Appendix A. Description of Adherence to PCORI's Methodology Standards

Standard Category	Standard	Is this standard applicable to your research project?	List sections and pages of the DFRR where you address this standard	If applicable, describe how and why the study deviated from this standard?
Standards for Formulating Research Questions	RQ-1: Identify Gaps in Evidence	Yes	• **Background**, pages 4-5 • **Methods**, E2.a.2., page 12 • **Results**, F1.b., F1.C., pages 26-27	N/A
	RQ-2: Develop a Formal Study Protocol	Yes	• **Methods**, E6., page 25	N/A
	RQ-3: Identify Specific Populations and Health Decision(s) Affected by the Research	N/A		The products from this project were outcome instruments that do not inform a specific decision, although they can be used as outcome tools.
	RQ-4: Identify and Assess Participant Subgroups	Yes	• **Methods**, E2., pages 11-15 • **Results,** F1.b., F1.c., F1.g., F2., F3.a., F5.b., F6.a.2., pages 26-31, 33-35	N/A
	RQ-5: Select Appropriate Interventions and Comparators	N/A		
	RQ-6: Measure Outcomes that People Representing the Population of Interest Notice and Care About	Yes	• **Background**, pages 3-5	N/A
	PC-1: Engage people representing the population of interest and other relevant stakeholders in ways that	Yes	• **Engagement (D.)**, D1., page 6	N/A

	are appropriate and necessary in a given research context.			
Standards Associated with Patient-Centeredness	PC-2: Identify, Select, Recruit, and Retain Study Participants Representative of the Spectrum of the Population of Interest and Ensure that Data Are Collected Thoroughly and Systematically from All Study Participants	Yes	• **Methods**, E2.a., E2.b., pages 11-15 • **Results**, F1.c., F1.g., F2., F3.a., pages 27-31	N/A
	PC-3: Use Patient-Reported Outcomes When Patients or People at Risk of a Condition Are the Best Source of Information	N/A		We developed patient-reported outcome measures for children.
	PC-4: Support dissemination and implementation of study results	Yes	• **Engagement (D.)**, D5.e., page 10	N/A
Standards for Data Integrity and Rigorous Analyses	IR-1: Assess Data Source Adequacy	Yes	• **Methods,** E3.b., page 17	N/A
	IR-2: Describe Data Linkage Plans, if Applicable	N/A		
	IR-3: A priori, Specify Plans for Data Analysis that Correspond to Major Aims	Yes	• **Methods,** E3., pages 15-21	N/A
	IR-4: Document Validated Scales and Tests	Yes	• **Results,** F6.a.2., page 34	N/A
	IR-5: Use Sensitivity Analyses to Determine the Impact of Key Assumptions	Yes	• **Results,** F5., page 33, also see Tables 4-7 & 10	N/A
	IR-6: Provide Sufficient Information in Reports to Allow for Assessments of the Study's Internal and External Validity	Yes	• **Results,** F2., page 30, also see Tables 1 & 2	N/A
Standards for Preventing and Handling Missing Data	MD-1: Describe in Protocol Methods to Prevent and Monitor Missing Data	Yes		We addressed this in the protocols; however, our study had <1% missing for all data elements (# missing data elements / (# participants * # variables).
	MD-2: Describe Statistical Methods to Handle Missing Data in Protocol	N/A		n/a because our rates of missingness were negligible.

	MD-3: Use Validated Methods to Deal with Missing Data that Properly Account for Statistical Uncertainty Due to Missingness	N/A		
	MD-4: Record and Report All Reasons for Dropout and Missing Data, and Account for All Patients in Reports	Yes	**Results**, F3.a., page 31	N/A
	MD-5: Examine Sensitivity of Inferences to Missing Data Methods and Assumptions, and Incorporate into Interpretation	N/A		
The standards for specific study designs and methods are not relevant to this project.				