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Construct validity of the PROMIS PF-10 in patients with inflammatory rheumatic diseases and severe limitations in physical functioning

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Objective: Assessing the construct validity of the Patient-Reported Outcomes Measurement Information System Physical Function 10-Item Short Form (PROMIS PF-10) in a subpopulation of rheumatoid arthritis (RA) or axial spondyloarthritis (axSpA) patients with severe limitations in physical functioning (PF).

Method: RA/axSpA patients with severe functional limitations completed the PROMIS PF-10, Health Assessment Questionnaire – Disability Index (HAQ-DI for RA) or Bath Ankylosing Spondylitis Functional Index (BASFI for axSpA), 36-item Short Form Health Survey (SF-36), EuroQol 5-dimensions 5-level (index score, EQ-VAS), and performed the Six-Minute Walk Test (6MWT). Construct validity was assessed by computing Spearman rank or Pearson correlation coefficients and testing hypotheses about correlations between the PROMIS PF-10 and measures of PF and quality of life.

Results: Data from 316 patients (180 RA/136 axSpA, 91.7%/47.8% female, mean ± sd age 58.6 ± 13.2/54.0 ± 11.3 years) were analysed. The median (IQR) PROMIS PF-10 score was 34.5 (31.4–37.6) in RA and 36.0 (32.8–38.3) in axSpA patients. The PROMIS PF-10 correlated strongly with the HAQ-DI, BASFI, and EQ-5D-5L index score ($r > 0.6$), moderately with the SF-36 Physical Component Summary score, EQ-VAS, and 6MWT ($0.30 \leq r \leq 0.60$), and weakly with the SF-36 Mental Component Summary score ($r < 0.30$). Five of six hypotheses (83%) were confirmed in both groups.

Conclusion: The overall strong correlation of the PROMIS PF-10 with measures of PF and moderate to weak correlations with outcomes measuring different constructs were confirmed in subpopulations of RA and axSpA patients with severe functional limitations, supporting its construct validity.

Rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) are the most common inflammatory rheumatic diseases (RMD). Both can have a major impact on physical functioning, which is therefore one of the core domains to evaluate the effect of interventions in research and clinical practice (1–3). Regarding the measurement of physical functioning, the Six-Minute Walk Test (6MWT) (4) is a widely used and valid performance-based test, while commonly used and valid Patient-Reported Outcome Measures (PROMs) include the Health Assessment Questionnaire – Disability Index (HAQ-DI) (5) for RA and the Bath Ankylosing Spondylitis Functional Index (BASFI) (6) for axSpA patients. Physical functioning is also one of the (sub)scales of some generic PROMs, reflecting health-related quality of life (HRQoL), of which the 36-item Short Form Health Survey (SF-36) (7) and the EuroQol 5-Dimensions 5-level (EQ-5D-5L) (8) are the most frequently used.

Trial Registration: [Netherlands National Trial Register, https://trialsearch.who.int/Trial2.aspx?TrialID=NL8235, L-EXTRA (NL8235)] and [Netherlands National Trial Register, https://trialsearch.who.int/Trial2.aspx?TrialID=NL8238, L-EXSPA (NL8238)]

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To facilitate the comparison of various domains of health status (i.e. biological, psychological, and social aspects) among patients with similar or different conditions, the Patient-Reported Outcomes Measurement Information System (PROMIS) (9) was developed. It makes use of several item banks, one being the PROMIS physical function (PROMIS PF) item bank. The PROMIS PF 10-item short form (PROMIS PF-10) is a questionnaire based on a selection of specific items of the PROMIS PF item bank (10, 11). A Dutch-Flemish version of the PROMIS PF item bank was developed (12) and the construct validity of the PROMIS PF-10 was confirmed in three observational studies of patients with RA (13–15). All three studies showed moderate to strong correlations with self-reported measures of physical functioning or HRQoL (i.e. HAQ-DI and SF-36) and weak correlations with other PROMIS item banks measuring a different construct (e.g. depression and anxiety) (13–15). Only one observational study examined the construct validity of PROMIS PF-10 in patients with ankylosing spondylitis (AS), showing a strong correlation with the BASFI (16). All of these studies mainly included patients with stable disease, no comorbid conditions, a relatively short disease duration, and favourable functional ability (mean HAQ-DI < 1.0 and BASFI 3.06) (13–16). The relatively favourable average level of physical functioning in those studies is substantiated by the observation that the lowest (worst) reported PROMIS-PF-10 scores were 24.1 (13) and 25.1 (16), respectively, whereas its range is 13.5 (worst) to 61.9 (best).

No study has examined the construct validity of the PROMIS PF-10 in patients with RA and axSpA (including AS) who have severe limitations in physical functioning. This is relevant, as patients with RA and axSpA with severe functional limitations due to, for example, persisting disease activity, joint damage, or comorbid diseases, constitute a minor yet clinically important subgroup of patients, but are nevertheless often excluded from clinical trials. Clinimetric properties of an outcome measure may differ based on the population in which they are measured, as they may be affected by factors such as important disease characteristics (17–19).

It is unknown whether the previous conclusions regarding the construct validity of the PROMIS PF-10 are applicable to RA and axSpA patients with severe disability and whether a possible floor effect of the PROMIS PF-10 is present. Moreover, unlike the SF-36 Physical Functioning scale, performance-based measures of physical function, such as the 6MWT, have not been previously used in studies of the construct validity of the PROMIS PF-10. Therefore, the aim of this study was to assess the construct validity of the PROMIS PF-10 in a subpopulation of patients with RA and axSpA and severe functional disability.

Method

Study design

Data from two national randomized controlled trials (RCTs) were used (20). The objectives of the RCTs are to determine the effect of longstanding exercise therapy compared to usual care in patients with RA [Longstanding EXercise Therapy in patients with RA (L-EXTRA) study] and axSpA [Longstanding EXercise therapy in patients with axSpA (L-EXSPA) study] with severe limitations in physical functioning. In these studies, the level of physical functioning as experienced by the patient over 12 months is evaluated using various measurement instruments. Details about the design of these ongoing studies have been published before (20). Recruitment and inclusion started in March 2020. Both studies are conducted in accordance with the Declaration of Helsinki (21), were approved by the Medical Ethics Committee of the Leiden University Medical Center (numbers NL70093.058.19 and NL69866.058.19), and were registered in the Netherlands National Trial Register (https://www.trialregister.nl/): L-EXTRA (NL8235) and L-EXSPA (NL8238). Written informed consent was obtained from all participants. The reporting of this study is conducted in line with the checklist hypotheses testing for construct validity from the COSMIN Study Design checklist for patient-reported outcome measurement instruments (22).

Participants

Inclusion criteria for the L-EXTRA and L-EXSPA studies (20) were: (i) adult patients with a clinical diagnosis of RA or axSpA; (ii) with one or more severe functional disabilities despite adequate medical treatment of the rheumatic condition, resulting in limitations in daily activities involving self-care, transfers, and/or mobility indoors or outdoors; (iii) functional disability directly or indirectly related to the rheumatic condition, and caused by, for example, persisting or progressive high disease activity despite optimal medical treatment and/or severe joint damage and/or deformities and/or severe comorbidity; and (iv) functional disability cannot or could not be stopped or improved by a short, intermittent exercise therapy intervention. Exclusion criteria were: (i) individual treatment by a physical therapist or a multidisciplinary team in the setting of a rehabilitation centre or rheumatology clinic or centre in the past 3 months; and (ii) in need of admission to a hospital, rehabilitation centre, or rheumatology clinic, or other forms of intensive, multidisciplinary care.

After the presence of severe limitations in physical functioning, as described above, and absence of recent physical therapy or multidisciplinary treatment had been determined in a semi-structured interview between one of the researchers (MvW or MT) and the potential participant, the treating rheumatologist was, with

written permission from the patient, informed about the patient's application. The treating rheumatologist was asked to confirm the clinical diagnosis of RA or axSpA, implementation of adequate pharmacological treatment, the likely relationship between the functional disability and the rheumatic condition, the proven or likely failure of a short physical therapy intervention, and the absence of a need for hospitalization or multidisciplinary treatment. For the current analysis, data from included patients from both studies were used if their baseline assessment was completed by 15 November 2021.

Assessments

At baseline, sociodemographic and disease characteristics, and measures of physical functioning and quality of life were collected.

Sociodemographic and disease characteristics. Sociodemographic characteristics included sex (female or male), age (years), relationship status (married or registered partnership; unmarried, divorced, or widowed; household composition (living alone or with other people), and highest educational level (low: primary school or lower vocational education; medium: lower general secondary school or intermediate vocational education; or high: higher general secondary school, higher vocational education, or university). Self-reported height (m) and weight (kg) were registered to calculate the Body Mass Index (BMI).

Disease characteristics included self-reported symptom duration (years) and the need to use adaptive devices or receive help from a person in daily life (yes/no). Comorbidities were recorded using a questionnaire developed by the Dutch Central Bureau of Statistics (CBS), asking for the presence or absence of 19 different comorbidities in the previous year (23). We divided the comorbidities into three domains: (i) musculoskeletal comorbidities: severe back pain (including slipped disc); severe neck or shoulder pain; severe elbow, wrist, or hand pain; and other chronic rheumatic diseases; (ii) non-musculoskeletal comorbidities: asthma or chronic obstructive pulmonary disease ; (severe) cardiac disorder or coronary disease; arteriosclerosis (abdomen or legs); hypertension; (consequences of) stroke; severe bowel disorder; diabetes mellitus; migraine; psoriasis; chronic eczema; cancer; and incontinence of urine; and (iii) sensory impairments: hearing impairments (group and face-to-face conversation); vision impairments (short and long distance); and dizziness in combination with falling (yes/no).

Measures of physical functioning

PROMIS PF-10. The PROMIS PF-10 (24) is a generic outcome for measuring physical functioning in chronic diseases. It contains 10 questions from the PROMIS PF item bank, which are all scored on a five-point scale that ranges from 1 to 5, with higher scores indicating better functioning. To calculate the total score, the data must be uploaded into a scoring system program (25), after which the raw scores and the T-scores are calculated. In this study, the short form version PROMIS PF-10a was used. The PROMIS PF-10 T-score can range from 13.5 to 61.9 (26), where a higher score means better physical functioning. A validated Dutch version was used and calculations were standardized to the Dutch population (27).

HAQ-DI. The HAQ-DI (4) consists of 20 items about the ability to perform daily activities, divided over eight domains. Each item has four answering options ranging from 0 (not difficult to perform) to 3 (unable to perform). The total HAQ-DI score is calculated as the mean of the highest scores of the eight domains. Scores were calculated according to the standard scoring rule, which takes the use of assistive devices and/or help from others into account. The total score ranges from 0 to 3, with 0 meaning no functional disability and 3 meaning major disability in physical functioning. For this study, a validated Dutch translation of the HAQ-DI was used (28). The HAQ-DI was only assessed in RA patients.

BASFI. The BASFI (5) consists of eight specific questions regarding physical functioning and two questions reflecting the patient's ability to cope with everyday life. All 10 questions are scored from 0 (easy) to 10 (impossible to perform). The average score is then calculated, ranging from 0 (no impairment) to 10 (severe impairment in physical function). A validated Dutch translation was used (29). The BASFI was only assessed in axSpA patients.

6MWT. The 6MWT (6) measures the distance in metres that a patient is able to walk in 6 minutes, and includes assessment of the patient's gait, gait speed, and endurance. A standardized Dutch translation of the instructions was used (30) and the 6MWT was administered according to the protocol (30) by two trained researchers (MvW and MT).

Measures of HRQoL

SF-36. The SF-36 (7) consists of 36 items grouped into eight scales, comprising physical functioning (PF), social functioning (SF), role physical (RP), role emotional (RE), vitality (VT), mental health (MH), bodily pain (BP), and general health (GH). Weighted sums of the eight scales yield two summary scores: the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. All scales and summary scores range from 0 to 100, with a higher score indicating a better health status. A validated Dutch translation was used and calculations were standardized to the Dutch population (31).

EQ-5D-5L. The EQ-5D-5L (8) is a generic questionnaire that consists of five questions on self-care, usual activities, pain/discomfort, mobility, and anxiety/depression. All questions have five response levels, ranging from 1 (no problem) to 5(a major problem). These scores are converted into a single index score ranging from −0.446 to 1.000 (32), where a score below zero represents a state that is considered to be worse than death (33). In addition, patients reported their self-perceived health status with a visual analogue scale (EQ-VAS) ranging from 0 (worst) to 100 (best imaginable health state). For the EQ-5D-5L, a validated Dutch translation was used and calculations were standardized to the Dutch population (33).

Data and statistical analysis

Data for the self-reported questionnaires were obtained through OnlineProms®(2020, Interactive Studios), a program specially developed for completing and saving PROMs online. Outcomes of the 6MWT were recorded by two researchers and then uploaded to OnlineProms. All data were exported on 15 November 2021. Statistical analysis was performed with SPSS version 25.0 for Windows (IBM Corp, Armonk, NY, USA).

Distribution of variables. Data were presented as mean and standard deviation or median and interquartile range (IQR), where appropriate. Distribution of the data was analysed with the Kolmogorov–Smirnov test and the occurrence of outliers was analysed. Results were considered statistically significant if the p value was < 0.05. All analyses were performed separately for the axSpA and RA patient groups.

Floor and ceiling effects. Floor or ceiling effects were considered to be present when 15% or more of the patients had the lowest or highest absolute score. If floor and ceiling effects are present, extreme items at the bottom and top of the scale are likely to be missing, indicating a limited content validity (34, 35).

Construct validity of the PROMIS PF-10. The construct validity of the PROMIS PF-10 was reported by the COSMIN Study Design checklist for patient-reported outcome measurement instruments (22). For both RA and axSpA, six hypotheses were formulated a priori, about the strength of correlations with other measures of physical functioning, HRQoL, and performance testing. Correlations were calculated using Pearson's (normal distribution) or Spearman's (non-normal distribution) correlation coefficients. Correlation coefficients were presented as r with the 95% confidence interval. The strengths of the correlations were designated as weak ($r < 0.30$), moderate ($0.30 \leq r \leq 0.60$), or strong ($r > 0.60$) (14, 36). Based on previous research, it was hypothesized that the PROMIS PF-10 would correlate strongly with other measures of physical functioning [HAQ-DI in RA patients (14, 15) and BASFI in axSpA patients (16)]. Moderate correlations were expected with measures assessing a combination of dimensions of HRQoL (SF-36 PCS, EQ-5D-5L index score, EQ-VAS) or performance-based tests (6MWT). A weak correlation was expected with measures primarily measuring a construct other than physical function (SF-36 MCS). Of these six hypotheses, the correlation coefficients were calculated separately for both RA and axSpA patients. According to the quality criteria for measures of health status questionnaires (34), sufficient construct validity was considered to be present if at least five out of six of the hypotheses (≥ 75%) for each disease were confirmed.

Results

Patient characteristics

The study flowchart of the recruitment of patients is shown in Figure 1. Patient characteristics are presented in Table 1. The proportion of female patients and the mean ± sd age were higher in the RA than in the axSpA group (RA 91.7% female, age 58.6 ± 13.2 years; axSpA 47.8% female, age 54.0 ± 11.3 years). Self-reported symptom duration was longer than 20 years in both groups. The need for help and/or assistive device(s) was 58.9% in RA and 39.0% in axSpA patients. In both groups, high blood pressure and lung diseases were among the three most common forms of comorbidities. In RA, migraine or severe headache, and in axSpA, bowel disorder were also among the three most frequent comorbidities.

Measures of physical functioning and HRQoL

The descriptive statistics of the measures of physical functioning and quality of life are shown in Table 2.

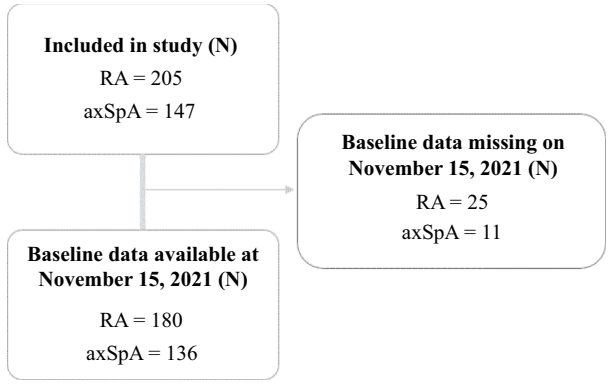

Figure 1. Study flowchart of two randomized controlled trials on exercise therapy in rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) patients.

Table 1. Baseline characteristics of patients with rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) participating in the L-EXTRA and L-EXSPA studies.

	RA (N = 180)	axSpA (N = 136)
Female	165 (91.7)	65 (47.8)
Age (years)	58.6 ± 13.2	54.0 ± 11.3
Self-reported symptom duration (years)	21.0 (10.0–30.0)	25.0 (14.0–35.0)
Civil status	(N = 179)	
Married or registered partnership	99 (55.3)	90 (66.2)
Unmarried, divorced, or widowed	80 (44.7)	46 (33.8)
Household composition		
Single-person household	60 (33.3)	31 (22.8)
Living with partner and/or children or others	120 (66.7)	105 (77.2)
Education*		
Low	73 (40.6)	33 (24.3)
Medium	54 (30.0)	50 (36.8)
High	53 (29.4)	53 (39.0)
BMI (kg/m^2)	27.7 ± 6.0	28.4 ± 5.3
Number of comorbidities	(N = 178)	(N = 135)
0	12 (6.7)	8 (5.9)
1–2	45 (25.3)	29 (21.5)
3–4	64 (36.0)	49 (36.3)
≥ 5	57 (32.0)	49 (36.3)
Need for help and/or assistive device(s)	106 (58.9)	53 (39.0)

Data are shown as n (%), mean ± sd, or median (interquartile range).
*Low, primary school or lower vocational education; medium, lower general secondary school or intermediate vocational education; high, higher general secondary school, higher vocational education, or university.
L-EXTRA, Longstanding-EXercise Therapy in patients with RA; L-EXSPA, Longstanding-EXercise therapy in patients with axSpA; BMI, Body Mass Index.

The PROMIS PF-10 scores were distributed normally in both RA and axSpA patients, as seen in Figures 2 and 3. The median (IQR) PROMIS PF-10 score was 34.5 (31.4–37.6) in RA and 36.0 (32.8–38.3) in axSpA patients. The SF-36 PCS was distributed normally in both RA and axSpA, as was the EQ-VAS in RA patients and the BASFI in patients with axSpA. All other measures (HAQ-DI, SF-36 MCS, EQ-5D-5L index score, and 6MWT) were not normally distributed. In both groups, there were patients with a negative EQ-5D-5L index score (n = 6 RA, n = 5 axSpA), indicating a health status worse than death. There were no floor or ceiling effects for the PROMIS PF-10 or any of the physical functioning measures (BASFI, HAQ-DI, and 6MWT) and HRQoL measures (EQ-5D-5L, EQ-VAS, and SF-36 MCS/PCS) in either RA or axSpA patients (data not shown). Separate scale scores of the SF-36 are shown in the Supplementary Table S1.

Table 2. PROMIS PF-10 and other physical functioning and health-related quality of life in patients with rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA).

	RA (N = 180)	axSpA (N = 136)
PROMIS PF-10 (13.5–61.9)	34.5 (31.4–37.6)	36.0 (32.8–38.3)
HAQ-DI (0–3)	1.6 (1.4–2.0)	–
BASFI (0–10)	–	6.4 (4.8–7.8)
6MWT (m)	300.5 (243.3–364.5)	410.0 (327.9–460.0)
SF-36 (0–100)		
MCS score	48.9 (37.4–57.4)	49.0 (34.9–54.8)
PCS score	29.0 (23.5–35.2)	28.1 (23.4–32.5)
EQ-5D-5L		
Index score (–0.446 to 1)	0.6 (0.3–0.7)	0.6 (0.3–0.7)
EQ-VAS (0–100 mm)	59.0 (40.3–70.0)	56.0 (40.0–70.0)

Data are shown as median (interquartile range).
PROMIS PF-10, Patient-Reported Outcomes Measurement Information System Physical Function 10-Item Short Form; HAQ-DI, Health Assessment Questionnaire – Disability Index; BASFI, Bath Ankylosing Spondylitis Functional Index; 6MWT, Six-Minute Walk Test; SF-36, 36-item Short Form Health Survey; MCS, Mental Component Summary score; PCS, Physical Component Summary score; EQ-5D-5L, EuroQol 5-dimensions 5-level; EQ-VAS, EuroQol Visual Analogue Scale.

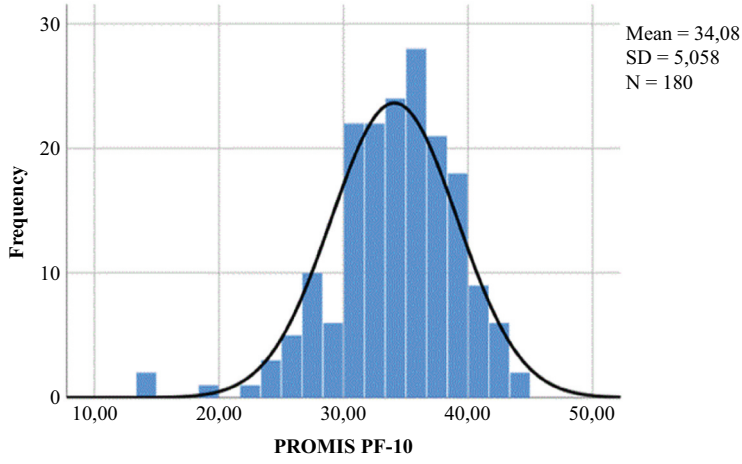

Figure 2. Distribution of the Patient-Reported Outcomes Measurement Information System Physical Function 10-Item Short Form (PROMIS PF-10) in patients with rheumatoid arthritis.

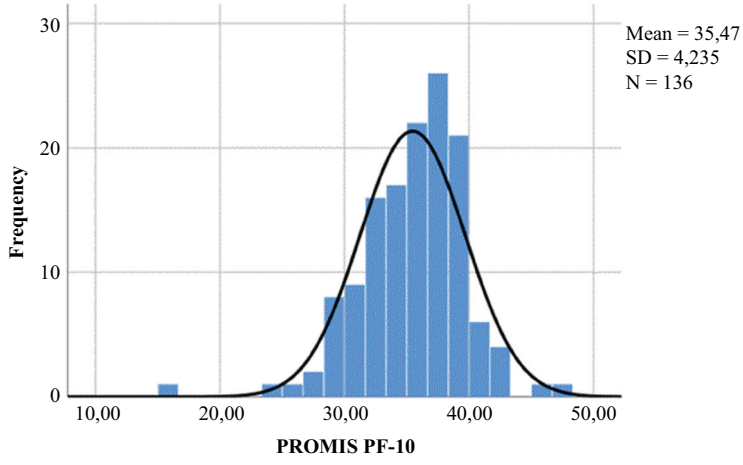

Figure 3. Distribution of the Patient-Reported Outcomes Measurement Information System Physical Function 10-Item Short Form (PROMIS PF-10) in patients with axial spondyloarthritis.

Correlations between PROMIS PF-10 and measures of physical functioning

The strengths of the correlations between the PROMIS PF-10 and the measures of physical functioning are shown in Table 3. All correlations between the PROMIS PF-10 and measures of physical functioning were statistically significant. In RA, the PROMIS PF-10 showed a strong correlation with the HAQ-DI (r = −0.75) and a moderate correlation with the 6MWT (r = 0.49), both as hypothesized. In axSpA, the PROMIS PF-10 correlated strongly with the BASFI (r = −0.68) and moderately with the 6MWT (r = 0.43), also both as hypothesized. These results confirm both hypotheses for both patient groups for measures of physical functioning.

Correlations between PROMIS PF-10 and measures of HRQoL

The correlations between the PROMIS PF-10 and the measures of HRQoL are also shown in Table 3. Correlations between the PROMIS PF-10 and HRQoL measurements were statistically significant, except for the correlations with the SF-36 MCS in both patient groups. In RA, the PROMIS PF-10 correlated strongly with the EQ-5D-5L index (r = 0.62), a correlation slightly higher than hypothesized. Correlations were moderate with the SF-36 PCS (r = 0.57) and EQ-VAS (r = 0.38) and weak with the SF-36 MCS (r = 0.11), all as hypothesized. In axSpA, the PROMIS PF-10 correlated strongly with the EQ-5D-5L index (r = 0.61), whereas a moderate correlation was hypothesized. The PROMIS PF-10 correlated moderately with the SF-36 PCS and EQ-VAS (r = 0.53 and r = 0.44). Correlations were weak with the SF-36 MCS (r = 0.06), which was hypothesized. Correlations between the PROMIS PF-10 and SF-36 scales are shown in the Supplementary Table S2. With these results, three of the four hypotheses were confirmed in RA and in axSpA patients.

Construct validity of the PROMIS PF-10

In both RA and axSpA patients, five of the six hypotheses (≥ 75%) were confirmed (83%). The data thus support sufficient the construct validity of the PROMIS

Table 3. Correlations between the PROMIS PF-10 and other measures of physical functioning and health-related quality of life.

		RA (N = 180)			axSpA (N = 136)		
Hypotheses	Assessment	Correlation coefficient	95% CI	Hypothesis confirmed	Correlation coefficient	95% CI	Hypothesis confirmed
Strong (r > 0.60)	HAQ-DI	–0.75	–0.81 to –0.68	Yes	–	–	–
	BASFI	–	–	–	–0.68*	–0.76 to –0.58	Yes
Moderate	SF-36 PCS	0.57*	0.46 to 0.66	Yes	0.53*	0.40 to 0.64	Yes
(0.30 ≤ r ≤ 0.60)	EQ-5D-5L index score	0.62	0.52 to 0.70	No	0.61	0.49 to 0.71	No
	EQ-VAS	0.38*	0.25 to 0.50	Yes	0.44	0.29 to 0.57	Yes
	6MWT	0.49	0.37 to 0.59	Yes	0.43	0.28 to 0.56	Yes
Weak (r < 0.30)	SF-36 MCS	0.11	–0.04 to 0.25	Yes	0.06	–0.11 to 0.23	Yes

*Pearson correlation, normal distribution of the data.
PROMIS PF-10, Patient-Reported Outcomes Measurement Information System Physical Function 10-Item Short Form; RA, rheumatoid arthritis; axSpA, axial spondyloarthritis; CI, confidence interval; HAQ-DI, Health Assessment Questionnaire – Disability Index; BASFI, Bath Ankylosing Spondylitis Functional Index; SF-36, 36-item Short Form Health Survey; PCS, Physical Component Summary score; EQ-5D-5L, EuroQol 5-dimensions 5-levels; EQ-VAS, EuroQol Visual Analogue Scale; 6MWT, Six-Minute Walk Test; MCS, Mental Component Summary score.

PF-10 in RA and axSpA patients with severe limitations in physical functioning.

Discussion

This study confirmed the construct validity of the PROMIS PF-10 as an outcome measure in a subpopulation of RA and axSpA patients with severe limitation in physical functioning. No floor and ceiling effects were observed. Our findings in this subpopulation of RA and axSpA patients are consistent with those in previous cohorts of patients with RA and axSpA and an overall better health status. The PROMIS PF-10 showed strong associations with the HAQ-DI and BASFI (13–16) and a low correlation with the SF-36 MCS, including mental health, role emotional, social function, and vitality, the latter confirming that the PROMIS PF-10 indeed assesses a different construct than mental functioning. The correlation between the PROMIS PF-10 and the EQ-5D-5L in RA and axSpA patients was slightly higher than expected. We could not compare these scores with previous studies including an RA or axSpA population, as these did not include a measure of HRQoL.

The PROMIS PF-10 scores observed in this study were considerably lower [RA: 34.5 (31.4–37.6); axSpA: 36.0 (32.8–38.3)] than in two previous studies in RA (mean ± sd scores of 43.3 ± 9.0 and 40.2 ± 10.5) and one study in AS patients (mean ± sd score of 46.56 ± 9.8) (13, 15, 16), with the lowest reported score being 24.1 in RA (13). In addition, our study showed that scores of other measures of physical function also indicated more limitations in physical function. The median (IQR) HAQ-DI score [1.6 (1.4–2.0)] and BASFI score [6.4 (4.8–7.8)] were higher than those reported in previous studies on the use of the PROMIS PF-10 in RA [mean ± sd 0.3 ± 0.4 (13) and 0.9 ± 0.8 (15)] and axSpA patients [3.06 ± 2.63 (16)]. Thus, the considerably lower average scores of the PROMIS PF-10 and higher HAQ-DI and BASFI scores in our study indeed indicate that subpopulations with more limitations in physical functioning were selected and the PROMIS PF-10 can discriminate between populations with different levels of physical functioning.

In general, patients with considerable limitations in physical functioning and/or comorbidities are underrepresented in research, although they constitute a relevant subpopulation in clinical practice. The same holds for research into the methodological properties of measurement instruments, despite the fact that clinimetric properties of an outcome measure may differ depending on the population in which they are measured (17–19). As such, the findings of the present study add information to the knowledge base about the construct validity of the PROMIS PF-10 (13–16). In a severely disabled population, in particular, floor effects of specific measurements can be an issue (35). In our study, in contrast with previous populations (13–16), there were some patients with very low scores, but this proportion was less than 15%, indicating that the PROMIS PF-10 displayed no floor effect. This contributes to the view that the PROMIS PF-10 differentiates well between patients, even at the extreme low ends of the of disability spectrum, and is able to capture limitations in physical functioning in this range.

A limitation of this study is the lack of information about disease activity. In previous studies, the PROMIS PF-10 showed low correlations with disease activity, measured with the Clinical Disease Activity Index (CDAI), 100 mm VAS disease activity, Ankylosing Spondylitis Disease Activity Score (ASDAS), and 10-point numerical ratings scale (13–16). Also, no information was collected on skeletal muscle mass or muscle strength during this study. A decrease in both muscle

mass and strength is a common feature in chronic diseases such as RA and axSpA and is associated with impaired physical functioning (37–39). In RA, lower muscle strength is correlated with poorer functional ability (38) and elderly RA patients have a reduced skeletal muscle mass, which aggravates physical dysfunction (37). In future research, the inclusion of both muscle mass and muscle strength should be considered, where muscle strength can be measured validly, reliably, and more easily in clinical practice, e.g. by measuring handgrip strength (38, 39). Moreover, other clinimetric properties, including responsiveness to change and ability to discriminate between intervention and control conditions, in this population should be determined in the future.

Conclusion

This study supports the construct validity in RA and axSpA patients with severe limitations in physical functioning. The majority of the hypotheses on correlations between the PROMIS PF-10 and measures of physical functioning and HRQoL were confirmed (83% in RA and axSpA). As the PROMIS PF-10 is a generic, brief, and easy-to-use instrument, it seems to be a potentially valuable addition to currently used instruments to assess physical functioning in patients with RA and axSpA. Because of its generic nature, its use may facilitate comparisons of functional status across groups of patients with different conditions.

Ethics

The L-EXTRA and L-EXSPA studies have been approved by the Medical Ethical Committee of the Leiden-Den Haag-Delft (METC LDD; L-EXTRA: NL69866.058.19; L-EXSPA: NL70093.058.19) and the two studies are conducted in agreement with the Declaration of Helsinki (2013) and in compliance with the General Data Protection Regulations and the Dutch Medical Research Involving Human Subjects Act. Written informed consent was obtained from all engaged participants in the study.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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Data availability statement

The data underlying this article can be shared upon reasonable request by corresponding author.

Author contributions

Substantial contributions to the conception and design of the work (TPM Vliet Vlieland, CHM van den Ende, MGJ Gademan, SFE van Weely); analysis and interpretation of the data (MAT van Wissen, B Straathof, TPM Vliet Vlieland, MGJ Gademan, SFE van Weely); drafting the article or revising it critically for important intellectual content (MAT van Wissen, B Straathof, TPM Vliet Vlieland, CHM van den Ende, MMH Teuwen, WF Peter, AA den Broeder, WB van den Hout, D van Schaardenburg, AM van Tubergen, MGJ Gademan, SFE van Weely); final approval of the version to be published (MAT van Wissen, B Straathof, TPM Vliet Vlieland, CHM van den Ende, MMH Teuwen, WF Peter, AA den Broeder, WB van den Hout, D van Schaardenburg, AM van Tubergen, MGJ Gademan, SFE van Weely); and agreement to be accountable for appropriate portions of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (MAT van Wissen, B Straathof, TPM Vliet Vlieland, CHM van den Ende, MMH Teuwen, WF Peter, AA den Broeder, WB van den Hout, D van Schaardenburg, AM van Tubergen, MGJ Gademan, SFE van Weely).

Supplementary material

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