

Appendix I: Cosmin criteria Responsiveness Box B

Design requirements	Very good	Adequate	Doubtful	Inadequate	Reported on page:
1. Formulate hypotheses about expected relationships between the change scores on the PROM under study and (change scores on) other outcome measurement	Hypotheses will be formulated including the expected direction and magnitude of the correlations stated		Hypotheses vague or will not be formulated but possible to deduce what was expected	Unclear what is expected	8-9
2. Provide a clear description of the construct(s) measured by the comparator instrument(s)	Constructs measured by the comparator instrument(s) is/are clearly described		Constructs measured by the comparator instrument(s) is/are not clearly described		6-7
3. Provide information that the measurement properties of the comparator instrument(s) are sufficient	Sufficient measurement properties of the comparator instrument(s) in a population similar to the study population	Sufficient measurement properties of the comparator instrument(s) but not sure if these apply to the study population	Some information on measurement properties (or a reference to a study on measurement properties) of the comparator instrument(s) in any study population	No information on the measurement properties of the comparator instrument(s), or evidence of insufficient measurement properties of the comparator	6-7
4. Use an appropriate time schedule for assessments of PROM of interest and comparison instruments	PROM and comparison instrument will be administered at the same time at all occasions	PROM and comparison instrument not administered at the same time, but assumable that patient will not change in the interim period at all occasions	PROM and comparison instrument will not be administered at the same time, but unclear if patients will change	PROM and comparison instrument will not be administered at the same time, and patients are expected to change	7
5. Use an appropriate time interval between first and second measurements	Time interval appropriate			Time interval NOT appropriate	7
6. Describe anything likely to occur in the interim period (e.g. intervention, other relevant events)	Anything likely to occur during the interim period (e.g. treatment) is adequately described		Unclear or NOT described what will likely to occur during the interim period		6
7. Ensure that a proportion of the patients is likely to change (i.e. improvement or deterioration) on the construct to be measured	Part of the patients is likely to change (evidence provided)	NO evidence provided, but assumable that part of the patients will change	Unclear if part of the patients will change	Patients will likely NOT change	4
8. Perform the analysis in a sample with an appropriate number of patients (taking into account expected number of missing values)	≥ 100 patients	50-99 patients	30-49 patients	< 30 patients	7, 10
Statistical methods	Very good	Adequate	Doubtful	Inadequate	
9. Ensure that the statistical methods are adequate for the hypotheses to be tested	Statistical methods are appropriate	Assumable that statistical methods are appropriate	Statistical methods are not optimal	Statistical methods are NOT appropriate	7-9
10. Provide a clear description of how missing items will be handled	The way missing items will be handled is clearly described		The way missing items will be handled is not clearly described		8