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Psychometric evaluation of the electronic faces thermometer scale for pain assessment in children 8–17 years old: A study protocol

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Abstract

It is often a challenge for a child to communicate their pain, and their possibilities to do so should be strengthened in healthcare settings. Digital self-assessment provides a potential solution for person-centered care in pain management and promotes child participation when a child is ill. A child's perception of pain assessment differs when it is assessed using digital or analog formats. As we move into the digital era, there is an urgent need to validate digital pain assessment tools, including the newly developed electronic Faces Thermometer Scale (eFTS). This study protocol describes three studies with the overall aim to evaluate psychometric properties of the eFTS for assessing pain in children 8–17 years of age. A multi-site project design combining quantitative and qualitative methods will be used for three observational studies. Study 1: 100 Swedish-speaking children will report the level of anticipated pain from vignettes describing painful situations in four levels of pain and a think-aloud method will be used for data collection. Data will be analyzed with phenomenography as well as descriptive and comparative statistics. Study 2: 600 children aged 8–17 years at pediatric and dental settings in Sweden, Denmark, Iceland, and USA will be included. Children will assess their pain intensity due to medical or dental procedures, surgery, or acute pain using three different pain Scales for each time point; the eFTS, the Faces Pain Scale Revised, and the Coloured Analogue Scale. Descriptive and comparative statistics will be used, with subanalysis taking cultural context into consideration. Study 3: A subgroup of 20 children out of these 600 children will be purposely included in an interview to describe experiences of grading their own pain using the eFTS. Qualitative data will be analyzed with content analysis. Our pilot studies showed high level of adherence to the study procedure and rendered only a small revision of background questionnaires. Preliminary analysis indicated that the instruments are adequate to be used by children and that the analysis plan is feasible. A digital pain assessment tool contributes to an increase in pain assessment in pediatric care. The Medical Research Council framework for complex interventions in healthcare supports a thorough

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development of a new scale. By evaluating psychometric properties in several settings by both qualitative and quantitative methods, the eFTS will become a well-validated tool to strengthen the child's voice within healthcare.

KEYWORDS
digital tool, eFTS, pain assessment, pediatric pain, psychometric evaluation, validation

1 | INTRODUCTION

Pain is a personal experience that is influenced by biological, psychological, and socio-cultural factors as interpreted by the individual child. Pain is defined by The International Association for the Study of Pain as (Raja et al.).[1] A child's ability and preference for how to communicate pain is dependent on various factors, such as age, gender, language ability, ethnicity, and cultural background, as well as situational aspects.[2,3] Ill children have the right to take an active part in their own care.[4,5] It is important to capture the child's own perspective,[6] and children's self-reports should be the primary source of information on pain intensity to impact healthcare decisions where possible.[7] Despite this, the frequency of use of pain Scales for self-report in clinical practice is limited.[8,9] One possible barrier may be the use of analog pain Scales. These types of assessments are predominantly dependent on the healthcare professional's presence, time, and willingness to use the assessment tool.

Currently, there is a paradigm shift from using analog tools to digital tools in pain assessment.[10] New digital technologies can provide new opportunities to let children decide when to assess their pain themselves and children have shown a preference for the use of digital assessment tools over paper versions.[11] With the development and refinement of digital tools, real-time appraisal of pain will increase,[6] which may empower children to engage in pain management in all of their natural environments.[12] The child's perception of pain assessment may differ between the digital format and an analog assessment tool. Therefore, it is very challenging to translate analog tools unequivocally into a digital tool. Furthermore, children communicate present and non-present pain differently,[13,14] and there might be a discrepancy between the child's experience of pain and thoughts about pain.[43] A review found no superiority of a "culturally based" self-report tool in relation to a universal tool.[2] A universal valid tool that is feasible to use for children in various settings has therefore the potential to strengthen the child's voice within healthcare.[15] Consequently, there is an urgent need to explore and test such new digital tools for validity and reliability in various situations to facilitate improved pain management for children.[10]

Based on the above concerns in earlier studies, a digital symptom management tool, the Pictorial support in person-centered care for children (PicPecc), has been developed.[16] The development followed the UK Medical Research Council's (MRC) guidance for development and evaluation of complex interventions in healthcare[17,18] and is based on a systematic review focusing on self-reported pain intensity when children suffer acute pain as well as qualitative interviews with children with cancer, caregivers, and healthcare professionals.[16] The development, supported by universal design for maximum accessibility and equality, resulted in an interactive digital smartphone- or tablet-based symptom management tool in the form of the PicPecc App, which is free to download from Google Play and the App Store® (Android and Apple).[16] Figure 1 a-f displays different sections of fronts in PicPecc, each with its own function. The child chooses which symptom to assess: anxiety, appetite, fear, feelings, nausea, pain, or sleep (Figure 1b). The application includes the electronic Faces Thermometer Scale (eFTS), which the child uses for assessing different symptoms. In the eFTS, the level of symptom is visualized as a one-item measure with color, a face with an expression

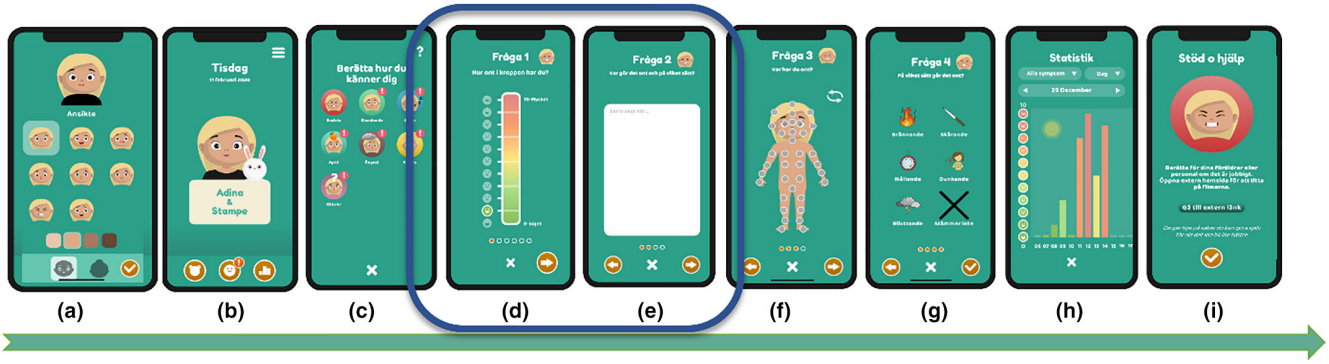


FIGURE 1 Pictorial support in person-centered care for children with options for the child to create an avatar (a), create a name and choose a pet (b), choose between symptoms (c), assess and report level of symptoms by the use of the electronic Faces Thermometer Scale (d), an open-ended symptom-related question (e), use a body map (f), respond to choose pictures of symptoms (g), get an overview of assessment scores (h) and receive suggestions for self-support (i).

representing the intensity of pain and with 11 numeric rating scale steps: 0 (no pain) – 10 (much pain) (Figure 1c). The child assesses a symptom by moving the finger on the eFTS until the color, face or numeric represents their appraised level of pain. Besides assessing symptoms, the child can also respond to an open-ended symptom-related question (Figure 1d), get an overview of assessment scores (Figure 1e) and get suggestions for self-support (Figure 1f).[16]

As a next step of developing PicPecc, a series of studies evaluating psychometric properties and usability is currently being performed. This study protocol describes three studies with the overall aim to evaluate psychometric properties of the eFTS for assessing pain in children 8–17 years of age. The hypotheses are:

1. The eFTS will show acceptable content validity for assessing pain in children by discriminating between no, low, medium and high levels of anticipated pain.
2. The eFTS will show acceptable convergent and construct validity for assessing pain in children in relation to faces pain scale–revised (FPS-R) and Coloured analogue scale (CAS).
3. The eFTS will be reliable to use for real-time and non-real-time pain assessment in children.
4. The eFTS will show acceptable specificity.
5. Children can relate to and express their pain by using the eFTS.

2 | METHODS

2.1 | Design

A multisite study combining quantitative and qualitative methods will be used. In this protocol, three observational studies will be implemented to evaluate the psychometric properties of the eFTS as described in Table 1. The project and selected measurement properties align with the recommendations of the COnsensus-based Standards for the selection of health Measurement INstruments checklist (COSMIN) study design checklist for patient-reported outcome measurement instruments.[19] In this study specifically, we will evaluate: (1) content validity in terms of relevance and comprehensibility, (2) construct validity including convergent and discriminative validity evaluating expected relationships with two other outcome measures, (3) cross-cultural validity in terms of similar behavior of eFTS in different populations, and (4) responsiveness in terms of longitudinal validity and test–retest reliability. The study is registered at ClinicalTrials.gov (NCT05329467).

2.2 | Participants and sample size calculation

Children between 8 and 17 years old with a variety of diagnoses (e.g., cancer, diabetes, minor trauma, dental caries) and reasons for care (e.g., surgery, medical, and dental procedures) are eligible. Each of the care facilities provides care for children with various pediatric illnesses or health conditions, and together the care facilities represent a variety in orientation and scale. Exclusion criteria in all studies are: (1) clinical instability (e.g., end-of-life care or illness necessitating admission to intensive care), (2) not understanding the instructions or being able to give informed consent or assent, and (3) participate in the data collection either autonomously or with support from a caregiver due to language barriers or developmental impairment.

2.2.1 | Study 1

Consecutive inclusion will be used to recruit 100 Swedish-speaking children visiting the Pediatric Pain Unit or the Pediatric Cancer Unit at the University Hospital in Linköping. The sample size is based on Belter et al.[20] who showed that 50 children in one group were sufficient for evaluation of anticipated pain using Charleston Pediatric Pain Pictures (CPPP). Therefore, the children in our study are divided into two groups based on age: 8–12 years and 13–17 years.

2.2.2 | Study 2

A convenience sample of 600 children hospitalized at a pediatric department or visiting a dental health clinic in Sweden (Skåne University Hospital, Faculty of Odontology, Malmö, or University Hospital of Linköping), Denmark (Rigshospitalet Copenhagen), Iceland (Landspitali University Hospital), or the United States (Children's Healthcare of Atlanta, Atlanta, Georgia) will be included in subgroups

TABLE 1 Overview of the three studies in this protocol.

Study	Design and analysis	Sample size	Data collection method	Outcome
1	A convergent mixed methods design using descriptive and comparative statistical analysis and phenomenography	100	• Questionnaire • Digital self-ratings • Think-aloud conversation	Content (Relevance & Comprehensibility) validity Non-real-time pain assessment
2	Descriptive, comparative, and correlational study design using parametric and non-parametric statistical analysis	600	• Questionnaire • Digital self-ratings	Construct (Convergent & Discriminative validity) Cross-cultural validity Reliability (test–retest) and responsiveness
3	Qualitative study design via content analysis	20	• Individual interviews	Content (comprehensibility) Real-time pain assessment

representing four types of pain. Every pain situation comes with its own characteristics, and therefore, different Scales might be feasible for different kinds of pain. In this study, children will therefore be divided into subgroups according to underlying reason for pain. Group 1: Children with no pain. The child's condition will be confirmed by asking the children themselves if they have "any pain" or "any hurt." Children stating no pain will be included. Group 2: Children experiencing acute pain requiring pain treatment/pain management. The painful condition will be confirmed by asking the children themselves if they have "any pain" or "any hurt." Group 3: Children who will undergo medical or dental procedures that are associated with pain (e.g., intramuscular injections, lumbar punctures, dental caries removal, or wound care) while awake and without strong sedatives. Group 4: Children who will undergo minor surgery in general anesthesia. The sample size is based on a power calculation from prior evidence on the correlations between Faces Pain Scale – Revised (FPS-R) and Coloured Analogue Scale (CAS) paired sample *t*-tests for pre- and post-analgesia pain scores and test–retest reliability. Based on exact correlation bivariate normal model and *t*-tests means using Gpower 3 (Faul et al.),[21] the difference between two dependent means (matched pairs) was used for sample size calculations. With α of 0.05, β of 0.99, and two-tailed tests, the required sample sizes for the correlation (effect size = 0.78 or 0.82), and pre- and post-*t*-tests on the analgesia pain scores (mean difference = 1.61, standard deviation [SD] = 2) were 17, and from 23 to 30. With α of 0.05, β of 0.95, and two-tailed tests, the required sample size for the test–retest reliability ranged from 129 to 175.[22,23] The number of children included in each group will vary between the four countries.

2.2.3 | Study 3

A subgroup of about 20 children participating in Study 2 will be purposefully invited to an interview for the qualitative evaluation of the use of pain assessment Scales. A variation in age, gender, illness, and prior experience to pain will be sought to enrich the data.

2.3 | Instruments and materials

2.3.1 | The tool to be validated in all studies

eFTS

The eFTS will be presented to the child on a tablet computer and a study standard script will be read: "This scale shows how much pain one can have. Down here means no pain at all, the scale shows increasing level of pain and up here shows that it is very painful. Now, show me on the scale, how much pain you feel right now."

In the first step, the child will assess the pain by moving their finger on the eFTS until the color, face, or numeric represents their appraised level of pain.[16] In the second step, the child will answer the question *what are you doing right now*? (Figure 1).

2.3.2 | Validation tool used in study 1

The Charleston Pediatric Pain Pictures

Charleston Pediatric Pain Pictures (CPPP)[20] constitutes 17 pictures each illustrating a child in a situation that has been defined into one of four categories: no pain, low pain, moderate pain, or high pain. Each picture is supplemented with a vignette explaining the circumstances for what is shown in the picture (Figure 2). The child will observe each picture in a predetermined order and hear the vignette. After each picture, the child will be asked to grade the level of pain that they anticipate that they themselves would have felt in that situation. Figure 2 shows two examples of the CPPP (Figure 2).

2.3.3 | Validation tools used in study 2

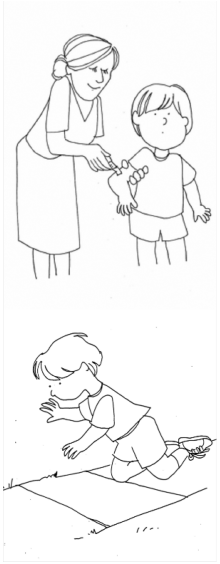
FPS-R and CAS

The Faces Pain Scale-Revised (FPS-R) and Coloured Analogue Scale (CAS) are two commonly used analog pain Scales for self-report that show good validity and reliability in psychometric evaluations with children.[23] The FPS-R and CAS will be used as gold standard for comparability of validity. A systematic review strongly recommended the use of the FPS-R and the CAS for acute pain assessment, but also weakly endorsed its use in post-operative pain assessment in children above the age of seven.[24] Forward and backward translations from Swedish to English, Icelandic, and Danish for questions in the PicPecc was performed by bilingual researchers in their respective language.

The FPS-R consists of six faces on a horizontal plastic strip, each face representing an increasing degree of pain moving from left to right with a corresponding numerical score from 0 to 10. Each child will be shown the faces on the strip and they will be instructed to select the face that symbolizes their intensity of pain[25] (Figure 3a).

The CAS is a vertical plastic strip with a wedge-shaped color-gradated figure on the one side, a numerical scale on the other scored from 0 to 10 in 0.25 units, and a moveable slider. A decrease of the CAS by 2.4 cm has been confirmed as a clinically significant change. The child will be shown the side of the instrument with the wedge-shaped figure with the slider positioned in the middle, and then read a standard script: "Move the slider to the place that shows how much pain you have. This end means you have no pain (slider moved to the bottom) – this end means you have the worst pain (slider moved to the top)." The slider will be moved back to the middle of the scale before the child uses the scale[26] (Figure 3b).

The FPS-R and the CAS are interpreted as 0–3 (no/mild pain), 4–6 (moderate pain), and 7–10 (severe pain). The FPS-R and the CAS have shown a strong convergent (0.92) and discriminant validity ($p < 0.001$) as well as responsivity ($p < 0.001$), and a test–retest reliability at 0.77 and 0.89 (Pearson's correlations), respectively,[20] with lower levels for children under 7 years of age.[23] Figure 3 illustrates the two analog pain Scales FPS-R and CAS used for validation.



"In this picture, you are at home and you have a band-aid on your arm. Your mother's taking the band-aid off your arm. Now show me how much hurt you would have here."

"In this picture, you were outside running on the sidewalk. You fell down on the sidewalk and your knees got scraped. Now show me how much hurt you would have here."

FIGURE 2 Two examples of the Charleston Pediatric Pain Pictures illustrating a painful situation and its corresponding vignettes.[20]

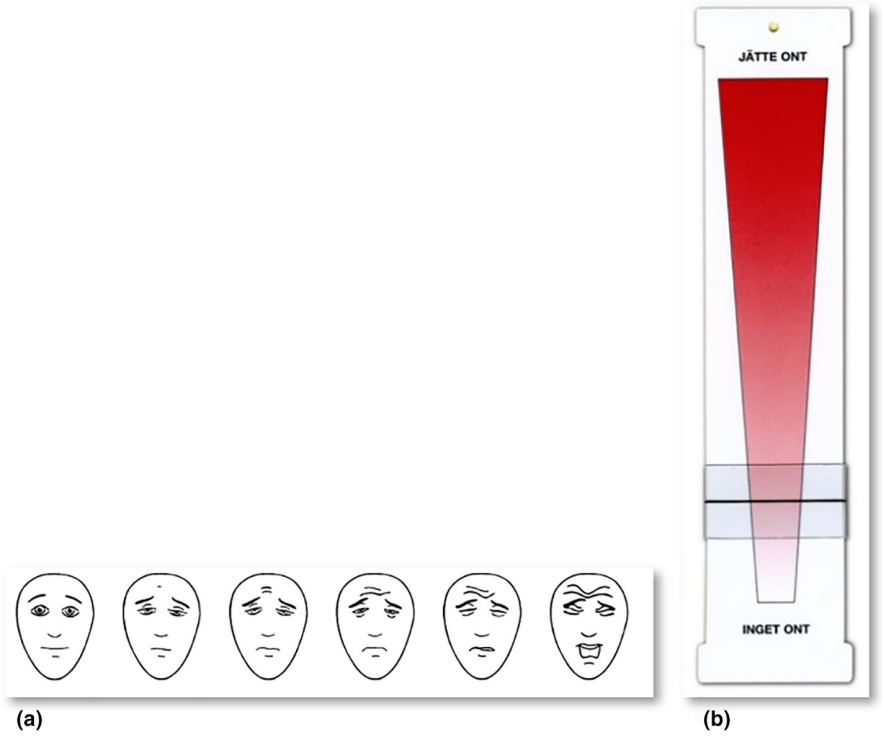


FIGURE 3 Tools used for validation (a) the faces pain Scale-Revised[25] and (b) the Coloured Analogue Scale[26]

2.3.4 | Interview guide

An interview guide will be used during semistructured interviews elucidating children's experiences of assessing their pain with a pain scale. Questions on how the child experiences describing their pain with an analog and a digital assessment tool and potential challenges as well as advantages with the different tools will be included.

2.4 | Translation and language evaluation

All assessments will be performed in the child's primary language. In all encounters the words "hurt" or "pain" or their equivalents in the Scandinavian languages, will be used interchangeably by the nurse, depending on what seem to be most understandable for each child.

The questions and instructions in the eFTS were first established in Swedish. The research group decided collectively on the best English equivalents and researchers fluent in Danish and Icelandic proceeded with translations to these two languages. Furthermore, the translation process of the 17 vignettes in the CPPP[20] from English to Swedish aimed to capture the conceptual equivalent of the source language of the painful situations adhering to the COSMIN guidelines.[19] A forward translation from English to Swedish was performed by a registered nurse specialized in pediatric and pain care. Terms and phrases that had posed problems were identified and a group of four researchers as well

as registered nurses specializing in children conducted a first linguistic evaluation. The version that all parties agreed upon was then back-translated by a professional translator who was blinded to the original English version. Finally, the back-translated version was compared to the original by the nurse and researcher. In case of a discrepancy, a second linguistic evaluation supported the final choice of word or phrasing ending in a final translation with all differences resolved.[19]

2.5 | Procedure and data collection

Data collection will follow a predetermined study protocol for each study and site. We estimate it will take 12–18 months at each site to fulfill power calculation requirements.

2.5.1 | Study 1

A pediatric nurse specialized in pain management and part of the research team will perform the data collection. Each child will be given an introduction to the eFTS on a tablet and to the concept of CPPP. Thereafter, each child will be shown one picture, hear its related vignette and then will be asked to grade the level of pain that they expect the child in the picture to experience. The child will furthermore be asked to describe how they reason and what helps them decide on level of pain using a "think-aloud" method (Charters).[27] The child's verbal expressions will be recorded digitally and transcribed verbatim. Background data on age, gender, reason for hospital visit, and ongoing pain treatment will be collected by a study-specific paper questionnaire from the child before starting the assessments.

A pilot study including 10 children showed positive responsiveness from children with a good comprehensiveness and comprehensibility to study procedure. Children were positive regarding participation and fulfilled the assessments of anticipated pain for all 17 CPPP using the whole width (0–10) of the eFTS for grading.

2.5.2 | Study 2

The attending nurse/physician/dentist will identify eligible study participants and provide the child and their caregivers with oral and written information about the study before seeking formal informed consent. The child will be allocated a personal study code. For each child, the nurse/physician/dentist will draw an envelope containing a predetermined order of assessment, for example, eFTS→FPS-R→CAS or FPS-R→CAS→eFTS. The nurse/physician/dentist will present each of the three Scales to the child in the same order as assigned and the same order of assessment will be used for all assessments to avoid assessment bias. Data on pain assessment will be collected at specific time points according to which group the child assigned to and according to setting, for example, post-surgery (Figure 4a) and post dental procedures (Figure 4b).

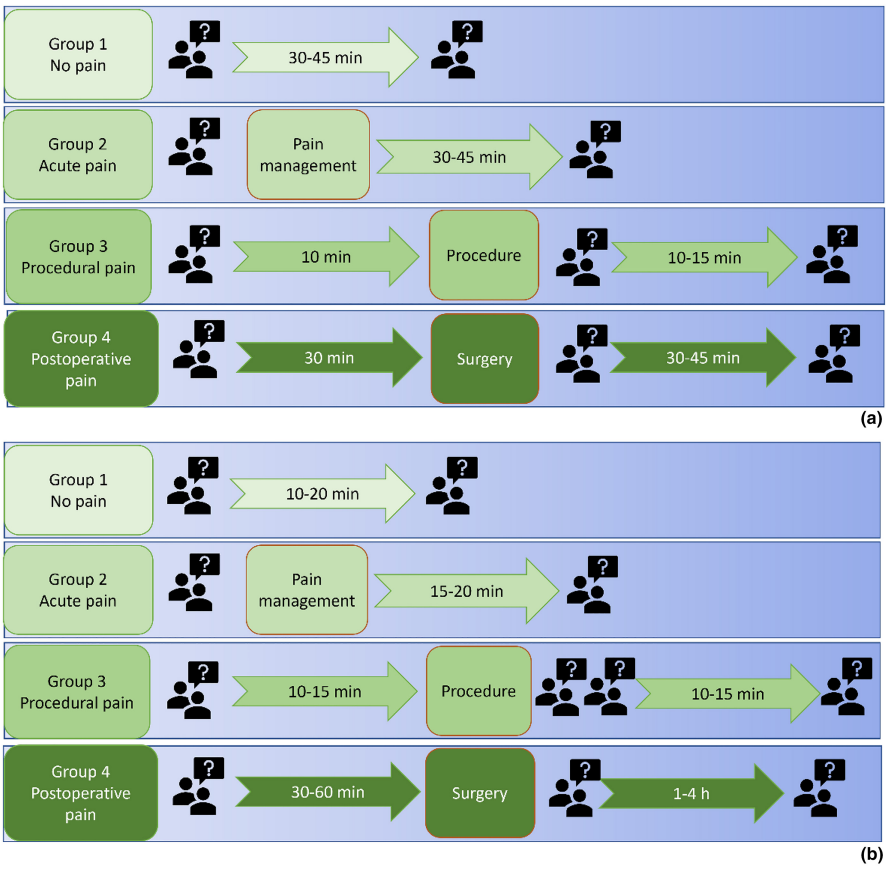


FIGURE 4 Data collection procedure in the: (a) post-surgery pain setting and (b) dental pain setting

Data from the eFTS assessment will be transformed by the nurse and documented together with data from FPS-R and CAS into a coded individual paper study form. At all follow-up assessments, the child will be asked whether they experience more, less, or about the same level of pain as at the previous assessment.

Demographic data, for example, age, gender, native spoken language, and ethnicity, will be collected through a questionnaire filled out by the child or caregiver. Data on diagnosis, reason for care and information on pain management between assessment one and two, will be collected through a questionnaire in the study form filled out by the nurse. Study forms will be collected from each site by the research group (local PI at each site) and transformed and stored at a secure digital database at Lund University.

Before starting data inclusion at a site, the study protocol will be evaluated for cultural sensitivity with healthcare staff and five children, adjusted for setting-specific time points for assessment, and will be used to perform pilot studies.

A pilot study including eight children at a pediatric surgery day-care department in Sweden was performed. Two pediatric nurses familiar to the study purpose, design, and procedure and who were specialized in pain management at a pediatric surgery day-care unit were in charge of the recruitment and the data collection. The pilot study showed positive responses from nurses, children, and caregivers, with high levels of acceptability of the study procedure. Children reported all three pain assessment tools (FPS-R, CAS, eFTS) relevant and with good comprehensiveness and comprehensibility to the instruments and study procedure. There were no dropouts, and the pilot test rendered no alterations in procedure other than a small revision of the background questionnaire.

A pilot study at a pediatric cancer department in USA and another at a department of pediatric dentistry in Sweden showed outcomes similar to the primary site.

Figure 4 illustrates time points for pain assessment in a post-surgery and a dental procedure setting (Figure 4).

2.5.3 | Study 3

On pre-scheduled days, a researcher will be available at the participating pediatric department to conduct interviews. On completion of the last pain assessment, the nurse will identify eligible children for the interview study and provide them with written and oral information on the study. Children, at the age of 15 or above, or the child's caregiver provides written consent, the researcher will approach them for further information and planning. Children under the age of 15 will be asked for written or oral assent. A semistructured interview conducted by the researcher will take place in a close proximity with the pain assessment at a time and place chosen by the child. The interview will be digitally recorded and transcribed verbatim.

2.6 | Data management and analysis plan

Data from questionnaires and eFTS will be transformed into Excel files and exported to SPSS 26 for analysis. Transcribed qualitative data will be analyzed using NVivo 12 Pro.

2.6.1 | Study 1

Quantitative data will be analyzed for content validity using descriptive statistics such as frequency (%) mean and SD, as well as comparative statistics using parametric (e.g., paired *t*-test) and non-parametric statistics (e.g., Mann–Whitney U test) based on data distribution. Verbatim transcribed think-aloud data will be analyzed using phenomenographic analysis[28] to describe children's conception of assessing anticipated pain, and the relevance and comprehensibility in dealing the aspects of pain presented in the CPPP. Two researchers in our team will take the lead in the qualitative analysis with another two researchers involved in discussing decisions regarding the identification of concepts and categories. A convergent mixed methods approach will then be applied to understand children's conception of pain and pain assessment in a more comprehensive way.

2.6.2 | Study 2

Psychometric properties in terms of validity and reliability of the eFTS in relation to the FPS-R and the CAS in our study population will be determined using statistics, such as frequency (%) and mean (SD). Comparative statistics will be performed using with most adequate tests (e.g., Pearson's correlation or regression analysis) depending on the data distribution. For all three measures, children with no pain will present a cut-off score of 0–3 and children with pain will present a cut-off score of 4–10. Convergent validity will be assessed by determining correlations (e.g., Pearson's correlation analysis) and agreement (e.g., *t*-test) between the eFTS, the FPS-R, and the CAS for self-assessing pain in children. Discriminant validity will be assessed to determine to what extent the FTS measures only the construct pain, and not something else (e.g., anxiety) by comparing the initial mean eFTS, FPS-R, and CAS scores in children with painful conditions versus those with non-painful conditions. Discriminant validity will be determined by Pearson's correlation coefficients. Construct validity (responsivity) in children with painful conditions will be determined by comparing the initial mean eFTS, FPS-R, and CAS pain scores with their respective post-treatment pain score. A paired *t*-test will be used for pre- and post-pain scores. We will assess children with no pain in a similar fashion and expect that there should be no difference between the initial and 30- to 45-min scores. Regarding the reliability of eFTS, the criterion validity

and test–retest reliability will be assessed. We will evaluate the reproducibility with Pearson's correlation coefficients, and test the discriminant validity with the eta-squared statistics when compared with the other nonelectronic single-item pain assessments. Repeated measures of analysis of variance will be used to analyze their pain from pre- to post-treatment. For each analysis, psychometric values corresponding to those of the FPS-R and CAS will be considered acceptable.

2.6.3 | Subgroup analysis with cultural perspectives

Cross-cultural validity of the eFTS will be ensured by using published guidelines for translational processes and by the application of subgroup analysis. Specific information on the socio-cultural characteristics—that is, country location (Sweden, Denmark, United States, Iceland), age (8–17 years old), gender (girls and boys), mother tongue (predominant vs. non-predominant language) and country of origin (predominant vs. non-predominant)—of the children will be provided and used for subgroup analysis. We will, for example, expect similar scores in no pain groups independent of socio-cultural characteristics, as well as agreement between tools, and similar correlation patterns, independent of socio-cultural background (construct validity). Subgroup analyses have been used to test the psychometric validity and reliability of pediatric pain assessment tools on the basis that socio-cultural factors relate to children's ability to describe, experience, and communicate pain.[23]

2.6.4 | Study 3

Transcribed interviews will be analyzed following the structured stepwise method of inductive qualitative content analysis[29] to describe the relevance and comprehensibility through children's experience of performing pain assessment, including the use of eFTS. Two researchers will perform the primary analysis and a further two researchers will be involved in the analysis for reflection, revision, and abstraction following the hermeneutic spiral of incorporating parts and the whole.

2.7 | Ethical considerations

The study abides by each country's laws and regulations and by the WMA Declaration of Helsinki.[30] The national ethical review board in each country will approve the study before start. The Swedish Ethical Review Authority (Dnr; 2020-05119, 2021-01213 & 2021-04152) approved this study. All children and their caregivers will receive oral and written age-adjusted information with emphasis put on voluntary participation and explanation that participation will not affect the child's care. Informed consent from caregivers and children from the age of 15 and assent from children below the age of 15 will be collected. So far, no studies evaluating pain assessment in children experiencing pain have reported any risks and we judge that the possible benefits will outdo the costs of participation.

2.8 | Preliminary analysis

To assess feasibility of the quantitative analysis plan, preliminary results were evaluated for study 1 and 2 after a first period of data collection.

2.8.1 | Study 1

Preliminary analysis of the first 30 children indicated a trend of heterogenous conformity between the participants' grading of anticipated pain in the eFTS in relation to CPPP with a high level of agreement for some pictures and a somewhat lower level for other pictures.

2.8.2 | Study 2

The first 24 children experiencing postsurgical pain in a pediatric department in Sweden completed the study with three assessments each—a total of 72 data points. These represented a variety in age, gender, and mother tongue. The mean age was 12.75 years. Nine of the 24 children were girls (37.5%), 19 (79%) had Swedish as their mother tongue, and 21 (87.5%) were born in Sweden. Pain scores for all three Scales were interpreted on a scale from 0 to 10. Primary analysis shows the expected variation in pain level with the median for each pain scale being: FPS-R 2 (min 0; max 8), CAS 2 (min 0; max 9), eFTS 3 (min 0; max 8).

2.8.3 | Timeline and realization

Funding and ethical approval were applied for in 2020. Data collection started in May 2021 and is planned to end in December 2023 or when the stipulated number of participants has been included. Scientific discussions are being held monthly to discuss challenges, ensure conformity between data collection sites, and agree on alterations and additions to the original project plan (Table 2). Dissemination of findings will take place through publication of 4–6 peer-reviewed journal articles, presentations at national and international conferences, and workshops with stakeholders. Table 2 declares additions and alterations of the project plan (Table 2).

3 | DISCUSSION

This study protocol describes a psychometric evaluation of a newly developed eFTS in children aged 8–17 years,[16] the results of which

TABLE 2 Additions and alterations from the original project plan.

Initial plan	Addition and alteration
Inclusion of four subgroups: no pain, post-surgery, procedural and acute pain in parallel (study 2)	As the included care settings experienced different strains due to the Covid-19 pandemic, the gathering of the data in the subgroups started at different time points
Validation was planned in different pediatric settings	Pediatric dental settings were added for two reasons: (1) to compensate for the slower inclusion rate in pediatric settings due to the Covid-19 pandemic; (2) adding a cohort of participants from a different setting will contribute to a more comprehensive validation (Ethical approval 2021-01213)
60 participants in Linköping for content validity (study 2)	To facilitate analysis in two age groups, sample size was increased to 100 participants (Ethical approval 2021-04152)

can be used to further develop the eFTS as a pain scale. A well-validated digital solution may give the children themselves a chance to participate in their own pain assessment procedure as well as in their own care.

Each study in the protocol will contribute with specific outcomes on psychometric validity and reliability to capture psychometric values of the eFTS across a broad spectrum. By describing how children reflect when choosing from the 11 gradients for anticipated and real-time pain in the scale, study 1 and 3 contributes to understand the relevance and comprehensibility of the eFTS. Study 2 provides a solid ground for the validity and reliability comparable to the present gold standard for pain assessment in children. The inclusion of 150 children in each group in study 2 is based on a power calculation and its accuracy is supported by COSMIN stating >50-> 100 participants as very good for the analysis planned.[19] By conducting the studies according to COSMIN, we will attain the standards for each aspect of the evaluated psychometric properties. At the same time, pain is a personal internal experience and one pain experience cannot fully be compared to another neither between children nor within one child over time. This must be taken into consideration whenever interpreting children's reported level of pain as well as results of a study aiming at validating pain measures.

We will use the MRC framework[18] to aid us in the development, feasibility testing, evaluation, and implementation of this complex intervention. It describes the core elements to consider in each of the phases required to launch a new scale for symptom assessment. In the development phase, it is the context, guidance of a theory, the stakeholders' involvement, key uncertainties, refinement of the intervention (measurement), and finally the costs that need to be addressed for the acceptance of the intervention to proceed into a final study of its effectiveness. The *context* may highly affect the outcome of an intervention. In the design of this study, we have therefore thoroughly discussed the heterogenic context in which the eFTS will potentially be used, and included a variety of settings in terms of diagnosis, sites, and different age of participants in the validation. This contributes to a more comprehensive validation. The *theory* of person-centered care and child participation in their own care,[31] former studies of pain assessment methods,[32] and theories of the effect of culture on pain assessment[3] have guided the development of the validation design of the eFTS. Children in various situations and families as well as professionals as *stakeholders* have been involved in different ways throughout the process and in the development of the eFTS. The study group includes several clinically active physicians and nurses to assure alliance with clinical relevance. The key uncertainties have been discussed and identified throughout the planning process of this study within the study group. These discussions together with inputs of external researchers and clinicians have led to some *refinement* of the original design and the instrument itself. Adding subanalysis with a cultural perspective is one example of this and alterations in the language and text contents of the eFTS. An analysis for *alternative costs* has not been performed within this eFTS validation project; however, health economic evaluations are part of additional projects on PicPecc. Taking these six core elements into consideration throughout the validation process will power the decision on how to proceed in next steps in research using the eFTS. Will further development be needed or is there a need to test the measurement further for feasibility in an active clinical context?

There is a general understanding that culture plays a role in pain assessment and that pain assessment tools need to be validated across various cultural backgrounds.[33] The quality of pain assessment tools is strengthened when its psychometrics are tested using diverse groups, aiding the accuracy and ability to capture factors that can impact pain intensity ratings.[34] Studies show that the validity and reliability of pain assessment scores can vary due to varying socio-cultural characteristics.[22] Identifying any differences in validity and reliability based on patient characteristics may thus impact the generalizability and implementation of the eFTS pain assessment tools. By including several background variables of socio-cultural characteristics, the validation study will be able to evaluate the effects of different factors on the assessment process in the use of the eFTS. The mixed method approach also strengthens this evaluation by providing a more comprehensive understanding of children's assessments, conceptions, and experiences of using the eFTS.

3.1 | Limitations

The inclusion criteria restrict the inclusion of children who are not able to communicate in other languages than English, Swedish, Danish, or Icelandic. This is an impediment as cultural contexts can have an impact on the perception of, response to, and communication of pain. Still, the possibility for including children not only with English, Swedish, Danish, or Icelandic as mother tongue, provides

opportunities to recruit children with various cultural backgrounds and obtain a heterogeneity in data adequate for a first cross-cultural validation. At the same time, psychometric properties for the FPS-R and the CAS have been mainly evaluated with similar inclusion and exclusion criteria as ours for the eFTS, which means that we use comparable populations. Inclusion criteria do not exclude inclusion of children with mild intellectual cognitive, communicative, intellectual, or other neurodevelopmental impairments. However, no demographic data on this will be collected which is a limitation for generalization and limits usability in a clinical setting. Future studies should include children living in other continents than Europe and USA, children with explicit neurodevelopmental and communicative impairments and children in younger ages. In these studies, we will ask children to use the eFTS as a one-dimensional tool. However, preliminary results show that different children tend to pay attention to different parts of the scale, namely the faces from happy to sad, the 0–10 grading scale and the color-shading changing from green to red. These differing responses will be further elucidated in study 3 and could potentially also be investigated in an additional study focusing on internal consistency among these three parts. Additional studies could aim at evaluating internal consistency among the three parts.

AUTHOR CONTRIBUTIONS

CC, MB, JB, PS, GK, OK, HH, and SN initiated and developed the study design. AH and HB contributed in parts of the design. JB provided statistical expertise and SN and OK conducted the primary statistical analysis. All authors contributed to refinement and revision of the study protocol and approved the final manuscript.

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