

We expected people in early disease stages having at least a 3.65 pts higher FMCS compared to people in advanced disease stages according the minimally important difference experienced by people with PD.

H0: FMCS in people with PIGD-dominant phenotype = FMCS in people without PIGD-dominant phenotype

HA: FMCS in people with PIGD-dominant phenotype < FMCS in people without PIGD-dominant phenotype

We expected people with a PIGD-dominant phenotype having at least a 3.65 pts lower FMCS compared to people without according the minimally important difference experienced by people with PD.

H0: Absolute correlation (r_s) of the FMCS with the MDS-UPDRS II = Absolute correlation (r_s) of the FMCS with the MDS-UPDRS III

HA: Absolute correlation (r_s) of the FMCS with the MDS-UPDRS II > Absolute correlation (r_s) of the FMCS with the MDS-UPDRS III

We expected the absolute correlation (r_s) of the FMCS with the MDS-UPDRS II to be significantly stronger than the absolute correlation (r_s) of the FMCS with the MDS-UPDRS III, as the clinician-assessed motor symptoms do not consider the subjective point of view of PwP compared to the PROM of functional mobility.

H0: Absolute correlation (r_s) of the FMCS with the BDI-I = Absolute correlation (r_s) of the TUG with the BDI-I.
HA: Absolute correlation (r_s) of the FMCS with the BDI-I > Absolute correlation (r_s) of the TUG with the BDI-I.

We expected the absolute correlation (r_s) of the FMCS with the BDI-I to be significantly stronger than the absolute correlation (r_s) of the TUG and the BDI-I as the BDI-I and the FMCS are both patient-reported outcomes compared to the

objective TUG. Consequently, the FCMS should reflect the emotional state of the PwP better than a physical performance test of functional mobility like the TUG.

2 Supplementary tables

2.1 Table S1: Characteristics of comparator instruments

Comparator instruments	Construct it intends to measure	Assessment type	Details	Measurement properties	Recomm-ended by MDS	Original Scale
Timed Up and Go (TUG)	Functional Mobility	Assessor Observation	Measures a similar construct, but not a patient-reported outcome measure. The participant is required to get up from a standard chair, walk at a comfortable and safe speed to a line 3 m away, then turn at the line and walk back to the chair to sit down [24].	Adequate test-retest and inter-rater reliability in PD, with ICCs above 0.70. Known-group validity in PD is demonstrated by the test's ability to discriminate between early and middle disease stages, postural instability–gait difficulty dominant, and tremor-dominant types of PD. Construct validity in PD is demonstrated by correlations with walking speed, stride length, and turning ability [24].	✓ [24]	[25]
MDS-UPDRS-based PIGD Score	Postural Instabilities and Gait Difficulty	Patient-Reported and Clinician-Assessed Outcome Measure	Based on five MDS-UPDRS items relevant to gait and postural instability (items 13-15, 29, and 30) [24]. Combination of patient-reported and clinician-assessed outcome measures.	Good internal consistency, and moderate to good interrater reliability. Adequate face- and construct validity [24].	✓[24]	[26]
MDS-UPDRS II	Motor Symptoms in Daily Living	Patient-Reported Outcome Measure	Five of the 13 items assess impairments, not a disability (speech, salivation/drooling, chewing/swallowing, tremor, and freezing). The eight disability items assess eating, dressing, hygiene, handwriting, doing hobbies/activities (new), turning in bed, getting out of bed/car/chair (new), walking, and balance [27].	Good internal consistency and validity with high correlation with the UPDRS-ADL. Cut-off values were determined as: 0 to 2 points, no disability; 3 to 16, mild; 17 to 31, moderate; and ≥32, severe [24].	✓[24]	[28]
MDS-UPDRS III	Motor Symptoms	Clinician-Assessed Outcome Measure	Motor examination (33 scores based on 18 questions with several right, left or other body distributions scores).	Good internal consistency and validity with high correlation with the	NA	[29]

			Instructions for the rater to give or demonstrate to the patient and is completed by the rater.	older version, UPDRS part III.		
Beck Depression Inventory (BDI-I)	Symptoms of Depression	Patient-Reported Outcome Measure	One of the most used self-rated instruments for major depression in clinical practice. Weighted toward psychological symptoms of depression. Used to measure the severity of depression and as a screening instrument [30].	High test-retest reliability and internal consistency. Good concurrent and discriminant validity. Correlates with biological markers of depression and appears to be valid in patients with significant cognitive impairment. Valid across cultures [24].	✓[24]	[31]

Note. MDS: Movement Disorders Society, UPDRS: Unified Parkinson's Disease Rating Scale, PIGD: Postural Instabilities and Gait Difficulty

2.2 Table S2: Sociodemographic and disease-related variables

Variables	Instruments	Recommended by MDS	Original Scale
Age (y.)			
Male sex			
Children (n)		NA	
Years of education			
Disease duration (y.)			
Disease stage	Hoehn and Yahr (H&Y)	✓[32]	[33]
Cognition	Montreal Cognitive Assessment (MoCA)	✓[34]	[35]
Patient-Reported Non-Motor Symptoms	MDS-UPDRS I Score	NA	[36]
Clinician-Assessed Motor Complication	MDS-UPDRS IV Score	NA	[36]
Health-Related Quality of Life Score	PDQ-39	✓[37]	[2]

2.3 Table S3 Sociodemographic and health-related characteristics of the participants (N = 253) included in cross-sectional analysis involving the TUG

Characteristics	Mean (SD) / n (%)	Min. - Max.	Median (IQR)	Missing N (%)
Sociodemographic characteristics				
Age (y.)	67.3 (10.2)	22.9 - 92.7	68.6 (59.9 – 74.4)	0 (0.0%)
Children (n)	1.8 (1.1)	0.0 - 6.0	2.0 (1.0 - 2.0)	1 (0.04%)
Years of Education	13.5 (4.0)	5.0 - 25.0	13.0 (11.0 – 16.0)	0 (0.0%)
Language most fluent				0 (0.0%)
French	65 (26.3%)			
German	33 (13.4%)			
Luxembourgish	113 (45.7%)			
Other	36 (14.6%)			
Male sex	177 (71.7%)			0 (0.0%)
Marital status				1 (0.04%)
Single	7 (2.8%)			
Married / Partnered	193 (78.1%)			
Divorced / Widowed	44 (17.8%)			
Retired	162 (65.6%)			3 (0.1%)
Health-related characteristics				
Hoehn and Yahr (H&Y) Disease Stages				0 (0.0%)
H&Y 1	11 (4.5%)			
H&Y 1.5	21 (8.5%)			
H&Y 2	132 (53.4%)			
H&Y 2.5	55 (22.3%)			
H&Y 3	22 (8.9%)			
H&Y 4	6 (2.4%)			
H&Y 5	0 (0.0%)			
Disease duration (y.)	6.6 (5.0)	0.0 - 24.8	5.4 (2.8 – 8.6)	5 (2.0 %)
MoCA (0 – 30)[b]	25.4 (3.8)	10.0 - 30.0	26.0 (424.0 – 28.0)	7 (2.8%)
BDI-I (0 – 63)[a]	9.0 (7.4)	0.0 - 51.0	7.5 (4.0 – 12.0)	27 (10.7%)
MDS-UPDRS I (0 – 52)[a]	10.2 (6.1)	0.0 - 33.0	8.5 (6.0 - 14.0)	25 (9.9%)
MDS-UPDRS II (0 – 52)[a]	10.9 (7.8)	0.0 - 34.0	9.0 (5.0 - 16.0)	21 (8.3%)
MDS-UPDRS III (0 – 132)[a]	34.5 (13.8)	5.0 - 75.0	34.0 (25.0 - 45.0)	7 (2.8%)
MDS-UPDRS IV (0 – 24)[a]	1.3 (2.8)	0.0 - 15.0	0.0 (0.0 – 0.8)	3 (1.2%)
MDS-UPDRS-based PIGD Score (0 – 20)[a]	3.2 (3.1)	0.0 - 20.0	2.0 (1.0 - 5.0)	21 (8.3%)
PDQ-39 (0 – 100)[a]	20.6 (15.4)	0.0 - 82.1	18.6 (7.7 - 28.2)	26 (10.3%)
FMCS (0 – 100)[b]	79.4 (19.4)	4.7 - 100.0	84.4 (67.2 - 95.3)	24 (9.5 %)
TUG[b]	12.5 (5.0)	6.2 – 51.4	11.4 (9.8 – 13.3)	0 (0.0%)

[a] *higher scores indicating more severe impairment.*
[b] *higher scores indicating less severe impairment.*

2.4 Table S4: Characteristics of PIGD comparator groups

Variables	Not PIGD dominant (N = 399)	PIGD dominant (N = 305)
Age (y)	67.3 (14.7)	69.9 (13.3)
Male sex	286 (71.7%)	186 (70.0%)
Children (n)	2 (1)	2 (2)
Years of education	13 (6)	12 (6)
Disease duration (y)	2.6 (4.4)	5.2 (8.2)
MoCA	26 (5)	25 (5)
BDI-I	7.0 (7.5)	10.0 (8.0)
MDS-UPDRS I	8.0 (8.0)	10.0 (10.0)
MDS-UPDRS II	7.0 (8.8)	13.5 (13.0)
MDS-UPDRS III	31.0 (19.0)	37.5 (23.3)
MDS-UPDRS IV	0 (0)	0 (5)
FMCS Score	87.5 (22.7)	64.1 (34.4)

Note. categorical variables: counts (%), numerical variables: median (IQR)

2.5 Table S5: Characteristics of disease stages comparator groups

Variables	Early disease stage (N = 508)	Moderate-advanced disease stage (N = 225)
Age (y)	67.0 (14.2)	73.1 (13.2)
Male sex	350 (68.9%)	137 (60.9%)
Children (n)	2 (1)	2 (2)
Years of education	13 (6)	12 (4)
Disease duration (y)	2.7 (4.8)	6.0 (7.7)
MoCA	26 (5)	24 (6)
BDI-I	7 (8)	11 (8)
MDS-UPDRS I	8 (7)	13 (11)
MDS-UPDRS II	8 (8)	16 (13)
MDS-UPDRS III	29 (18)	45 (22)
MDS-UPDRS IV	0.0 (0.0)	0.0 (4.3)
FMCS Score	86.0 (23.4)	57.8 (37.5)

Note. categorical variables: counts (%), numerical variables: median (IQR)

2.6 Table S6: FMCS by various subgroups

Characteristics	Categories	Mean (SD)
Sociodemographic characteristics		
Years of Education	< 13 y.	73 (24)
	≥ 13 y.	76 (21)
Retired	No	78 (19)
	Yes	72 (24)
Health-related characteristics		
Phenotype	Tremor (≥ 1.15)	84 (16)
	Intermediate (<1.15 & >0.90)	74 (21)
	PIGD (≤ 0.90)	62 (24)
Hoehn and Yahr (H&Y) Disease Stages	H&Y 1	89 (12.9)
	H&Y 1.5	86 (16.5)
	H&Y 2	79 (18.4)
	H&Y 2.5	66 (19.8)
	H&Y 3	59 (23.3)
	H&Y 4	34 (19.2)
	H&Y 5	36 (34.0)
Depression (BDI-I)	None or minimal depression (< 10)	84 (16)
	Mild depression (10 - 18)	65 (23)
	Moderate depression (19 - 29)	54 (23)
	Severe depression (≥ 30)	38 (23)
Levodopa Equivalent Daily Dose	Below median	79 (21)
	Above median	64 (23)
Completion by a proxy	No	76 (21)
	Yes	51 (31)

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