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The effect of caries increment on oral health-related quality of life among adolescents in Brazil: a 3-year longitudinal study

Abstract: This study aimed to assess the effect of caries increment on Oral Health-related Quality of Life (OHRQoL) of Brazilian adolescents and to evaluate the responsiveness of the Child Perceptions Questionnaire (CPQ₁₁₋₁₄) in this group. A population-based sample of 515 Brazilian 12-year-olds from a large city located in the southeast of Brazil was evaluated according to a random multistage sampling design at baseline and 291 at three years follow-up, using the DMFT index and the CPQ₁₁₋₁₄ instrument. To evaluate the responsiveness to change, the measures of effect size and longitudinal construct validity were used. It was verified that OHRQoL among adolescents with DMFT increment across the three years worsened significantly (p<0.05) in relation to their counterparts. The effect size varied from small to moderate. The longitudinal construct validity of CPQ₁₁₋₁₄ was satisfactory. Caries increment impacted on OHRQoL of adolescents in Brazil. The CPQ₁₁₋₁₄ instrument demonstrated acceptable responsiveness properties.

Keywords: Adolescent; Dental Caries; Incidence; Longitudinal Studies; Quality of Life.

Introduction

During the last few decades, several studies have focused on subjective perceptions of oral health for clinical trials, epidemiologic research and evaluation of health care programs.¹ This trend has been supported by increasing awareness of the limitations of normative measures to promote patients' wellbeing and full satisfaction with health care.^{2,3} The construct of Oral Health-related Quality of Life (OHRQoL), and instruments created to assess this, has been investigated as an important contributor to the planning and evaluation of public health and health promotion programs.^{1,4}

In this context, special attention has been dedicated to the evaluation of the impact of oral disorders on OHRQoL of children and adolescents using specific instruments.^{5,6} Researchers have emphasized the need for studies investigating OHRQoL in longitudinal studies in order to evaluate how it is impacted by different variables, including dental caries.^{1,2,7} Observational studies are an important category of epidemiological study designs to demonstrate the changes in OHRQoL that occur naturally over time in

populations, as may be found in the studies with elderly people⁸ and children and adolescents^{2,79,10,11,12} using different assessment tools.

However, to investigate how different variables impact on OHRQoL over time, the OHRQoL instrument needs to demonstrate adequate psychometric properties and responsiveness. Responsiveness relates to the ability of a health status measure to detect change in health status over time.^{2,13} Analysis of responsiveness makes it easier for researchers and policy makers to interpret quality of life scores over time, and to thus determine the magnitude of the change measured by a specific question.^{13,14}

Although there have been some publications evaluating longitudinally OHRQoL changes in children and adolescents^{2,7,14,15,16,17,18}, few have investigated the responsiveness properties of the CPQ₁₁₋₁₄ instrument.^{2,9,19} To our knowledge, there are only three published studies that investigated the responsiveness of CPQ₁₁₋₁₄, one that investigated Cambodian children taking part in basic dental care programs¹⁹, and two that evaluated adolescents in New Zealand.9 All studies showed that the responsiveness of CPQ₁₁₋₁₄ was satisfactory. However because OHRQoL is mediated by diverse personal, social and environmental factors, it is important to consider the complexity of scores mechanism and the conceptual basis underpinning the instrument in different population groups and cultures.^{14,20}

The objective of the present study was to assess the effect of caries increment on Oral Health-related Quality of Life (OHRQoL), measured by the CPQ instrument, of Brazilian adolescents over a 3 year period and to evaluate the responsiveness of the Child Perceptions Questionnaire (CPQ₁₁₋₁₄) in this group.

Methodology

This longitudinal study was approved by a Research Ethics Committee of a Brazilian Dental School (Protocol No. 147/2012). Written, informed was provided by all parents/guardians.

Sample size was estimated assuming a 95% confidence level, with an accuracy of 20% in the DMFT estimate and a minimum test power of 0.80 (β = 0.20), with a significance level of 5% (α = 0.05) for

medium and large effect sizes. Based on a previous conglomerate analysis of a population-based study⁶, an average DMFT of 2.30, a standard deviation of 2.72 and a design effect (deff) of 2 was considered, requiring a minimum sample size of 268. Considering losses to follow-up, a sample of 515 12-year olds was analysed at baseline (2012). After three years, the re-evaluated sample size was 291, providing a minimum power of 0.80 for hypothesis testing. The principal researcher (who conducted the clinical examinations) returned to the schools, with all participants being again invited to take part in the study.

Measures

The dental clinical examinations was performed according to the World Health Organization (WHO) recommendations.²¹ All adolescents were assessed in the school environment, under natural light, using CPI probes and plane surface mouth mirrors (Golgran, São Paulo, Brazil). Assessments at both time points were performed by a single, calibrated dentist. A Gold Standard examiner conducted the calibration process, with practical and theoretical phases. A kappa value of over 0.91 was obtained for the intra- and inter- examiner calibration.

The DMFT index (decayed, missing and filled teeth in the permanent dentition) was used to assess caries experience, using WHO criteria.²⁰ To compare the impact of DMFT increment on OHRQoL of adolescents, two groups were created: G1 – without DMFT increment; and G2 – with DMFT increment. The DMFT increment was calculated by subtracting the DMFT values at baseline from estimates collected at 3-year follow-up.

OHRQoL was measured using the CPQ₁₁₋₁₄ instrument.^{22,23} The CPQ₁₁₋₁₄ has 35 questions answered on a Likert scale, ranging from 0 (never) to 4 (every day or almost every day). The sum of responses is calculated for all questions (overall CPQ₁₁₋₁₄) and for each of the 4 domains (Oral Symptoms - OS, Functional Limitations - FL, Emotional Well-being - EWB, Social Well-being - SWB). Lower values represent better OHRQoL. Global questions related to adolescents' perception of their oral health ("Would you say that the health of your teeth, lips, jaws and mouth is..." – answers from 'excellent' to 'poor') and their

perception of how their oral condition affects their life overall ("How much does the condition of your teeth, lips, jaws or mouth affect your life overall?" – answers from 'not at all' to 'very much') were also included. The questionnaire was self-administered within the school environment with the help of the researcher.²⁴

At the 3-year follow-up, a Global Transition Judgment (GTJ) was included^{.9,14}. The specific question was: "Since I examined you at age 12, has the health of your teeth, lips, jaws or mouth changed?" with response options "no change", "worsened" or "improvement".² The GTJ is considered a gold standard for assessing changes in subjective perceptions as regards to OHRQoL, since these measurements are less influenced by an individual's mood¹⁴.

Data analysis

Statistical analysis was performed using descriptive and inferential methods. Characteristics of adolescents followed-up and not followed-up were compared (sex, school type, two global question and DMFT index), using, Chi-square test for proportions and Student's-*t* test for means. Descriptive data (mean and standard deviation) from the DMFT index at baseline and follow up were compared using Paired Student's-*t* Test.

The CPQ₁₁₋₁₄ scores were initially tested for normality (Kolmogorov-Smirnov test). The null hypothesis was rejected, with a level of significance lower than 0.01. In this case, the most appropriate statistical tests are non-parametric, used for samples with asymmetrical score distributions. Thus, the CPQ₁₁₋₁₄ scores (domains and overall) for all participants were evaluated over time by the nonparametric Wilcoxon test.

After stratifying the sample into the DMFT increment groups (G1 and G2), the nonparametric Wilcoxon test was used to investigate OHRQoL over time. For comparison between independent groups (G1 and G2) at two timepoints, the nonparametric Mann-Whitney test was applied. Supplementary analyses to support data interpretation were used with the same methodology and using the groups: school type (public and private) and sex (male and female).

To evaluate responsiveness to change, measures of effect size and longitudinal construct validity were used.^{25,26} The effect size measure was adopted to establish the magnitude of change observed in CPQ₁₁₋₁₄ over time,²⁵ for all participants and for two groups analyses. The formula used for Cohen was applied in this study:²⁷ "mean baseline score – mean follow-up score/standard deviation of baseline score". Effect size (magnitude of change) of less than 0.2 is considered small, from 0.3 to 0.7 moderate, with 0.8 or above considered large.²⁷

The longitudinal construct validity, according GTJ, was evaluated by means of the Kruskal-Wallis one-way analysis of variance, and subsequent use of Dunn's test for to analyze specific sample pairs in *post hoc* tests. The mean change in CPQ₁₁₋₁₄ scores was evaluated against the GTJ.^{2,14,16} According to this methodology, participants who reported worsened OHRQoL over time would present a negative value after subtraction; participants who reported improvement in their OHRQoL would present a positive value after subtraction.

Calculations of sample size and test power were performed using R (R Foundation for Statistical Computing, Vienna, Austria) and G*Power²⁸ programs. Data analysis was conducted with the Statistical Package for the Social Sciences (SPSS, version 23.0, SPSS Inc., Chicago, IL, USA), and a level of significance of 0.05 was used.

Results

At baseline, 515 participants were recruited from 22 schools. At 3-year follow-up, 291 participants were examined (56.5 per cent response rate). The causes of loss of follow-up were mainly due change of school (25.8%) or place of residence (19.1%), and an option to drop out of the study (54.6%).

Table 1 presents participant characteristics between those followed-up at 3-years and that loss to follow-up. The only statistically significant difference was school type (p < 0.05).

The DMFT characteristics of the 291 participants followed-up are shown in Table 2. The mean DMFT increment was 0.8, with statistically significant differences in both overall DMFT and each constituent part (D, M, F) between baseline and follow up.

	Total		Follo	owed	Not followed-up		
Variable	51	5	29	91	224		p-value
	n	%	Ν	%	n	%	
Sex							
Female	290	56.3	148	51.0	142	49.0	0.1588**
Male	225	43.7	143	63.5	82	46.5	
School type							
Public	363	70.5	238	65.6	125	34.4	< 0.0001**
Private	152	29.5	53	34.9	99	65.1	
Self-rated oral health							
Excellent	66	12.8	31	10.7%	35	15.6	0.0738**
Very good	91	17.7	49	16.8%	42	18.8	
Good	179	34.8	97	33.3%	82	36.6	
Global questions CPQ ₁₁₋₁₄							
Fair	148	28.7	91	31.3%	57	25.4	
Poor	31	6.0	23	7.9%	8	3.6	
Global impact of oral health on quality	of life						
Not at all	198	38.4	103	35.4%	95	42.4	0.1789**
Very little	144	28.0	91	31.3%	53	23.7	
Some	129	25.0	73	25.1%	56	25.0	
A lot	33	6.4	16	5.5%	17	7.6	
Very much	11	2.2	8	2.7%	3	1.3	
	mean	SD*	mean	SD*	mean	SD*	
DMFT index							
DMFT	1.1	1.7	1.0	1.7	1.2	1.7	0.1475***
D	0.3	0.8	0.3	0.8	0.3	0.9	0.2702***
М	0.0	0.2	0.0	0.2	0.0	0.2	0.4102***
F	0.7	14	0.7	1.3	0.8	15	0 1722***

Table 1. Comparison of the baseline gender, school type, global questions of CPQ_{11-14} and DMFT index according to the DMFT index of those followed- and not followed-up.

CPQ: Child Perceptions Questionnaire; DMFT: decayed, missing and filled teeth; *SD: standard deviation; **chi-square test; ***Student's-t test.

Table 2. Mean and standard deviation of clinical data according to the DMFT index at Baseline and Follow-up (n = 291).

Variable	Decayed		Missing		Filled		DMFT	
	Baseline	Follow up						
Mean	0.3	0.5	0.0	0.1	0.7	1.3	1.0	1.8
Standard deviation	0.8	1.1	0.2	0.3	1.3	1.7	1.7	2.3
p-value*	p = 0.0005		p = 0.0042		p < 0.0001		p < 0.0001	

*Paired Student's-t Test; Power > 0.99 for a medium effect size (dz = 0.5).

Table 3 shows a reduction in the overall and domain scores of CPQ_{11-14} across the 3-year time span, showing an improvement in OHRQoL over time. Changes in overall CPQ_{11-14} and in the EWB and SWB domains were statistically significant. Effect size scores (ES) were considered small for the domains and overall scores of the CPQ_{11-14} instrument.

The impact of caries incidence on CPQ₁₁₋₁₄ scores is reported in Table 4. It shows the results related to changes in OHRQoL among G1 participants (without DMFT increment) and G2 (with DMFT increment) over three years. Of the 291 individuals re-evaluated at follow-up, 190 (65.3%) showed no DMFT increment and 101 (34.7%) presented DMFT increment. The three years follow-up analyses in each group demonstrated an improvement in OHRQoL for G1 group (without DMFT increment) and in the SWB domain of G2 group (with DMFT increment). This fact is verified by the statistically significant difference for all CPQ₁₁₋₁₄ score reductions, indicating improvement in OHRQoL.

Conversely, there was an observed increase in overall CPQ₁₁₋₁₄ scores and in the OS and FL domains scores of CPQ₁₁₋₁₄ among G2 participants'.

When G1 and G2 were compared at Baseline for domains and overall CPQ_{11-14} , there were no statistically significant differences (p > 0.05). At 3-year follow-up, a statistically significant difference in all domains and overall CPQ₁₁₋₁₄ was observed. These results demonstrated that DMFT increment has a significant impact on the OHRQoL of adolescents compared with those without DMFT increment.

The effect size for each group is presented in Table 4. The values were considered moderate in the G1 group for overall CPQ_{11-14} scores and EWB and SWB domains scores; and small for OS and FL domains. In the G2 group, the effect size for overall score and all domain scores were considered small.

Table 5 presents the longitudinal construct validity using the GTJ responsiveness properties of the CPQ₁₁₋₁₄. In the results of difference between means, some "worsened" responses to GTJ presented negative

Table 3. Mean, standard deviation, median, overall scores and by domains CPQ_{11-14} instrument in the at baseline and after 3-year followed up in the overall group of Brazilian adolescents (n = 291).

Variable	Baseline				Follow-up		EC2	
	Mean (SD)	Median	Range	Mean (SD)	Median	Range	- p-value.	L3-
CPQ ₁₁₋₁₄ (overall score)	25.5 (23.4)	18	0–106	20.9 (19.7)	15	0–90	< 0.0001	0.20
Domains								
Oral Symptoms	5.8 (3.9)	5	0–24	5.5 (4.2)	5	0-18	0.0821	0.08
Functional limitation	5.2 (5.6)	3	0–28	4.8 (5.2)	3	0-24	0.2334	0.07
Emotional well-being	8.4 (8.7)	5	0–35	6.5 (7.8)	3	0–35	< 0.0001	0.22
Social well-being	6.0 (8.0)	3	0–38	4.2 (6.1)	1	0–26	< 0.0001	0.23

"Wilcoxon test: evaluation of significant difference between baseline and follow-up scores; ²Effect size; Power > 0.99 for a medium effect size (dz = 0.5).

Table 4. Mean, standard deviation, median, range of $CPQ_{11.14}$ and domain scores according to groups of adolescents and the effect size values of $CPQ_{11.14}$ instrument.

Comment	Baseline			Follow-up			Intra-group	EC***
Groups	Mean (SD)	Median	Range*	Mean (SD)	Median	Range*	p-value**	ES
G1 without DMFT increment								
CPQ ₁₁₋₁₄ (overall score)	25.8 (24.2)	17	0–106	18.4 (18.6)****	13	0–84	< 0.0001	0.3
Oral symptoms	5.7 (4.1)	5	0–24	4.8 (4.2)****	4	0–16	0.0013	0.2
Functional limitation	5.4 (5.9)	3	0–28	4.3 (4.9)****	2	0–24	0.0031	0.2
Emotional well-being	8.6 (8.9)	5	0–35	5.6 (7.3)****	2	0–32	< 0.0001	0.3
Social well-being	6 (8.2)	2	0–38	3.7 (5.7)****	1	0–26	< 0.0001	0.3
G2 with DMFT increment								
CPQ ₁₁₋₁₄ (overall score)	24.9 (21.9)	19	0–94	25.6 (20.9)****	20	0–90	0.1627	0.0
Oral symptoms	6.0 (3.6)	5	0–15	6.6 (3.9)****	6	0–18	0.0945	0.2
Functional limitation	4.7 (5.0)	3	0–20	5.7 (5.6)****	5	0–24	0.0330	0.2
Emotional well-being	8.2 (8.5)	6	0–33	8.2 (8.5)****	7	0–35	0.4737	0.0
Social well-being	6.1 (7.6)	3	0–36	5.2 (6.8)****	2	0–26	0.0397	0.1

*range: Minimum value- Maximum value, considering the variation of 0-148 in which 0 is considered good OHRQoL and 100 is considered poor OHRQoL;**longitudinal intra-group differences: p-value of Wilcoxon non-parametric test; ***effect size; ****statistically significant differences (p < 0.05) in inter-group differences (Mann-Whitney non-parametric test). Wilcoxon: Power > 0.99 e Mann-Whitney: Power = 0.97 for a medium effect size (dz = 0.5).

Groups	Number of	Mean of difference (= baseline score-follow-up score)						
	participants (%)	OS	FL	EWB	SWB	CPQ ₁₁₁₄		
G1 without DMFT increment								
Total	190	0.9	1.1	3.0	2.4	7.4		
Worsened	9 (4.7%)	-3.3°	-4.1°	1.3 ^{ns}	-0.3 ^{ns}	-6.4°		
No change	94 (49.5%)	1.1ªb	1.7 ^b	2.6 ^{ns}	2.2 ^{ns}	7.6 ^b		
Improvement	87 (45.8%)	1.1 ^b	1.0 ^b	3.6 ^{ns}	2.8 ^{ns}	8.6 ^b		
	p-value*	0.04	0.00	0.79	0.06	0.03		
G2 with DMFT increment								
Total	101	-0.6	-1.0	0.0	0.9	-0.7		
Worsened	23 (22.8%)	-2.6°	-3.1ª	0.7 ^{ns}	0.4 ^{ns}	-4.7 ns		
No change	53 (52.5%)	0.3 ^b	-0.4 ^b	-0.9 ^{ns}	0.9 ^{ns}	-0.2 ^{ns}		
Improvement	25 (24.7%)	-0.8ªb	-0.4ªb	1.5 ^{ns}	1.5 ^{ns}	1.8 ^{ns}		
	p-value*	0.00	0.02	0.18	0.75	0.07		

Table 5. Mean values of domains (Oral Symptoms, Functional Limitation, Emotional Well-Being and Social Well-Being) and overall change in the CPQ₁₁₋₁₄ scores according to Global Transition Judgment (GTJ) for two groups of Brazilian adolescents.

Dunn's test (after Kruskal-Wallis test*): different superscript letters denote significant differences between mean according GTJ and superscript (ns) denote no significant differences (p > 0.05). Kruskal-Wallis G1: Power = 0.92 e G2: Power = 0.82 for a medium effect size (f = 0.25).

CPQ₁₁₋₁₄ scores. For "no change" the scores were generally close to zero and for "improvement" most scores were positive. The responsiveness of CPQ₁₁₋₁₄ was considered satisfactory, especially in Oral Symptoms and Functional Limitation domains of CPQ₁₁₋₁₄ for two groups (p<0.05). In *post hoc* test for pairs of GTJ, for the Oral Symptoms and Functional Limitation domains of CPQ₁₁₋₁₄ the scores of 'worsened" GTJ always presented a statistically significant difference in comparison with the "no change" and/ or "improvement" answers.

Discussion

This study investigated changes in OHRQoL of Brazilian adolescents over three years. The results demonstrated longitudinal associations between DMFT increment and decreased OHRQoL, measured through the CPQ_{11-14} instrument. The responsiveness of CPQ_{11-14} in detecting OHRQoL change was considered acceptable according to effect size parameters and longitudinal construct validity values in the scientific literature.^{14,20}

The comparison of results of overall and domain scores of the CPQ_{11-14} instrument at baseline and 3-year follow up demonstrated that study participants had

an improvement in their OHRQoL over time. This reduction in the prevalence of impacts across the whole sample over time was also observed in in the few longitudinal studies already published,^{16,18,19} using the same OHRQoL instrument. One hypothesis, based on the theoretical underpinnings of OHRQoL^{1,14,25,29} is that the improvement may have occurred due to changes in the self-perception of body image, as well as changes in psychological, socioeconomic and environmental factors of adolescents at age 12 and 15, which may have directly influenced on their OHRQoL.^{2,7,10,11,12} In addition, a statistically significant improvement occurred in the emotional and social domains of CPQ₁₁₋₁₄, reinforcing this hypothesis.

However, when comparing the CPQ_{11-14} scores of G1 and G2 over time, a different trend was observed. In the without DMFT increment group, improvement over time in the CPQ_{11-14} scores were verified. This fact could be expected a priori due to several factors, including the absence of clinical changes and no pain and discomfort related to dental caries over time.^{2,18}

On the other hand, worsening CPQ_{11-14} scores over time were observed among the DMFT increment group. In this group, the Functional Limitation (FL) domain of CPQ_{11-14} presented worsening over time, with a statistically significant difference between the scores on baseline and follow-up. These results contrast with the findings of Page and Thomson² who found that caries experience (DMFS) impacted in oral symptoms and emotional well-being domain scores over time. It should also be considered that the DMFS, used by Page and Thomson,² represents a more detailed evaluation of the caries experience which could influenced the assessments of the changes in the CPQ_{11-14} .

When CPQ₁₁₋₁₄ scores of groups are compared over time, it is clear that the increase in DMFT had a significant impact on OHRQoL, as there was a statistically significant difference in all comparisons of CPQ₁₁₋₁₄ scores. Therefore, even considering the complexity involved in a OHRQoL measure,^{1,3,4,14} it is possible to consider that caries experience represents an important predictor of changes in OHRQoL over time.

In relation to responsiveness properties, the effect size results for overall CPQ_{11-14} , and EBW and SBW domains demonstrated that the scores were more responsive in the group without DMFT increment. These findings are in line with a study among Thai students aged 10–14 years, indicating that the use of CPQ_{11-14} may not be responsive to change or sensitive to the impact of low levels of disease.¹² In addition, researchers demonstrated that CPQ_{11-14} may not detect changes in OHRQoL when caries levels are low.^{2,19}

We observed a small effect size of CPQ_{11-14} , following the same trend observed in longitudinal studies of OHRQoL using other instruments.^{9,10,11,14} In the present study, the small effect size was observed especially in regard to oral symptom and functional limitation domains, which may have occurred due to the low incidence of caries, thereby reducing the accuracy of the instrument in detecting changes in OHRQoL over the three years.

Our study confirms that CPQ₁₁₋₁₄ scores were able to measure OHRQoL changes over time, in the oral symptoms and functional limitations domains according to the GTJ. According to a recent review about the quality of the OHRQoL measures for children,³⁰ there are still discussions about the ability of OHRQoL questionnaires to assess longitudinal changes in the perception of children and adolescents. This fact brings to light the need for studies in the area of longitudinal evaluations. The assessment of the OHRQoL is a broad construct and, according to the results obtained, properties of EWB and SWB domains for the DMFT increment group require complex interpretation because this age group experiences significant psychosocial interferences].¹²

Despite interventional studies demonstrating good responsiveness properties of the CPQ₁₁₋₁₄ ,^{2,7,9,10,11,12,31} they are short-term studies with patients who were actively seeking dental treatment. The self-perception treatment need was likely high, a fact that has a great influence on the instrument's discriminatory capacity. In the present study, we observed that the responsiveness of CPQ₁₁₋₁₄ in relation to caries increment over a longer period of time (three years) presented inconsistencies, corroborating the findings of other studies.^{14,32} Rodd et al.¹⁰ have previously reported that CPQ₁₁₋₁₄ presented limitations related to observational evaluation over longer periods in population-based samples. Thus, we consider that the present study brings an important contribution to this field of knowledge, demonstrating that the instrument may not be the best option for those who wish to assess longitudinal changes in OHRQoL in children and adolescents with low caries incidence. According to a recent systematic review, the incidence of caries is low in children and adolescents, a fact that should guide researchers in future studies with those populations.³³

This study has some limitations. OHRQoL is a complex construct and influenced by social and environmental factors, variables not measured in our analysis. Moreover, the low prevalence and incidence of dental caries, and the largest number of filled teeth in the studied population may have influenced the psychometric capacity of CPQ₁₁₋₁₄ on detecting longitudinal changes and in comparison between groups. This needs to be taken into consideration in interpretation of results and future studies. In the same way, there are other clinical features that might have influenced CPQ₁₁₋₁₄ scores, such as fluorosis and malocclusion, and deserve further investigation. Finally, the imbalance of the sample size can be considered as a limitation in the longitudinal construct validity evaluation. After three years, only

9 participants in G1 (without DMFT increment) worsened according to the Global Transition Judgment (GTJ). This promoted an imbalance in the sample size of the groups analyzed.

Conclusion

It was observed that increasing caries experience in adolescent over time worsened their OHRQoL in comparison to their counterpart. The longitudinal psychometric properties of CPQ₁₁₋₁₄ demonstrated a variation between small to moderate effect size and the instrument was considerable acceptable responsive to change.

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