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Vision-related quality of life in children: Cross-cultural adaptation and test–retest reliability of the Danish version of the paediatric refractive error profile 2

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Abstract

Purpose: To translate and cross-culturally adapt PREP2 into Danish and to investigate the face validity and reliability of Danish PREP2 through cognitive interviewing, Rasch and reliability analyses.

Methods: The Danish PREP2 was translated using a standardized procedure and then pretested following the Three-Steps-Interviews (TSTI) process. A total of 15 myopic children aged 7–14 wearing either orthokeratology lenses (ortho-k) or single-vision spectacles (SVS) were included in pretesting comprising cognitive interviews and Rasch analysis. Data from cognitive interviewing was analysed thematically according to Collins. Rasch analysis was used to pretest the psychometric properties in terms of person- and item-fit statistics. Reliability was assessed via test–retest using Intra-class correlation coefficient (ICC) in the CONTROL study population, which consisted of 60 Danish children aged 7–14 years wearing either ortho-k or SVS.

Results: Fifteen children participated in pilot studies comprising of cognitive interviewing and Rasch analysis and 44 out of 60 CONTROL children participated in test–retest reliability analysis. The translation process resulted in a Danish version of PREP2 corroborating the original. Pretesting highlighted issues in the contextualization of items and in marking responses. Thus, we introduced a digital format with help texts. Cognitive interviewing identified issues in the following Collins' themes: *comprehension* (understanding of concepts), *judgement* (ambiguity of items) and *response* (selecting answers). Rasch analysis indicated that help texts were useful for clarifying context. The ICC was 0.77 (95% CI: 0.66–0.85).

Conclusions: The cross-cultural adaptation of PREP2 was satisfactory and issues were identified and corrected through pretesting. The test–retest reliability showed substantial consistency. The instrument could be validated in a more generalizable setting in future studies. Trial registration: NCT03246464 (CONTROL study).

KEYWORDS

myopia, orthokeratology lenses, patient-reported outcome measures, psychometrics, quality of life

1 | INTRODUCTION

Myopia is a refractive error in which the optical power of the eye exceeds its axial length, leading to blurred

distance vision. It is a concern because high myopia is associated with sight-threatening complications. Myopia is progressive (Morgan et al., 2012), with faster progression reported in children (Karthikeyan

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et al., 2022). Ophthalmic interventions have been introduced to slow myopia progression in children and thus lower the risk of future complications. One such intervention is orthokeratology lenses (ortho-k), which are rigid, custom-moulded devices that are used every night during sleep (Prousalı et al., 2019). These lenses cause a temporary flattening of the central cornea, which can reduce or eliminate myopia correction (Jakobsen & Møller, 2022). The success of interventions like ortho-k requires *measurements of* both efficacy and acceptability. However, while efficacy can be measured objectively, acceptability can only be assessed through patient-reported outcomes (PROs), which typically measure the quality of life (QoL).

Various instruments can be used to assess vision-related (VR)-QoL (Lipson et al., 2022). The Pediatric Refractive Error Profile (PREP) instrument was designed to evaluate VR-QoL in children with refractive errors. However, since PREP does not offer high repeatability, it is not ideal for monitoring VR-QoL over time (Mohd-Ali et al., 2022). To account for this issue, a new version of the instrument (PREP2) was introduced, hence offering the possibility to monitor VR-QoL over time. This allows researchers to investigate the relationship between myopia correction and VR-QoL in children aged 8–14 years (Han et al., 2022). The theory behind PREP2 is that visual aids influence VR-QoL in children with myopia. As such, PREP2 is based on item response theory (IRT) (Johnston & Firth, 2013), since the scores of the questionnaire reflect the levels of VR-QoL in respondents (Andrich & Marais, 2019). Hence, any change in levels of VR-QoL can be attributed to corrective devices.

To achieve reliable results with a QoL instrument, it is crucial to investigate its psychometric properties, meaning the aptness of the measurement parameters (de Vet et al., 2011). PREP2 was originally developed for an English-speaking population in the United States of America (Andersen, 2013). In its original target population, the instrument has been assessed for the aptness of its measurement parameters using IRT and Rasch analysis. The psychometric properties of some subscales of the instrument were assessed in relation to a population of 94 myopic children aged 7–11 years old wearing either multifocal or single-vision contacts (Ticak et al., 2023).

However, for use in a different language and culture, it must be translated and adapted to maintain its psychometric properties (Beaton et al., 2000). The process of cross-cultural adaptation aims to maintain consistency between the source and target populations while evaluating the psychometric properties of the newly created instrument (de Vet et al., 2011). This can be achieved by investigating face validity and the ability of the instrument to reflect the construct, which in psychometrics refers to the core concept of measurement. This study offers to set standards for cross-cultural adaptations of psychometric instruments and their assessments of face validity and test–retest reliability through innovative methodologies.

Face validity is defined as the degree to which the content of an instrument adequately reflects the construct being measured (Mokkink et al., 2010). To investigate face validity, a qualitative assessment is often performed

when pretesting. If the investigation reveals the need for changes, these should be assessed before proceeding to further testing. Moreover, reflections of the construct can be evaluated quantitatively. According to IRT, a construct is measured indirectly through its manifestation (Andrich & Marais, 2019). To highlight this, constructs are often referred to as latent traits. Rasch analysis is used to investigate the capacity of an instrument to allow the latent trait to emerge. Comparing Rasch models of different previsions of PREP2 through person- and item-fit statistics can indicate whether adjustments are needed (Andrich & Marais, 2019). In short, person-fit evaluates how well scores of respondents fit the Rasch model, and item-fit assesses how well items fit the Rasch model's expectations. Goodness of fit to the model indicates whether the instrument adequately reflects the construct being measured.

Instrument validation usually includes an assessment of reliability. This can be done by examining test–retest reliability, which assesses the consistency of scores registered for the same scale by the same raters across two measurements throughout a time interval. It is expected that several items proposing to measure the same construct would produce consistent scores overtime. Hence, it indicates whether items are assessing the same construct (de Vet et al., 2011).

In its original target population, PREP2 has been only partially validated for children wearing either multifocal or single-vision contacts (Ticak et al., 2023). Hence, to our knowledge, PREP2 has never been validated for ortho-k users or translated into Danish. Thus, the objectives of this study were to translate and cross-culturally adapt PREP2 into Danish and assess face validity; evaluate pre-final versions of the Danish PREP2 by comparing the item- and person-fit statistics using Rasch analysis; and validate the questionnaire by investigating the test–retest reliability of the final version. Achieving these objectives would also imply to set the foundations for a thoroughly validation of PREP2 for ortho-k users.

2 | MATERIALS AND METHODS

2.1 | Design

We applied a cross-sectional design with two different study populations, one for assessing face validity (i.e., pretesting using both pilot tests and cognitive interviewing) and the second for assessing test–retest reliability. An overview of the study design is presented in [Figure 1](#).

2.2 | The paediatric refractive error profile 2 (PREP2)

PREP2 is a 56-item instrument with seven subscales, including 'Vision', 'Symptoms', 'Handling', 'Activities', 'Appearance', 'Peer perception' and 'Overall'. Each subscale has eight items, with an equal number of positively and negatively worded items. Even-numbered items are positively worded while odd-numbered items are negatively worded. Responses are recorded using a five-category Likert scale ('Strongly agree', 'Agree', 'Neutral',

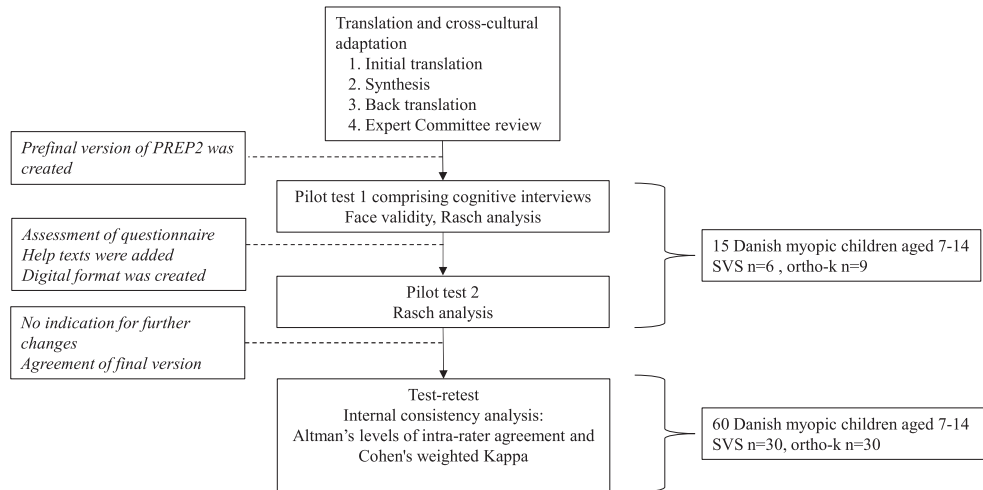


FIGURE 1 Study design overview. ortho-k, orthokeratological lenses; PREP2, Paediatric Refractive Error Profile 2.

‘Disagree’ and ‘Strongly disagree’). Details on the instrument can be found in Appendix C.

For positively worded items, ‘Strongly agree’ is ranked as five and ‘Strongly disagree’ is ranked as one. In negatively worded items, scores are adjusted by reversing the ranking, such that ‘Strongly agree’ is ranked as one and ‘Strongly disagree’ is ranked as five. The overall VR-QoL score is obtained by converting each category to a 0–100-point scale by subtracting one from the Likert ranking and multiplying by 25. For example, $5-1=4(25)=100$. Consequently, a score of 100 represents very good VR-QoL, whereas a score of 0 represents very poor VR-QoL (Andersen, 2013).

2.3 | Translation and cross-cultural adaptation

Cross-cultural adaptation of the instrument followed the guidelines of Beaton et al. (2000) which included five stages: translation, synthesis, back translation, and expert committee review and pre-testing. After obtaining authorization to use the PREP2 from its developer (Dr Jeffrey Walline, Associate Dean for Research, College of Optometry, Ohio State University, Columbus, OH, USA), the original PREP2 was independently translated from English to Danish by a physician (author TMJ) and a linguistic professional, both of whom have Danish as a first language. The two independent translations (T1 and T2) were compared and discussed by the translators until consensus was reached and translation T-12 was developed (i.e., consensus on T1 and T2). Afterwards, T-12 was independently translated back into English by an educational professional and an orthoptist (author RE); both have English as a first language and neither had any knowledge of the original version. Thus, two independent back-translations (BT1 and BT2) were produced and the five translations (T1, T2, T-12, BT1, and BT2) were thoroughly reviewed and compared with the original version by an expert committee including the translators, a language specialist and a methods specialist. With the involvement of the developer, the pre-final version was reviewed semantically, idiomatically, and conceptually.

2.4 | Assessing face validity by cognitive interviewing and Collins' themes (2003)

Pilot test participants were recruited between March and April 2018. To ensure variability in sex, age, and type of visual aid (single-vision spectacles [SVS] and ortho-k), the participants were purposively selected for inclusion. Although the English version of the instrument was developed for children aged 8–14 years, the Danish pilot population was younger (7–14 years old). This was purposely decided because the instrument was intended to be used in the clinical study of near-sightedness; Treatment with orthokeratology lenses (CONTROL) study population, which included children from 6 to 14 years old at the date of inclusion (Jakobsen & Møller, 2022). Pilot test 1 was conducted between April and July 2018 and pilot test 2 was conducted between October and November 2018.

After thorough revision, the pre-final version of Danish PREP2 was pretested in pilot 1, which involved cognitive interviewing (face validation) as described by Beaton et al. (2000), Collins (2003) and Tony et al. (2008). During cognitive interviews, respondents were asked to complete a paper version of PREP2 following the Three-Step Test-Interview (TSTI) process. This method tests the interaction between the instrument and the respondent by combining three stages: (1) thinking aloud (reading items aloud and voicing thoughts) and observation; (2) probing; and (3) debriefing (Tony et al., 2008). Probing questions had a clarifying scope, such as examining the comprehension of words, context, or cognitive processes behind responses. During debriefing, the interviewer encouraged respondents and their parents to comment freely about PREP2.

To ensure compliance with the TSTI process (Tony et al., 2008), respondents were instructed before the start of the interview on how to think aloud correctly and in what TSTI consists of. Data from the cognitive interviews were analysed using the framework by Collins (2003): *comprehension* (understanding of concepts), *retrieval* (retrieval of information), *judgement* (ambiguity of items), and *response* (selecting answers). In short, data from cognitive interviewing was collected

in a report listing recurrent issues, meaning recurrent comments or issues respondents had expressed upon specific items. Hence, these issues were carefully classified within the above-mentioned themes. Scores on PREP2 were collected separately from cognitive interviewing data and stored in REDCap. Pilot test 2 was conducted with different modalities, namely, using a digital layout comprising of help texts introducing items. Help texts were differentiated for each subgroup (SVS or ortho-k). Details on the distribution of help texts can be found in Appendix B. The collected scores on PREP2 for both pilots was used in constructing Rasch analysis.

2.5 | Item- and person-fit statistics between both pilot studies

Polytomous Rasch models were constructed for both pilot studies to calculate item- and person-fit statistics at overall, subscale, and item levels. These parameters indicate the goodness of fit between expected and observed data, respectively at model, subscale, and item levels. In short, person-fit at overall level assesses goodness of fit between respondents' scores across all items and the predictions of the Rasch model for the whole scale. On the subscale level, person-fit evaluates the goodness of fit between respondents' scores and the model predictions within specific domains of the scale. On item level, person-fit assesses the goodness of fit between the respondents' scores and the model predictions for each individual item on the scale.

On the other hand, item fit at overall level defines the goodness of fit of all items to the predictions of the Rasch model. Subscale level item-fit evaluates the goodness of fit of items within specific subscales to Rasch predictions for the same subscale. Item-level fit assesses the goodness of fit between each individual item and the predictions of the Rasch model.

When plotting a polytomous Rasch model, we expected VR-QoL to be reflected in PREP2. Hence, constructed models should fit with existing data. To check for this assumption, we compared the overall-, item- and person-fit statistics from the two pilot versions of PREP2. We hypothesized that by constructing polytomous Rasch models for each pilot, these statistics would show different degrees of fit to the model. A statistically better fit would suggest a more functional version of PREP2.

For the overall fit, we used the joint maximum likelihood calculation of estimates (JMLE), which simultaneously estimates person and item parameters. The process is repeated until convergence is reached (Wyse, 2021). At person and item level, a mean-square z-test statistic was computed. The test determines the likelihood of observing the reported mean-square values when the data fit the model. It produces two statistics, namely infit and outfit mean square. These statistics assess the degree to which observed scores at any level fit the Rasch model predictions within a specific range.

The theoretical expectation for both infit and outfit mean square is 1.0, as the model is expected to predict

registered scores. Values substantially lower than 1.0 (<0.5) indicate data dependency, whereas values substantially >1.0 (>1.5) indicate noticeable off-variable noise, which neither constructs nor degrades measurement. Values >2.0 are detrimental to model fit, as the off-variable noise is too large. Data were analysed using WINSTEPS (Version 5.4.3).

2.6 | Assessing test–retest reliability

After pilot test 2, the final version of PREP2 was administered within the CONTROL study population between November 2018 and March 2020 at the Department of Ophthalmology, Vejle Hospital, University Hospital of Southern Denmark. Briefly, the CONTROL study was a 1:1 randomized controlled trial that examined the efficacy and safety of ortho-k over 18 months in subjects who were referred by private ophthalmic practitioners. The inclusion criteria were one or both parents being ethnically Scandinavian, 6–12 years of age at the time of inclusion, cycloplegic spherical value of -0.5 to -4.75 D in both eyes and refractive astigmatism ≤ 2.5 D in both eyes. Further details have been reported elsewhere (Jakobsen & Møller, 2022).

Test–retest reliability was analysed in the CONTROL study population (Jakobsen & Møller, 2022) using a 7-day interval, following the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist (Mokkink et al., 2010). To measure test–retest reliability, we used the Intraclass Correlation Coefficient (ICC), evaluating the consistency of recorded scores for the same instrument after being administered on two separate occasions to the same raters (de Vet et al., 2011). In short, ICC establish the proportion of total variance in a set of observations that is attributable to the differences between measurements. According to de Vet et al. (2011), an ICC value close to 1 indicates high reliability between measurements, whereas a level close to 0 suggests poor reliability. The analyses were conducted using STATA, version 18 (StataCorp. 2021. Stata Statistical Software: Release 18; StataCorp LP, College Station, TX).

2.7 | Ethical considerations

The study was approved by the Danish Data Protection Agency, Region of Southern Denmark in agreement with the General Data Protection Regulation (GDPR) (Voigt & Von dem Bussche, 2017) and adhered to the Declaration of Helsinki. Participants and their legal guardians were informed both verbally and in writing about the terms and their rights before the study started. Participants gave their informed consent. The study was approved by the Regional Committee on Health Research Ethics and registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03246464). Data were stored digitally through the Odense Patient Data Explorative Network using Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, Tennessee).

3 | RESULTS

Fifteen children with myopia aged 7–14 years were included in both pilot studies comprising of cognitive interviews and 60 children aged 7–14 took part in the test–retest reliability analysis. All 15 children participated in the cognitive interviews during pilot test 1. Among these, nine children completed pilot test 2. The test–retest was carried out 12–18 months after initiation of the intervention (ortho-k or SVS) in the CONTROL study population, which consisted of 60 children with myopia aged 7–14 years old. Of the 60 children who were participating, 44 were included in the test–retest reliability analysis. The participants' characteristics are described in Table 1.

3.1 | Translation, cross-cultural adaptation and face validity

The translation and cross-cultural adaptation resulted in a Danish version of the PREP2 corroborating its original. To ensure corroboration, the guidelines of Beaton et al. (2000), the TSTI (Tony et al., 2008) process and the framework by Collins (2003) were crucial in crafting a proper translation, addressing cultural adaptation, semantic and conceptual equivalence between the two versions of PREP2. Pilot testing was used to carefully address these considerations. Hence, it was ensured that the newly created Danish version measured the intended construct accurately, enhancing its face validity.

Pilot test 1 highlighted some semantic ambiguities; for example, the literal translation of item 3 ('I'm happy with the way I look') can refer to both appearance and visual ability in Danish. Similar ambiguities were found regarding Collins' themes (2003), especially in terms of 'judgement' in pilot test 1 because no help texts were included to contextualize the items. Since many items lacked context, respondents had to self-assess, or judge, how to respond. Negative phrasing caused problems in 'comprehension'. Twelve errors (equivalent to 4% of all negatively worded questions) were recorded due to confusion over wording.

The TSTI showed that response categories did not match what children wanted to answer (fallacy in 'response'). 'Neither agree nor disagree' was used to indicate 'I do not know' or 'I cannot answer'. This was a particular issue with item 43 ('I can always see better than my friends'), where 20% of children selected the

neutral category as they lacked the knowledge to answer accurately. Some children suggested formulating items as questions requiring a dichotomous response (Yes/No). During the debriefing, parents reported trends of 'response editing', especially about visual aids and peer perception. 'Response editing' refers to the tendency of respondents to provide socially desirable responses (Collins, 2003). On paper, PREP2 presented all items simultaneously, increasing the risk that children would mark a cross in the wrong box. Children, especially younger ones, found marking crosses in the correct box to be difficult in this format. Appendix A summarizes results from the data analysis of cross-cultural adaptation and cognitive interviewing.

Data from the cognitive interviewing highlighted the need to implement minor adjustments to address errors made in marking answers and contextualization. These adjustments included the implementation of a digital layout and the addition of help texts. Digitization allowed only one question to be shown at a time, while issues in 'response' and 'judgement' were corrected with help texts that provided context for items. Digitization also allowed the presentation of targeted help texts; not all items included help texts and not all groups had help texts for the same item (details on help texts can be found in Appendix B). Negative phrasing was not addressed as this would have altered the structure of the original PREP2.

3.2 | Item- and person-fit statistics between pilots

Overall person-fit was 1.89 ± 0.01 (JMLE, $p < 0.001$) in pilot test 1, which increased to 3.26 ± 0.02 ($p = 0.01$) in pilot test 2 (Table 2). Overall item-fit was 1.39 ± 0.02 (JMLE, $p = 0.01$) and 1.41 ± 0.02 ($p = 0.02$) for pilots 1 and 2, respectively. Person- and item-fit statistics are shown in Table 2.

Comparing subscales from pilot tests 1 and 2, the person-fit increased within 'Symptoms' (1.40 ± 0.03 , $p = 0.02$ vs. 2.71 ± 0.06 , $p = 0.02$), 'Handling' (0.43 ± 0.01 , $p = 0.01$ vs. 0.73 ± 0.01 , $p = 0.01$), and 'Overall' (1.41 ± 0.03 , $p = 0.02$ vs. 2.74 ± 0.07 , $p = 0.03$). The item fit increased for subscales 'Appearance' and 'Handling', but decreased for subscales 'Overall vision', 'Symptoms', 'Peer Perception' and 'Activity'.

Table 3 shows the item fit after the addition of help texts. These texts improved the model fit for items 1, 4, 8, 17, 19, 29, and 36 (infit mean square 0.5–1.5). For items 31,

TABLE 1 Participant characteristics.

Characteristic	Pilot		CONTROL population
	Test 1	Test 2	Test–retest
Participants, <i>n</i> (M/F)	15 (9/6)	9 (5/4)	44 (16/28)
Age (mean±SD)	10.73±2.05	11.20±2.20	11.06±1.70
Visual aid			
Ortho-k, <i>n</i>	9	8	17
SVS, <i>n</i>	6	1	27

Abbreviations: F, female; M, male; Ortho-k, orthokeratology lenses; SVS, single-vision spectacles; SD, standard deviation.

TABLE 2 Overall and subscale fit coefficients in pilot tests 1 and 2.

Rasch model	Pilot 1		Pilot 2	
	Item fit \pm SD	Person-fit \pm SD	Item fit \pm SD	Person-fit \pm SD
Overall	1.39 \pm 0.02	1.89 \pm 0.01	1.41 \pm 0.02	3.26 \pm 0.02
Subscales				
Overall vision	1.73 \pm 0.02	1.37 \pm 0.03	1.46 \pm 0.03	0.88 \pm 0.02
Symptoms	1.04 \pm 0.01	1.40 \pm 0.03	0.76 \pm 0.01	2.71 \pm 0.06
Appearance	0.90 \pm 0.01	0.00 \pm 0.00*	1.29 \pm 0.03	0.00 \pm 0.00*
Activity	1.49 \pm 0.03	0.00 \pm 0.00*	0.00 \pm 0.03	0.00 \pm 0.00*
Handling	0.62 \pm 0.01	0.43 \pm 0.01	1.04 \pm 0.01	0.73 \pm 0.01
Peer perception	2.38 \pm 0.02	0.84 \pm 0.02	1.85 \pm 0.04	0.78 \pm 0.02
Overall	1.38 \pm 0.02	1.41 \pm 0.03	0.93 \pm 0.02	2.74 \pm 0.07

Note: Fit coefficients in pilot tests 1 and 2 by subscale. All $p < 0.05$, except where indicated by an asterisk (pilot 1, appearance, person-fit $p = 0.10$; pilot 1, activity, person-fit $p = 0.17$; pilot 2, person-fit, appearance $p = 0.12$; pilot 2, person-fit, activity $p = 0.27$).

Abbreviation: SD, standard deviation.

38, 42, 43, and 46, issues of over-predictability emerged after help text implementation (infit mean square < 0.5). For item 55, off-variable noise was detrimental to model fit (infit mean square > 2.0).

3.3 | Test–retest reliability

According to de Vet et al. (2011), the Danish PREP2 presents a good level of reliability, with an ICC of 0.77 (95% CI 0.66–0.85). The ICC was computed using the one-way random effect model, considering a single random factor influencing the measurements which is represented in this case by the different points in time where measurements have taken place. An ICC of 0.77 means that 77% of the total variance in the measurements can be attributed to true differences between the two points in time in which measurements took place, including random error. Hence, this value indicates substantial consistency.

4 | DISCUSSION

In this study, we translated and cross-culturally adapted the PREP2 questionnaire from English to Danish. Cognitive interviewing data from pilot test 1 was analysed according to Collins' framework (2003), highlighting some face validity issues. We found that adding help texts and digitizing the questionnaire allowed the VR-QoL construct to be better reflected as theorized by IRT since overall person- and item-fit statistics were improved. Thus, face validity was demonstrated. Test–retest reliability indicated substantial consistency.

4.1 | Translation, cross-cultural adaptation and face validity

Cognitive interviewing suggested that some PREP2 items had to be contextualized. Children often had to self-assess whether to answer questions literally and

thus provided inconsistent responses. In other words, before contextualization of items, respondents tended to conform answers to their own perception, or self-assessment, of item contents. Thus, it might have been possible that different children came up with different interpretations of item contents, hence generating inconsistent responses. Some items were found to be irrelevant for ortho-k, particularly the subscales 'Appearance', 'Activities' and 'Handling'. As ortho-k are worn only during sleep, children's appearance and discomfort when wearing visual aids during sports fall out of relevance. Likewise, handling of SVS and ortho-k are rather different, thus not mutually applicable. This suggests that some items were specifically formulated for some visual aids and not for others. As a result, children often used the neutral response category for items deemed irrelevant to their visual aid.

During TSTI, there may have been a tendency for children to respond positively rather than truthfully. According to Collins, it is a known issue that respondents may edit their answers to conform to perceptions of social desirability and self-presentation (2003). Hence, children may have exaggerated the benefits of visual aids and minimized the negative effects on peer perception due to the social desirability of those answers. In other words, children may not have felt comfortable enough to tell their interviewer about the discomfort associated with visual aids. TSTI also highlighted an underlying issue with the response options, as children struggled to match their answers with the options provided by the instrument.

Unfortunately, trends of response editing can weaken reliability of an instrument regardless of how solid and methodologically orthodox a translation and cross-cultural adaptation can be. Thus, Collins (2003) recommends avoiding these trends. A possible method to achieve this goal would be to blind respondents (de Vet et al., 2011). However, in the TSTI process described by Tony et al. (2008), it is crucial to keep respondents engaged with the instrument by thinking out aloud. Hence, it would be difficult to blind respondents when the interviewer has a massive role in keeping respondents engaged (Tony et al., 2008). Moreover, when performing a

TABLE 3 Item fit from pilot tests 1 and 2 after the addition of help texts.

Help texts	Pilot 1		Pilot 2			
	SVS	Ortho-k	Infit \pm SD	Outfit \pm SD	Infit \pm SD	Outfit \pm SD
1	x		0.78 \pm -0.58	1.10 \pm 0.38	1.02 \pm 0.18	1.12 \pm 0.42
3	x	x	0.75 \pm -0.34	0.59 \pm -0.53	0.78 \pm -0.14	0.59 \pm -0.24
4	x	x	0.96 \pm 0.04	1.38 \pm 0.90	1.62 \pm 1.11	1.45 \pm 0.84
8	x		1.77 \pm 1.99*	1.66 \pm 1.74*	1.02 \pm 0.20	1.03 \pm 0.21
9		x	1.21 \pm 0.67	1.97 \pm 1.97	0.71 \pm -0.64	0.64 \pm -0.88
10	x	x	1.50 \pm 1.17	1.90 \pm 1.55	1.91 \pm 1.65	1.90 \pm 1.59
11		x	0.50 \pm -1.23	0.51 \pm -0.78	1.62 \pm 1.11	2.14 \pm 1.60*
17		x	0.56 \pm -1.53	0.63 \pm -1.13	1.08 \pm 0.33	1.77 \pm 1.56
18		x	0.58 \pm -1.03	0.55 \pm -0.80	0.41 \pm -0.86*	0.37 \pm -1.01*
19		x	0.86 \pm -0.42	0.87 \pm -0.27	1.09 \pm 0.36	0.99 \pm 0.11
20		x	0.83 \pm -0.19	0.51 \pm -0.52	0.52 \pm -1.14	0.42 \pm -1.00
24	x	x	0.88 \pm -0.18	0.89 \pm -0.05	0.91 \pm -0.08	0.78 \pm -0.39
25		x	1.57 \pm 1.41	1.51 \pm 1.24	1.28 \pm 0.60	1.30 \pm 0.63
29	x		0.54 \pm -1.43	0.46 \pm -1.38	1.02 \pm 0.18	1.00 \pm 0.14
31	x	x	0.58 \pm -0.85	0.54 \pm -0.70	0.30 \pm -1.62*	0.34 \pm -1.41*
32		x	1.18 \pm 0.48	0.44 \pm -0.07	1.19 \pm 0.49	1.07 \pm 0.33
36	x		0.95 \pm -0.05	0.85 \pm -0.34	1.41 \pm 1.00	1.39 \pm 0.96
37		x	0.39 \pm -2.07	0.57 \pm -1.09	1.90 \pm 1.86	1.86 \pm 1.79
38	x	x	1.66 \pm 0.95	0.72 \pm 0.00	0.44 \pm -1.20*	0.38 \pm -1.36*
39		x	0.59 \pm -0.87	0.60 \pm -0.51	0.56 \pm -0.69	0.67 \pm -0.38
42	x	x	0.54 \pm -1.27	0.91 \pm -0.01	0.28 \pm -1.97*	0.27 \pm -1.57*
43	x		1.05 \pm 0.27	0.99 \pm 0.10	0.36 \pm -1.97*	0.36 \pm -1.97*
44		x	0.66 \pm -1.01	0.63 \pm -0.99	0.85 \pm -0.25	0.79 \pm -0.42
46		x	1.10 \pm 0.36	0.84 \pm -0.08	0.41 \pm -0.86*	0.37 \pm -1.01*
49	x	x	1.06 \pm 0.27	0.87 \pm -0.17	1.29 \pm 0.73	1.16 \pm 0.47
50	x		0.48 \pm -1.80	0.60 \pm -1.15	0.59 \pm -1.03	0.58 \pm -1.07
52		x	0.85 \pm -1.17	1.49 \pm 0.93	0.82 \pm -0.17	0.77 \pm -0.26
55		x	0.83 \pm -0.38	0.76 \pm -0.47	2.27 \pm 2.28*	2.12 \pm 1.98*

Note: Item-fit from pilot tests 1 and 2 after the addition of help texts. The asterisk indicates degrading values for the model fit.

Abbreviations: Ortho-k, orthokeratology lenses; SVS, single-vision spectacles; SD, standard deviation.

cross-cultural translation and adaptation, it is necessary to keep the original structure of the instrument to maintain its original psychometric properties intact (Beaton et al., 2000). Thus, issues related to response options were not addressed.

Errors can be frequent when response options are negatively worded. These options can create confusion due to the reverse logic of responding to negatively worded sentences (Park, 2019). Thus, children often misunderstood negative phrasing and gave a different answer from the one they intended. It is important to mention that pilot test 1 was not digitized and the PREP2 questionnaire is long; thus, it is possible that younger children lost their focus due to the length and the time required for completion. In general, negative wording should be avoided in psychometric instruments, especially when targeting a young audience (Park, 2019). However, as stated above, the original structure of the instrument must be respected during the cross-cultural adaptation process to maintain its original psychometric properties intact (Beaton et al., 2000). Hence, negative wording was kept in place.

4.2 | Item- and person-fit statistics between pilots

The person-fit statistic indicates the degree of separation that PREP2 can achieve among respondents. Larger degrees of separation indicate a larger sensitivity in tackling VR-QoL. In pilot test 2, the digital version of PREP2 presented an overall person-fit of 3.26. This value is desirable, as it can distinguish between at least three levels of VR-QoL in respondents. However, item-fit values of <3 indicate a low variability in recorded scores (Bond et al., 2020).

At the subscale and item levels, differences in person- and item-fit statistics could be due to sample characteristics, since pilot test 2 had a significantly higher proportion of ortho-k users than pilot 1. This was particularly evident for item 55 (*When I wear my vision correction, my friends like the way I look*), as the second pilot had more ortho-k respondents to whom the question is irrelevant. Issues in over-predictability might indicate redundancy, that is, virtually identical items that might be rephrased and represented throughout the

instrument (Boyle, 1991). Redundancy may also have resulted from the misuse of the neutral answer category since TSTI showed that it was a proxy for the inability to answer. Thus, due to sample size and profound differences in population characteristics between the two pilots, we cannot assess the precise impact of help texts at the subscale and item levels. However, the assessment highlighted the need to further explore the relationship between the contextualization of items and the overall performance of the instrument.

A similar study was conducted to cross-culturally adapt and validate PREP2 in a population of 104 Chinese children with myopia aged 8–12 years (Han et al., 2022). Similar to ours, that study also followed the guidelines of Beaton et al. (2000). However, preliminary testing did not lead to any significant change in its final version. In contrast to our study, the mentioned study did not perform cognitive interviewing, which may explain why no significant changes followed the cross-cultural adaptation. The test–retest reliability of the Chinese instrument was reported having ICC coefficients ranging from 0.86 to 0.92 across subscales, whereas we only report an ICC value of 0.77 for the whole scale. It would be difficult to compare these values due to the methodological differences among these studies. It is also important to note that in the above-mentioned study, patients wore either Defocus Incorporated Soft Contact (DISC) lenses or SVS. Hence, it did not encounter the challenge of irrelevant questions in ortho-k users.

As compared to Ticak et al. (2023), the item- and person-fit statistics of the present study are less fitting to the Rasch model. Hence, it could be argued that the Danish version of PREP2 is less valid than its original version. However, it is important to consider that this study aimed to validate the use of this instrument in a different population than Ticak et al. (2023), as the myopic children included in this study were wearing either SVS or ortho-k lenses. Regardless of the statistical techniques used, it is important to remember that in validation studies, results are strictly dependent on the study population (de Vet et al., 2011).

Moreover, as the objectives of this present study were to transfer the psychometric properties of the original instrument to a new target population, it was not feasible to selectively exclude irrelevant subscales from the analysis as done in Ticak et al. (2023). As we encountered issues in relevancy of items in ortho-k users, it could be argued that by eliminating problematic subscales, fit statistics of the model would improve. However, it is important to remember that it is not what is usually done in translation and cross-cultural adaptation of instruments (Beaton et al., 2000).

4.3 | Test–retest reliability

The reported ICC value of 0.77 indicated substantial consistency across measurements, with the 77% of variability attributed to true differences within the sample. This result is satisfactory; however, it could be further analysed in greater details by performing the same analysis in a larger sample, perhaps by computing different ICC values across subscales.

5 | LIMITATIONS

PREP2 has never been validated for ortho-k users. Many of the items were unable to target aspects of VR-QoL for users of these lenses. However, we could not establish a causal link between this hypothesis and the reported performance of Danish PREP2. Our study included children who were a year younger than the age group for which the instrument was developed. It is unclear whether this age difference might have played a role in the Danish PREP2 performance. Unfortunately, the pilot populations were not generally representative. Hence, the instrument should be further validated in a more generalizable setting. A broader discourse on construct validity should be developed.

To our knowledge, this study is the only one integrating help text to better contextualize items. Its original version lacks introductory texts. This might be considered as a deviation from the methodologies for cross-cultural adaptation and translation of psychometric instruments; however the addition of help texts in the Danish PREP2 was deemed necessary according to TSTI results. It is possible that the need for help text in Danish was caused by the semantics of the language itself. However, an overall conclusion cannot be reached. Unfortunately, the lack of help texts in non-Danish version does not allow contextualization of findings. Thus, it is not possible to generalize the results achieved by this study on this matter.

6 | CONCLUSION

Negative phrasing and applicability to ortho-k users were problematic for face validity, although the Danish PREP2 benefitted from the addition of help texts. However, the magnitude of their impact remains unclear at the subscale and item levels. In conclusion, the assessment of face validity produced satisfactory results with the addition of help text and digitalization. Test–retest reliability analysis showed a substantial level of consistency. Future studies should validate the instrument in a more generalizable setting.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT


The data that support the findings of this study are available from the corresponding author upon reasonable request.

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APPENDIX A

Results of face validity based on cognitive interviewing.

Items	Themes (Collins, 2003)			
	Retrieval	Judgement	Response	Comprehension
1, 8, 9, 24, 29, 36, 37, 38, 43, 44, 50		Children were unsure whether to answer questions in relation to their visual aid	Answers varied depending on whether the item specified 'with my visual aid on'	
2, 30, 42				Multiple interpretations of the word 'uncomfortable' in Danish.
3		Children were unsure whether they should answer questions in relation to their visual aid	The answer varied depending on whether the item specified 'with my visual aid on'	The concept of appearance was often misinterpreted as 'sight'
4, 10, 11, 17, 18, 19, 25, 31, 32, 39, 46, 52, 55			Irrelevant for ortho-k users. The neutral answer category was used for 'I don't know/I cannot answer'	
5, 21, 23, 25, 33, 38, 39, 53, 54				Negative wording confused children
13, 20, 41, 43			Some children reported that they did not know what their friends were thinking. The neutral answer category can thus mean 'don't know'	
27, 34, 35, 48			Response editing: children tended to answer positively rather than truthfully	

Note: Results of face validity based on the cognitive interviews.

APPENDIX B

Danish version of PREP2.

Items	Help texts	
	SVS	Ortho-k
1: Mit syn er meget skarpt, når jeg ser på noget langt væk (skoletavle eller biograf)	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
2: Mine øjne føles nogle gange ubehageligt	N/A	N/A
Item 3: Jeg er glad for mit udseende	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet
4: Når jeg dyrker sport eller laver andre aktiviteter, tager jeg nogle gange mit synshjælpemiddel af, fordi det generer mig	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du er aktiv eller dyrker sport	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du er aktiv eller dyrker sport
5: Når jeg leger udenfor har jeg aldrig problemer med mit synshjælpemiddel	N/A	N/A
6: Mine venner driller mig med mit synshjælpemiddel	N/A	N/A
7: Jeg er meget glad for mit synshjælpemiddel	N/A	N/A
8: Når jeg ser på noget langt væk, er mit syn ikke så skarpt, som jeg gerne ville have	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
9: Mine øjne føles altid behageligt	N/A	Spørgsmålet handler både om, når du bruger og ikke bruger dine linser
10: Jeg kan ikke lide den måde jeg ser ud på, når jeg bruger mit synshjælpemiddel	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet (også selv om man ikke kan se dit synshjælpemiddel)
11: Når jeg leger udenfor, har jeg aldrig problemer med mit synshjælpemiddel	N/A	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du leger
12: Mit synshjælpemiddel går nogle gange i stykker eller falder af/falder ud, når jeg bruger det	N/A	N/A
13: Mine venner vil gerne have samme slags synshjælpemiddel som mig	N/A	N/A
14: Jeg kan ikke lide mit synshjælpemiddel	N/A	N/A
15: Mit syn er meget skarpt, når jeg ser på noget tæt på (bog eller mobiltelefon)	N/A	N/A
16: Nogle gange klør eller svier mine øjne eller føles tørre	N/A	N/A
17: Mit synshjælpemiddel får mig til at se sej ud	N/A	Svar så godt du kan selv om du ikke bruger briller
18: Når jeg leger udenfor, irriterer mit synshjælpemiddel mig nogle gange	N/A	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du leger
19: Selv om jeg leger eller dyrker sport falder mit synshjælpemiddel aldrig af	N/A	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du leger eller dyrker sport
20: Mine venner kan ikke lide den måde jeg ser ud på, når jeg bruger mit synshjælpemiddel	N/A	Svar så godt du kan selv om du ikke bruger briller
21: Jeg har aldrig problemer med mit synshjælpemiddel	N/A	N/A
22: Når jeg læser, er mit syn ikke så skarpt, som jeg gerne vil have	N/A	N/A
23: Mine øjne føles aldrig irriterede	N/A	N/A
24: Jeg synes godt, jeg kunne se pænere ud	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet
25: Jeg bliver aldrig irriteret af mit synshjælpemiddel, når jeg er fysisk aktiv (sport, leg, dans og så videre)	N/A	Du skal svare ud fra, om dit synshjælpemiddel generer dig, når du er fysisk aktiv
26: Nogle gange er det svært at tage mit synshjælpemiddel af eller på	N/A	N/A

(continues)

APPENDIX B (Continued)

Items	Help texts	
	SVS	Ortho-k
27: Mine venner siger kun søde ting om mit synshjælpemiddel	N/A	N/A
28: Jeg ville ønske jeg havde en anden slags synshjælpemiddel	N/A	N/A
29: Mit syn er altid rigtig godt	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
30: Jeg føler mig nogle gange utilpas, når jeg bruger mit synshjælpemiddel	N/A	N/A
31: Jeg kan godt lide den måde jeg ser ud på, når jeg bruger mit synshjælpemiddel	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet	Spørgsmålet handler om den måde man ser ud på, når man kigger i spejlet
32: Jeg er dårligere til sport, fordi mit synshjælpemiddel driller mig	N/A	Du skal svare ud fra, om dit synshjælpemiddel gør dig dårligere til sport
33: Mit synshjælpemiddel er aldrig blevet væk eller gået i stykker	N/A	N/A
34: Mine venner siger nogle gange dumme ting om mit synshjælpemiddel	N/A	N/A
35: Jeg kan godt lide at have mit synshjælpemiddel på	N/A	N/A
36: Nogle gange er mit syn uskarpt	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
37: Mine øjne føles altid rigtig godt	N/A	Spørgsmålet handler både om, når du bruger og ikke bruger dine linser
38: Jeg kan ikke lide, hvordan jeg ser ud, når jeg kigger mig i spejlet	Spørgsmålet handler om, hvordan du opfatter dit udseende	Spørgsmålet handler om, hvordan du opfatter dit udseende
39: Jeg har aldrig problemer, når jeg bruger mit synshjælpemiddel i forbindelse med sport eller anden aktivitet	N/A	Du skal svare ud fra, om dit synshjælpemiddel giver dig problemer i forbindelse med sport eller anden aktivitet.
40: Det er nogle gange svært at pudse/rense mit synshjælpemiddel	N/A	N/A
41: Mine venner snakker aldrig om mit synshjælpemiddel	N/A	N/A
42: For det meste irriterer det mig, at bruge mit synshjælpemiddel	Spørgsmålet går på om du bliver irriteret, ikke om det generer dine øjne.	Spørgsmålet går på om du bliver irriteret, ikke om det generer dine øjne
43: Jeg ser altid bedre end mine venner	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
44: Nogle gange kan jeg ikke lide følelsen i mine øjne	N/A	Spørgsmålet handler både om, når du bruger og ikke bruger dine linser
45: Der er ingen, der lægger mærke til det, når jeg bruger mit synshjælpemiddel	N/A	N/A
46: Jeg kunne være bedre til sport, hvis jeg ikke skulle bruge mit synshjælpemiddel	N/A	Du skal svare ud fra, om dit synshjælpemiddel gør dig dårligere til sport
47: Det er let at tage mit synshjælpemiddel af og på	N/A	N/A
48: Mine venner griner nogle gange ad mit synshjælpemiddel	N/A	N/A
49: Jeg lægger slet ikke mærke til mit synshjælpemiddel	Spørgsmålet handler om hvor meget du tænker over, at du bruger et synshjælpemiddel	Spørgsmålet handler om hvor meget du tænker over, at du bruger et synshjælpemiddel
50: Mine venner ser for det meste bedre end mig	Når du svarer på spørgsmålet skal du svare ud fra, at du har dine briller/kontaktlinser på	N/A
51: Det er altid behageligt at have mit synshjælpemiddel på	N/A	N/A

APPENDIX B (Continued)

Items	Help texts	
	SVS	Ortho-k
52: Mit synshjælpemiddel gør mig mindre pæn	N/A	Svar så godt du kan selv om du ikke bruger briller
53: Jeg tænker aldrig over mit synshjælpemiddel, når jeg leger udenfor	N/A	N/A
54: Jeg kan ikke lide at pudse/rense mit synshjælpemiddel	N/A	N/A
55: Mine venner kan godt lide, den måde jeg ser ud på, når jeg har mit synshjælpemiddel på	N/A	Svar så godt du kan selv om du ikke bruger briller
56: Jeg hader at have mit synshjælpemiddel på	N/A	N/A

Note: Danish version of PREP2 with differentiated help texts by population subgroups.

APPENDIX C

Original version of PREP2.

Items	
Item 1	My vision is very clear when I look far away (movies or board at school)
Item 2	My eyes are sometimes uncomfortable
Item 3	I am happy with the way I look
Item 4	When I play sports or other activities, I sometimes don't wear vision correction because it bothers me
Item 5	When I play outdoors, I never have a problem with my vision correction
Item 6	My friends make fun of me because of my vision correction
Item 7	I love my vision correction
Item 8	When I look far away, my vision is not as clear as I would like it to be
Item 9	My eyes are always comfortable
Item 10	I do not like how I look when I wear my vision correction
Item 11	When I play outdoors, I never have a problem with my vision correction
Item 12	My vision correction sometimes breaks or falls off while I am wearing it
Item 13	My friends want the same kind of vision correction that I have
Item 14	I don't like my vision correction very much
Item 15	My vision is very clear when I look at something close (books or cell phones)
Item 16	My eyes sometime itch, burn, or feel dry
Item 17	My vision correction makes me look cool
Item 18	When I play outside, my vision correction sometimes bothers me
Item 19	When I am active, my vision correction never falls off
Item 20	My friends don't like how I look when I wear my vision correction
Item 21	I never have problems with my vision correction
Item 22	When I read, my vision is not as clear as I would like it to be
Item 23	My eyes never feel irritated
Item 24	I think that I could be better looking
Item 25	I am never bothered by my vision correction when I am active (sports, dance, etc.)
Item 26	My vision correction is sometimes hard to put on or take off
Item 27	My friends only say good things about my vision correction
Item 28	I wish I had a different kind of vision correction
Item 29	My vision is always excellent
Item 30	I am sometimes uncomfortable when I wear my vision correction
Item 31	When I wear my vision correction, I like how I look
Item 32	I am worse at sports because my vision correction bothers me
Item 33	My vision correction never gets lost or broken
Item 34	My friends sometimes say things that are not nice about my vision correction
Item 35	I like to wear my vision correction

(continues)

APPENDIX C (Continued)

Items	
Item 36	Sometimes my vision is not clear
Item 37	My eyes always feel great
Item 38	When I look in the mirror, I do not like how I look
Item 39	I never have any problems when I wear my vision correction while I play sports or do other activities
Item 40	Sometimes is hard to clean my vision correction
Item 41	My friends never mention my vision correction
Item 42	In general, wearing my vision correction bothers me
Item 43	I can always see better than my friends
Item 44	Sometimes I don't like how my eyes feel
Item 45	Nobody notices when I wear my vision correction
Item 46	I could be better at sports if I didn't have to wear vision correction
Item 47	It is easy to put on or take off my vision correction
Item 48	My friends sometimes laugh about my vision correction
Item 49	I don't even notice my vision correction
Item 50	My friends usually see better than me
Item 51	Wearing my vision correction is always comfortable
Item 52	Wearing my vision correction makes me look worse
Item 53	I can play outside without ever thinking about my vision correction
Item 54	I don't like cleaning my vision correction
Item 55	When I wear my vision correction, my friends like the way I look
Item 56	I hate wearing my vision correction

Note: Original version of PREP2.