

Concurrent validity and responsiveness to change of PROMIS-29

Research question: What is the concurrent validity and responsiveness to change of the PROMIS-29 (evaluated against the EQ-5D-5L)?

Both the EQ-5D-5L and PROMIS-29 will be delivered to all participants at baseline and three, six and 12 months post-randomisation in the main study. The concurrent validity and responsiveness to change of the PROMIS-29 will be measured relative to the EQ-5D-5L to see how well this test compares to the well-established EuroQoL test.

Concurrent validity indicates the amount of agreement between two different assessments. At all time points, the correlation will be calculated between each of the seven domain scores and the mental and physical health component scores of the PROMIS-29 and:

- the EQ-5D-5L index value, using Pearson’s correlation coefficient;
- the EQ-5D-5L VAS score, using Pearson’s correlation coefficient; and
- each domain of the EQ-5D-5L, using Kendall’s tau b.

Responsiveness, or sensitivity, to change is the ability of an instrument to detect clinically important change, even if that change is small. We shall evaluate internal responsiveness of the PROMIS-29 (mental and physical health component scores) and EQ-5D-5L (index value and VAS) by comparing change in scores using a paired t-test. Comparisons will be made between:

- baseline and three months
- baseline and six months
- baseline and 12 months
- three and six months
- six and 12 months

We shall also calculate the standardised response mean (SRM; mean change score divided by the standard deviation of the change scores) and Cohen’s d effect size (mean change score divided by the standard deviation of the earlier score) for each measure and time interval. Bootstrap 95% confidence intervals (CI) will be calculated for these measures.

Table A. Change metrics for each measure and time interval

PROM	Change metric	EQ-5D-5L	EQ-5D-5L VAS	PROMIS Physical Health	PROMIS Mental Health
Time interval					
3M-baseline	n				
	Mean change score (95% CI), p-value				
	SRM (95% CI)				
	Cohen’s d (95% CI)				
6M-baseline	n				
	Mean change score (95% CI), p-value				
	SRM (95% CI)				
	Cohen’s d (95% CI)				

12M-baseline	n				
	Mean change score (95% CI), p-value				
	SRM (95% CI)				
	Cohen's d (95% CI)				
6M-3M	n				
	Mean change score (95% CI), p-value				
	SRM (95% CI)				
	Cohen's d (95% CI)				
12M-6M	n				
	Mean change score (95% CI), p-value				
	SRM (95% CI)				
	Cohen's d (95% CI)				

We will evaluate external responsiveness of the PROMIS-29 by correlating change scores of the mental and physical health component scores with the change scores for EQ-5D-5L index values and VAS score.

Correlation of change scores of EQ-5D with change scores for PROMIS scores

PROM 1	PROM 2	n	Correlation	95% CI	p-value
Change in EQ-5D-5L index value	Change in PROMIS Physical Health				
	Change in PROMIS Mental Health				
Change in EQ-5D-5L VAS	Change in PROMIS Physical Health				
	Change in PROMIS Mental Health				

We shall categorise participants according to whether or not their scores changed by the MCID of 0.06 on the EQ-5D-5L index value between each time interval. Receiver operating characteristic (ROC) curves will be produced to assess how well the PROMIS mental and physical component scores discriminate between improved and non-improved participants (defined as EQ-5D-5L change score > MCID of 0.06). An area under the curve (AUC) value of 0.5 indicates a discriminatory value equivalent to chance.

REF: Shim J, Hamilton DF. Comparative responsiveness of the PROMIS-10 Global Health and EQ-5D questionnaires in patients undergoing total knee arthroplasty. Bone Joint J. 2019 Jul;101-B(7):832-837. doi: 10.1302/0301-620X.101B7.BJJ-2018-1543.R1. PMID: 31256677; PMCID: PMC6616061.

REF: Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. J Clin Epidemiol. 2000 May;53(5):459-68. doi: 10.1016/s0895-4356(99)00206-1. PMID: 10812317

