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ABSTRACT

Purpose: To optimize recognition and management of nausea in children with cancer using patient reported outcome measures (PROMs) and to identify preferences of children with cancer regarding two validated tools: the Baxter Retching Faces (BARF) scale and the Pediatric Nausea Assessment Tool (PeNAT).
Design and methods: This quantitative descriptive cross-sectional study ($n = 34$) used bespoke questionnaires to measure feasibility and face validity of the BARF and the PeNAT. Feasibility included the items: understanding, ease of use, and communication. Face validity was studied in terms of the degree in which the faces of both PROMs corresponded with children's feelings of nausea. A descriptive and comparative analysis of the data was performed.
Results: Both the BARF and the PeNAT were rated by the children as feasible, and no significant differences were found. However, regarding the item communication, the PeNAT did not reach the cut-off value (≥80% of all children scored neutral, agree or totally agree on the Likert scale). Regarding face validity, only the BARF reached the cut-off value and corresponded significantly better with children's feelings of nausea than the PeNAT.
Conclusion: According to children with cancer, only the BARF is both feasible and meets criteria for face validity. Therefore, the BARF is recommended as a PROM for reporting nausea in children with cancer. However, possible differences between age groups should be taken into account for future research.
Practice implications: This study will help health care professionals in making a patient-centered and informed choice when using a PROM for measuring nausea in children with cancer.

Introduction

Worldwide, 300,000 children are diagnosed with cancer every year which concerns an annual incidence of 600 children diagnosed with cancer in the Netherlands (Kaspers et al., 2019). These children are diagnosed with hematological (42%), solid (33%), and neuro-oncology (25%) (Princess Máxima Center, 2021). As an essential part of their treatment, most children receive chemotherapy with nausea and vomiting being the most feared side effects (Barbour, 2017; Mustian et al., 2008). The incidence of chemotherapy induced nausea and vomiting (CINV) is reported in up to 80% of children with cancer (National Cancer Institute, 2018). Despite recent advances and development of pharmacologic antiemetics and CINV guidelines, control of CINV in children with cancer remains challenging (Al Qadire & Alkhalaileh, 2018; Patelet al., 2021; Patel et al., 2022; Patel et al., 2023; Watcha et al., 2019). The main barriers for controlling CINV in this patient group are under-recognition of CINV and children underreporting their symptoms, resulting in increased risk for morbidity (Al Qadire & Alkhalaileh, 2018; Grunberg, 2012; Hawkins & Grunberg, 2009; Watcha et al., 2019). Even to parents, caregivers, and trained health care professionals, identification of CINV in children with cancer can be challenging (Ruggiero et al., 2018). This challenge is due to great variation in children's cognition, verbal abilities, and gross motor and fine motor abilities depending on age (Linder & Wawrzynski, 2018). Therefore, to improve CINV control in children with cancer, strategies to enhance early CINV recognition and management are needed (Grunberg, 2012).

The use of a validated patient reported outcome measure (PROM) for measuring the subjective feeling of nausea can contribute to early

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CINV recognition and management, which is possibly effective in reducing CINV in children with cancer (Dupuis et al., 2006; Watcha et al., 2019). Two known PROMs for self-report of nausea intensity in children are: the Baxter Retching Faces (BARF) scale and the Pediatric Nausea Assessment Tool (PeNAT) (Dupuis et al., 2006; Watcha et al., 2019). The BARF is a pictorial rating scale developed and validated for measuring nausea in children aged 7 to 18 years old. The BARF consists of six faces which are specifically designed in consultation with children and nurses for measuring nausea, ranging from zero to ten points, with zero being not nauseous and ten being severely nauseous or retching. Scores ≥4 are associated with patient-perceived need for anti-emetic. Sensitivity and validity of the BARF have been demonstrated (Baxter et al., 2011; Watcha et al., 2018; Watcha et al., 2019). The PeNAT is a pictorial rating scale specially developed to measure nausea in children with cancer aged 4 to 18 years old. The PeNAT consists of four faces which are derived from the Wong-Baker scale (Wong & Baker, 1988), and ranges from 1: not nauseous to 4: severely nauseous. Scores ≥3 are associated with patient-perceived need for anti-emetics. Reliability, criterion validity and construct validity of the PeNAT have been demonstrated (Dupuis et al., 2006).

However, which of both PROMs for assessing nausea should best be used in children with cancer? The voice and opinion of a child experiencing these subjective feelings of nausea should be decisive for answering this question. However, the opinion of children with cancer about these tools or their preference for either one are unknown. Therefore, knowledge regarding practical use and children's preferences of the BARF and the PeNAT is needed. This study is a quantitative, descriptive, cross-sectional study. The primary aim was to assess the feasibility of both the BARF and the PeNAT, i.e. to assess which PROM is most feasible according to children with cancer. Secondary, this study aimed to determine the face validity of both PROMs as assessed by children with cancer.

Methods

Participants

The heterogeneous study population consisted of children with cancer aged 4–18 years old who received chemotherapy at the Princess Máxima Center for pediatric oncology, and participated in a study concerning the pharmacokinetics of two anti-emetic drugs: (fos)aprepitant and dexamethasone. These patients received highly emetogenic chemotherapy and were expected to experience CINV. Data were collected between March and June 2021. Eligibility criteria were: able to speak and understand Dutch and experience with CINV (being nauseous at the time of measurement was not required). Children who met any of the following criteria were excluded from participation: (i) unable to rate a visual numeric scale due to developmental delay and/or visual impairment, (ii) undergone anaesthetics ≤24 h, (iii) suffering from increased intracranial pressure, and (iv) receiving end of life care. Parent(s) and/or children (aged 12 or above) were informed and approached through an information letter. Children were further informed by the researcher (EH) during their clinical admission or their next scheduled clinical appointment after consultation with the nurse about the child's fitness for participation. Children aged between 12 and 18 years old gave their informed consent, and additional consent was given by both parents or caregivers for children aged between 12 and 16 years. For children under the age of 12, only both parents or the child's guardian gave written consent for study participation. After completing informed consent, children were able to participate in this study.

Measures

The study parameters represented the concepts of feasibility and face validity as defined in the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) taxonomy (Mokkink et al., 2010). The main study parameter, feasibility, included: the patient-reported value gained from both PROMs, expressed in terms of understanding, ease of use, and communication. All three items of feasibility were explored both separately and joint as a sum score, referring to as total feasibility. The secondary study parameter, face validity, included: the preferences of children regarding the faces of both PROMs, expressed in terms of which faces of both PROMs corresponded most with their perceived feelings of nausea severity.

Both study parameters were assessed using a bespoke questionnaire. For assessing feasibility, questions were: “I find it easy to understand what the faces mean”, “I find it easy to choose a face that matches my feelings of nausea”, and “I find the faces helpful in telling the nurse how nauseous I am”. The same questions were asked for both PROMs. For face validity, children were asked in which degree both PROMs corresponded with their feelings of nausea, and both PROMs were compared to each other. Also, children were specifically asked whether the neutral face of the BARF or the neutral face of the PeNAT corresponded with their feelings when not feeling nauseous, since the expressions for ‘no nausea’ are different for both PROMs. For older children (aged 8–18 years), questions were answered through a five-point Likert scale (1: strongly disagree, 2: disagree, 3: neutral, 4: agree, 5: strongly agree). For younger children (aged 4–8 years), questions were answered through a three-point Likert scale (1: strongly disagree, 3: neutral, 5: strongly agree).

Procedures

To ensure that all children would understand the concept of CINV, to centre their attention on the feeling of nausea, and to explain how to use the BARF and the PeNAT, two procedures were used: one for older children (aged 8–18 years) and one for younger children (aged 4–8 years). For both age groups the same questions were asked. Depending on the child's response to the researcher's question about their preferences, the parent(s) could be present when the questionnaire was conducted, but the child was asked to provide the answer.

The older children completed the questionnaire individually on paper during their clinical admission, or their outpatient visit. If they preferred, the questionnaire was filled in digitally through a secured link at home. All questions were scored through a five-point Likert scale and the scores 3: neutral, 4: agree, and 5: strongly agree were labelled as ‘positive answers’.

For the younger children, the questionnaire was administered by the researcher (EH) in interview form. Both the faces of the BARF and the PeNAT were presented in adjacent pairs to block the child's tendency to choose the extremes of a scale (Baxter et al., 2011; Dupuis et al., 2006; Watcha et al., 2019). To help young children to make a decision, all questions were scored through a three-point Likert scale, which is more appropriate at this age (Chambers & Johnston, 2002). The scores 3: neutral, and 5: strongly agree were labelled as ‘positive answers’.

Data analysis

A descriptive and comparative data analysis was performed. Demographic data for baseline characteristics were analyzed using descriptive statistics. After completion of the questionnaire, percentages of ‘positive answers’ (3: neutral, 4: agree, or 5: strongly agree) were calculated.

A PROM for nausea was considered understandable, usable, and helpful in communication when ≥80% of the children answered the associated questions positive (meaning answers were ≥ 3). Total feasibility was reached when sum scores of understandability, usability and communication were positive (meaning the sum score of answers was ≥9) according to ≥80% of all children. A PROM for nausea was considered face valid when ≥80% of the children answered the questions regarding face validity positive. The 80% cut-off value was set by the researchers (EH and AB) in consultation with four independent experts in research in children with cancer (one psychologist, one pediatric oncologist, and

two nurse researchers). Finally, a Wilcoxon signed rank test was executed to compare understanding, ease of use, communication, face validity and total feasibility between the BARF and the PeNAT. *P* values of ≤0.05 were considered statistically significant. Additionally, differences between the two age groups were described.

Ethical considerations

This study was conducted according to the principles of the Declaration of Helsinki and was part of a pharmacokinetic study. Ethical approval was obtained from the Medical Ethical Committee (METC) of the Erasmus University of Rotterdam.

Results

Of the 43 children, three were too ill ($n = 3$) and one was not available ($n = 1$), which resulted in 39 eligible children. Five children refused to participate because the burden was too high ($n = 5$). Response rate was 87% and there were no missing data.

In total, 34 children (aged 4 to 18 years old) diagnosed with a hematological malignancy (2.9%), solid malignancy (64.7%), or brain malignancy (32.4%) participated in this study ($n = 34$) (Table 1). All children were treated according to treatment protocols consisting of highly emetogenic chemotherapy. However, 88% of the children ($n = 30$) were not feeling nauseous at the time of study participation.

Feasibility: understanding, ease of use and communication

With regard to the BARF, 94.1% of all children scored positive on understanding, 97.1% of all children scored positive on ease of use, and 85.3% of all children scored positive on communication (Fig. 1). According to the cut-off value of 80%, the BARF was found to be feasible for understanding, ease of use and communication. With respect to age, both the younger age group (4–8 years) and the older age group (8–18 years) scored positive on the questions regarding ease of use and communication of the BARF. However, only 75% of the younger age group rated its communication positive, which is below cut-off, whereas this score was 90.0% for the older age group.

With regard to the PeNAT, 82.9% of all children scored positive on understanding, 94.1% of all children scored positive on ease of use, and 79.4% of all children scored positive on communication (Fig. 1).

Table 1
Patient Characteristics.

Characteristic	*n*	%	*Mean*	Range
Gender				
Female	12	35.3		
Male	22	64.7		
Age at diagnosis in years			9.5	2–17
Age group				
4–8 years	12	35.3		
8–18 years	22	64.7		
Diagnosis				
Solid malignancies	22	64.7		
Brain malignancies	11	32.4		
Hematological malignancies	1	2.9		
Treatment protocol				
ACNS0331	5	14.7		
ACNS0332	3	8.8		
EpSSG NRSTS 2005	2	5.9		
EURAMOS-1	5	14.7		
EWING 2008	10	29.4		
NBL2009	3	8.8		
Other	6	17.6		

Note: $N = 34$.

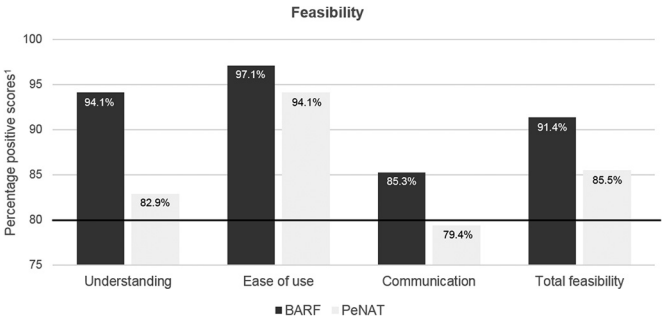

Fig. 1. Feasibility of the BARF and the PeNAT.
[1] The feasibility of the BARF and the PeNAT was measured at the level of three items: understanding, ease of use, and communication. When at least 80% of the children scored positive (≥3 on the Likert scale), the tool was considered understandable, usable, or helpful in communication. Total feasibility was reached when at least 80% of all children had a positive score (sum score of all three items (understanding, ease of use, and communication) of ≥9).

According to the cut-off value of 80%, the PeNAT was only found to be feasible for understanding and ease of use, because the cut-off value of 80% was not reached for communication. With respect to age, both age groups scored positive on the questions regarding ease of use. However, only 75% of the younger age group rated its understanding positive and 66.7% of the younger age group rated its communication positive, which is below cut-off. These scores were 90.0% and 86.4% respectively for the older age group (Fig. 2).

Between the BARF and the PeNAT, no significant differences were found for understanding, ease of use, and communication (Wilcoxon signed rank test: understanding ($Z = -1.701$, $p = .089$), ease of use ($Z = -0.321$, $p = .748$), and communication ($Z = -0.647$, $p = .518$)).

Total feasibility

Most children rated both the BARF (91.4%) and the PeNAT (85.5%) positive on total feasibility, which shows that the cut-off value of 80% was reached for both PROMs (Fig. 1). However, with respect to age, only 75% of the younger children rated the PeNAT as feasible and therefore the cut-off value for the younger age group was not reached (Fig. 2).

Total feasibility scores of both PROMs were not significantly different (Wilcoxon signed rank test ($Z = -1.109$, $p = .267$)).

Face validity

With regard to the BARF, 82.4% of all children scored positive on face validity, meaning that the BARF's faces corresponded to their perceived feeling of nausea (Fig. 3). According to the cut-off value of 80%, the BARF did reach the criteria for face validity for both age groups (Fig. 3). However, the specific neutral face of the BARF reflected the feelings of only 44.1% of all the children, which is below cut-off (Fig. 4).

With regard to the PeNAT, only 55.9% of all children scored positive on face validity. Therefore, according to the cut-off value of 80%, the PeNAT did not reach the face validity criteria for both age groups (Fig. 3). However, the neutral face of the PeNAT reflected the feelings of 82.4% of all children, which shows that the neutral face of the PeNAT reached face validity. With respect to age, only 58.3% of the younger children scored the neutral face of the PeNAT positive on face validity which is below cut-off (Fig. 4).

Testing revealed that the BARF scored significantly higher on overall face validity than the PeNAT (Wilcoxon signed rank test ($Z = 2.079$, $p = .038$)), whereas the PeNAT's neutral face corresponded significantly more with children's feelings of no nausea than the BARF's neutral face (Wilcoxon signed tank test ($Z = 2.403$, $p = .016$)).

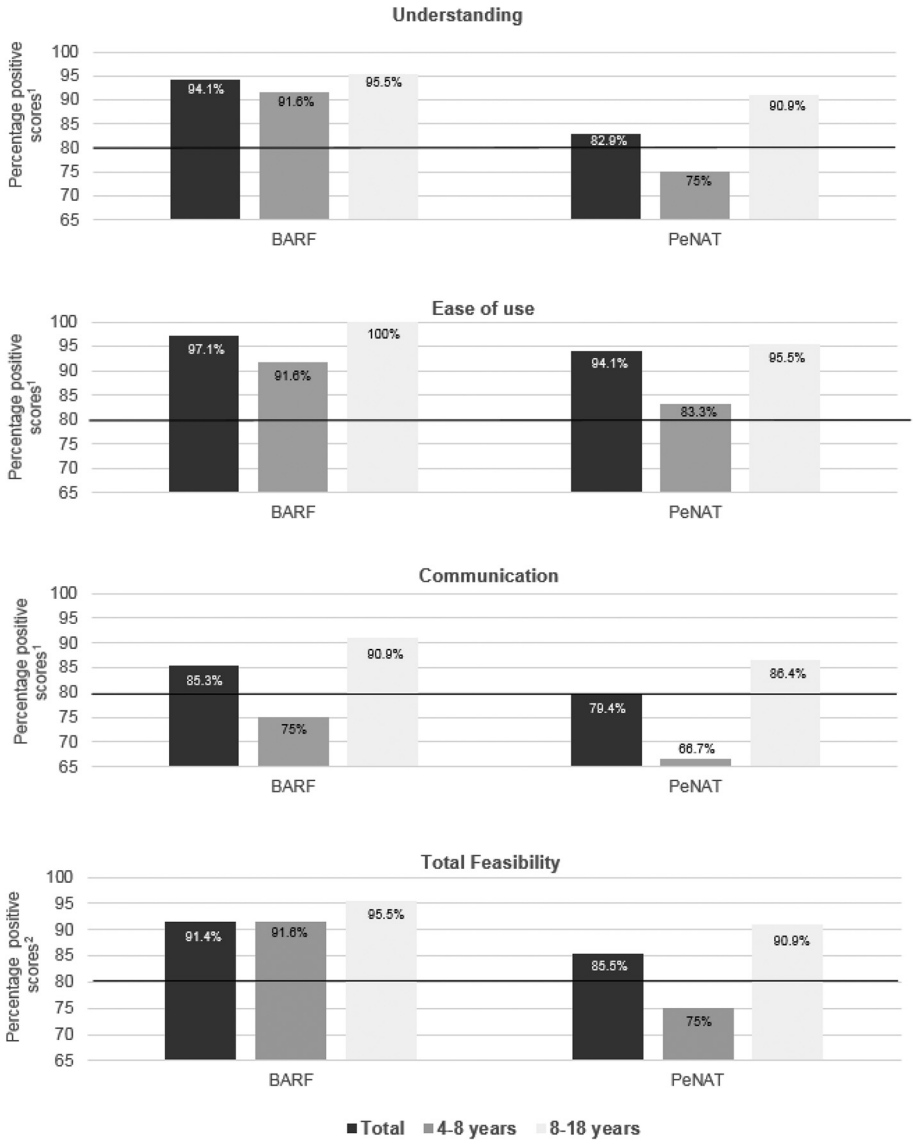

Fig. 2. Feasibility of the BARF and the PeNAT – divided into age groups.
[1] The feasibility of the BARF and the PeNAT was measured at the level of three items: understanding, ease of use, and communication. When at least 80% of the children scored positive (≥3 on the Likert scale), the tool was considered understandable, usable, or helpful in communication. [2] Total feasibility was reached when at least 80% of all children had a positive score (sum score of all three items (understanding, ease of use, and communication) of ≥9).

Discussion

This study showed that both the BARF and the PeNAT are feasible PROMs for the assessment of nausea in children with cancer, meaning that both PROMs are equally helpful in reporting the severity of nausea in children. However, the PeNAT scored moderate on the item 'communication' in the total group of children. Besides, the younger children (aged 4–8 years) scored the item 'communication' below cut-off (80%) for the BARF and the PeNAT, which means that they believe both PROMs are not helpful in communication about their feelings of nausea. In addition, younger children scored the item 'understanding' of the PeNAT below the cut-off value, which shows that they did not find it easy to understand what the faces of the PeNAT mean. All children scored the BARF significantly better on face validity than the PeNAT. In fact, the PeNAT scored below cut-off which means that the PeNAT does not reach the criteria for face validity. Overall, the results of this study show that the BARF is both a feasible instrument and meets the criteria for face validity, whereas the PeNAT is only feasible. The BARF is therefore best used as a PROM for reporting nausea in children with cancer.

For both feasibility and face validity of the two PROMs, lower scores in the younger age group were noticed, however differences between younger and older children could not be statistically compared due to a small study population. One explanation for lower scores in younger children could be that PROMs are more difficult to use for younger children due to their age related mental development. Younger children are more likely to use the matching strategy, a strategy where they link their given score to their specific experience with the face expression, as they are not able to use a strategy based on a mature mental model of a scale, a strategy where the child selects a point along an underlying continuum (Tomlinson et al., 2010). A second explanation for the lower scores in younger children could be that all questionnaires were taken at a time when only 11.8% ($n = 4$) of all children were feeling nauseous, which means that most children had to recall a hypothetical situation based on previous personal experiences with nausea when completing the questionnaire. This may be an explanation for the lower feasibility

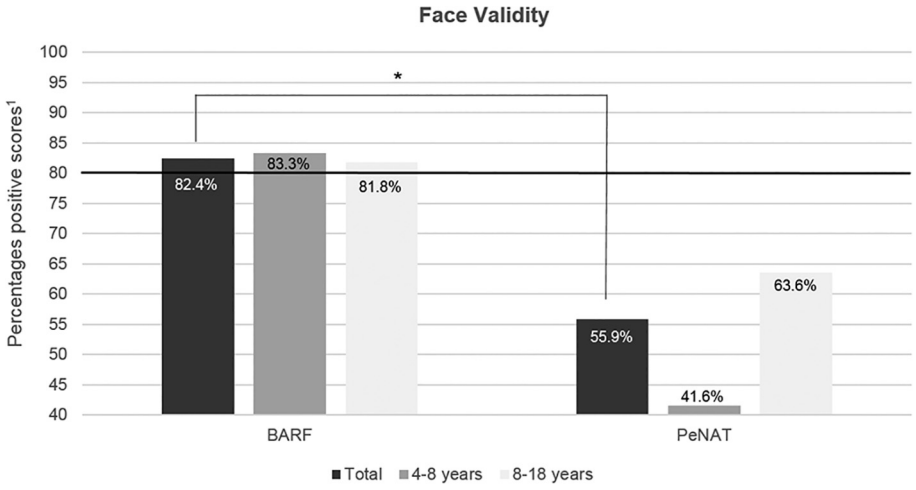

Fig. 3. Face validity of the BARF and the PeNAT.
[1] Face validity was reached when at least 80% of the children had a positive score (≥3) on the Likert scale. Statistical significance (p-values) is shown as * $p < .05$.

scores in the younger age group, because younger children are less likely to recall a hypothetical situation than older children. Finally, the cut-off value of 80% as used in this study is rather high and strict because we wanted the PROM to be feasible for the majority of the children when using the PROM in clinical practice. Previous studies regarding pain measurement and measuring quality of life in children show cut-off values of 60% and 70% (Gall et al., 2015; Varni et al., 2003). With this lower cut-off values both PROMs would have been considered to be feasible for both older and younger children in this study.

Although the PeNAT is specifically developed for children with cancer, and the BARF is not, the BARF performed better on face validity. An obvious explanation is that the faces of the BARF were specifically developed and designed to represent nausea, whereas the faces of the PeNAT were derived from an existing pain measurement instrument (Baxter et al., 2011; Dupuis et al., 2006; Watcha et al., 2018; Wong & Baker, 1988). However, children rated the neutral face of the PeNAT significantly better in reflecting their feelings of no nausea in comparison with the BARF's neutral face. The BARF uses a neutral face with a straight mouth for the expression of 'no nausea', whereas the PeNAT uses a smiling face for the representation of 'no nausea'. Because most children were not feeling nauseous or ill at the time of participation, the specific expressions of the neutral faces of both PROMs probably did make a difference for children who primarily use the matching strategy (Tomlinson et al., 2010). Outcomes could be different when children are feeling nauseous or ill, at the time of rating face validity of both neutral faces. When children are feeling well, it is obvious that they prefer the smiling neutral face of the PeNAT.

One strength of this study was that we compared the BARF and the PeNAT on feasibility and face validity in children with cancer, which provides new knowledge regarding the use and preferences of the BARF and the PeNAT in this particular patient group. Next, this study had a high response rate (87%), which means that response bias was minimized since a minimum questionnaire response rate of 60% is recommended in oncology studies (Parekh et al., 2020). In addition, all included children had experienced nausea and were as such experts to rate feasibility and face validity of both PROMs. Therefore, the validity of the findings in this study was met (Parekh et al., 2020).

A limitation of this study was that most children were included while visiting the outpatient clinic for a regular check visit and were not nauseous or ill at the time of data collection. In addition, the study

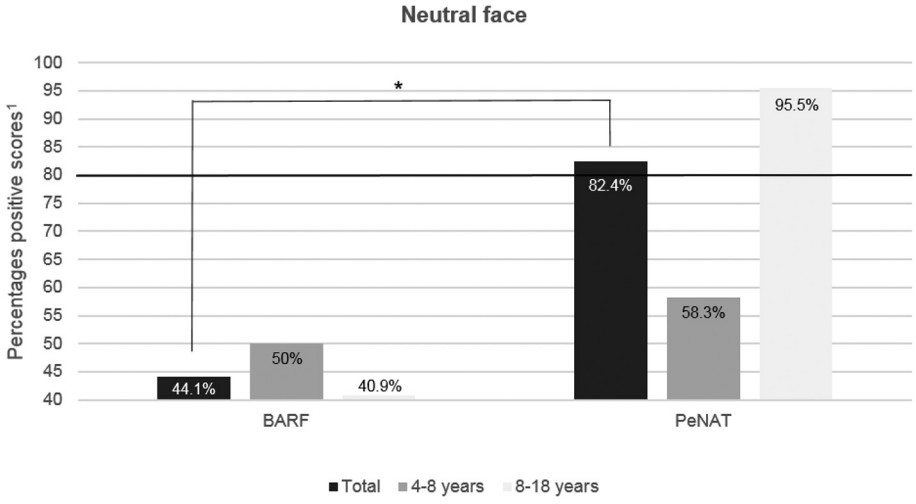

Fig. 4. Face validity of the neutral faces of the BARF and the PeNAT
[1] Face validity of the neutral face was reached when at least 80% of the children had a positive score (≥3) on the Likert scale. Statistical significance (p-values) is shown as * $p < .05$.

sample was rather small, therefore it would be recommended for future research to study the feasibility and face validity of both PROMs in a larger group children who are feeling nauseous and to compare differences between age groups.

Practice implications

Nurses should strive, whenever they can, to use PROMs for patient self-report of nausea to support the child's voice (Montgomery et al., 2020). PROMs help establish a nursing diagnosis, assess the severity of symptoms of nausea, evaluate the effect of nursing interventions, and communicate with other healthcare professionals involved in the child's treatment, all of which contributes to strengthening the clinical autonomy of nurses (Weston, 2008). Finally, the use of PROMs is beneficial within scientific (nursing) research, because it contributes to the objectification of subjective research outcomes, such as nausea.

Conclusion

Both the BARF and the PeNAT are feasible PROMs for the assessment of nausea in children with cancer, however the PeNAT helps children only moderately to communicate about their feelings of nausea. In addition, the BARF met criteria for face validity whereas the PeNAT did not. However, the low presence of nausea and possible differences between age groups should be taken into account when interpreting these results. This study will help health care professionals in making a patient-centered and informed choice when using a PROM for measuring nausea in children with cancer.

Ethics approval and consent to participate

This study was approved by the Medical Ethics Review Committee (MEC-2018-1578 amendment A-0004 NL67072.078.18).

Consent for publication

Not applicable.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

CRediT authorship contribution statement

Els C. Haverkate: Writing – original draft, Visualization, Methodology, Formal analysis, Conceptualization. **Evelien de Vos-Kerkhof:** Writing – review & editing. **Marianne D. van de Wetering:** Writing – review & editing. **Janneke M. de Man-van Ginkel:** Writing – review & editing. **Wim J.E. Tissing:** Writing – review & editing, Supervision. **Aeltsje Brinksma:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The author(s) declared that there is no conflict of interest.
The authors report no actual or potential conflicts of interests.
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