Research proposal

The Dutch version of the Parents' Postoperative Pain Measure (PPPM) – validity and reliability

De Nederlandse versie van de Parents' Postoperative Pain Measure (PPPM) – validiteit en betrouwbaarheid

Short title: Validity & reliability of Dutch form PPPM

Acronym-ID: PPPM-D-form.

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Principal investigator: Zoriana Zawodny MD

Scientific project leader: Liesbet Goubert PhD – Professor of Clinical Health Psychology
Ghent Health Psychology Lab, Department of Experimental-Clinical and Health Psychology, Gent University, Belgium

Project leader: Johan Berghmans MD PhD

Department of Anesthesiology ZNA Middelheim
Lindendreef 1, 2020 Antwerp
Secretariat: +32-32803981
email: johan.berghmans@zna.be
johan.berghmans@Ugent.be

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Research team

1. Z. Zawodny MD – Trainee in Anesthesiology ZNA Middelheim – Queen Paola Children's Hospital Antwerp, Department of Anesthesiology, KULeuven, Belgium
2. J. Berghmans MD PhD. – Anesthesiologist ZNA Middelheim – Queen Paola Children's Hospital Antwerp – Department of Anesthesiology, UGent, Belgium & Department of Anesthesiology Erasmus MC – Sophia Children's Hospital, Rotterdam, The Netherlands
3. L. Goubert PhD. – Professor of Clinical Health Psychology, Ghent Health Psychology Lab, Department of Experimental-Clinical and Health Psychology, Gent University, Belgium
4. L. Van Linthout MD – Anesthesiologist Department of Anesthesiology and Algology, University Hospital Gasthuisberg, Belgium, Department of Anesthesiology and Algology, GZA Hospitals, Antwerp, Belgium
5. M.J. Poley Dr. PhD. – Institute for Medical Technology Assessment (iMTA) & Institute for Health Care Management Erasmus University Rotterdam (iBMG), The Netherlands
6. M. H. Lauwers MD – Anesthesiologist ZNA Jan Palfijn, Antwerp, Belgium
7. E. Van Hoecke PhD. – Department of Pediatric Psychology, University Hospital Gent, Department of Interal Medicine and Pediatrics, UGent, Belgium
8. M. Beeckman PhD. – Department of Experimental Clinical and Health Psychology, UGent, Belgium
9. E. Utens PhD. – Professor of Psychology: Research Institute of Child Development and Education, University of Amsterdam/de Bascule, Academic Center for Child and Adolescent Psychiatry, Academic Medical Center, Amsterdam / Erasmus MC – Sophia Children's Hospital, Department Child and Adolescent Psychiatry/Psychology, Rotterdam, The Netherlands
10. J. De Graaff MD PhD. – Department of Anesthesiology Erasmus MC – Sophia Children's Hospital, Rotterdam, The Netherlands
11. M. De Vel RN. – Department of Nursing – Queen Paola Children's Hospital, Antwerp

Abbreviations

PPPM: Parents' Postoperative Pain Measure

PPPM-D: Parents' Postoperative Pain Measure – Dutch version

NRS-11: Numerical Rating Scale

FPS-R: Faces Pain Scale Revised

1. Summary

Background and rationale:

Postoperative pain at home in children is a major underestimated issue. Global pain rating scales used by parents are of limited value because of many observer biases and absence of specific objective criteria. Behavior rating scales fill this gap and the Parents' Postoperative Pain Measure (PPPM) was specifically designed for parents to assess their child's pain at home after surgery. It is an assessment tool with high internal consistency and inter-rater reliability. The PPPM shows good concurrent and sensitivity/specificity in selecting children with significant pain. Furthermore content validity is established.

Aims of the study:

To establish the reliability, validity, and sensitivity to change overtime (longitudinal sensitivity) of the Dutch version of the Parents' Postoperative Pain Measure (PPPM-D) in the assessment of postoperative pain among children aged between 2 and 12 years.

Methods:

A formal forward-back-forward translation procedure to translate the PPPM into Dutch (PPPM-D) will be carried out. Furthermore an expert panel of two psychologists and two anesthesiologists will evaluate the translation. This prospective observational study aims to include 120 children stratified according to: 1. child's age - age between 2-5 and between 6-12 years of age (dichotomy based on the child's ability to self-report of pain intensity by using the Faces Pain Scale Revised – FPS-R); 2. into different kinds of surgery (general, orthopedic, urologic, maxillofacial and otolaryngologic) related to the expected level of postoperative pain intensity levels (mild, moderate, severe). After receiving precise instructions one accompanying parent will complete the PPPM-D at the day of surgery (before the intervention) and directly after surgery in the evening and this parent will later rate the child's pain twice a day (morning – evening) during the first 5 postoperative days. Parallel with the PPPM assessments, parents will also use a Numerical Rating Scale (NRS) to

assess the pain of their child. Also children between 6 and 12 years will rate their pain intensity twice a day during 5 days postoperative by using the Faces Pain Scale revised (FPS-R).

The reliability and validity will be investigated at different levels:

1. Internal consistency reliability: Cronbach's alpha at the consecutive 5 postoperative days of the PPPM-D;
2. Convergent validity (a type of construct validity): 1. correlations between PPPM-D with both NRS and FPS-R; 2. comparison based on the different used cut-off values related to the respectively used scales PPPM-D, NRS and FPS-R to distinguish between different levels of pain - mild, moderate, severe;
3. Known-groups validity (a type of construct validity): assessing differences between minor, medial and major surgeries regarding the expected pain intensity levels;
4. To study the sensitivity to change overtime of the PPPM-D.

2. Introduction & Rationale

Nowadays a lot of pediatric surgery under anesthesia is often performed on a day-case basis. This approach has a lot of advantages for both the child and parents such as less disruption of family life and advantageous economic reasons, but unfortunately one of the main disadvantages is the existence high frequency of significant postoperative pain at home after day-case surgery in up to 80% (1-5). This was pointed out by Andrew Wolf (6) in 1999 in his '*Tears at bedtime: a pitfall of extending paediatric day-case surgery without extending analgesia*'.

This implies that parents should become very important partners in postoperative care at home after surgery especially related to pain assessment and management (1, 4, 7).

Several predictors can influence children's postoperative pain and parental pain management of their child (1). Parents tend to undertreat their child's postoperative pain and the reasons why remain unclear and seem very complex. Among described predictors withheld: 1. parental personality (8); 2. parental state/trait anxiety (2); 3. level of education (2); 4. cultural/religious reasons (9, 10); 5. parental misconceptions (8, 9, 11). Rony *et al* showed parents do not adhere to the prescribed pain management (4, 5) because of the following misconceptions about pain medication (11): 1. 52% of parents believe that analgesics are addictive; 2. 73% have concerns about side effects; 3. 37% even believe that analgesics work better when children receive them less often!

Also a lot of parents were surprised or did not expect that their child could have a high level of persistent postoperative pain (7) There seems to be a discrepancy between high postoperative pain ratings at home provided by parents and the low dosing of analgesics which may point towards parents having no difficulty in recognizing and assessing their child's pain (3-5, 7). It must be said that parents also tend to underestimate their child's pain and that they show poor levels of agreement with their children's pain self-reports (12).

Furthermore one should take into account different child related factors influencing children's postoperative pain: 1. high levels of preoperative anxiety (13, 14); 2. the child's postoperative pain anxiety (15); 3. refusal to take medication (16).
Hospital related organizational system factors, (1) such as poor communication between health care professionals and insufficient provided information, (7) might also contribute to higher levels of children's postoperative pain at home.
Pain management in children at home is a complex matter and it therefore needs a good and reliable pain assessment tool (17). Self-report can be considered as the 'gold standard' in pain assessment, but it is not always possible/suitable in young children. As a result this claim might be an overstatement because it ignores the overall complexity of pain assessment (18). Depending on their age, development status and emotional state, children may lack the appropriate verbal and cognitive skills to provide reliable self-reports.
Furthermore, most research in parental pain assessment has been done by using global assessment tools such as f.i a Visual Analogue Scale (VAS), a Numerical Rating Scale (NRS) or Faces Pain Scale (FPS-R) and also these instruments have their drawbacks because they are subject to a lot of observer bias in absence of specific objective criteria (17, 18). Consequently, in these circumstances it will be difficult for parents to take decisions regarding their child's pain management (f.i. adhere to the prescribed pain medication regime) (7). Therefore, it is essential to endorse a valid, reliable measure for children's pain that can easily be used by parents at home and at the same time this behavior rating scale could improve parental pain assessment.
The Parents' Postoperative Pain Measure (PPPM) (10, 17) is a specifically developed 15-item questionnaire which assesses behavior changes and verbal pain behavior at home after surgery (attachment 1). Parents have to answer each question by using a simple yes or no. Other options are not possible and positive answers (yes) are added up.

The PPPM was developed and preliminary validated for children aged 7-12 years by Christine Chambers *et al.* (17). Both internal consistency reliability and convergent validity

with child-related pain was high. There was also a positive correlation between the PPPM and emotional distress on Day 1 and on Day 2. Furthermore no significant interactions were found between the child's age and sex or main effect for the child's age or sex. Child related pain decreased from Day 1 to Day 2 and the same pattern was found for the PPPM. Based on a cut-off score of 6, PPPM was able to distinguish between children who underwent no/low pain surgery or moderate to high pain surgery (reference Faces Pain Scale 3-6)(19), as measured by sensitivity and specificity.

Furthermore also the reliability and validity of the PPPM was extended to 2-6 year old children (10) showing good internal consistency and good correlations between the PPPM scores and the child related pain intensity FPS in older children (≥ 6 years) and parental global pain ratings (FPS) in young children (< 6 years). However, construct validity was never established beyond day 3 postoperative. A further study revealed that the PPPM scores followed the pattern of children's self-reported pain intensity but was not related to state-anxiety (20).

Furthermore the PPPM is a proposed tool by core outcome domains and measures for pediatric acute and chronic/recurrent pain clinical trials (PedIMMPACT) recommendations (21) and has been used in several studies (3, 22, 23).

The PPPM has been translated into German (24), Finish (25), Swedish (Ljungman, 2002 unpublished data) and Korean (26).

The aim of the present study is to assess the validity, reliability and the sensitivity to change overtime up to five day postoperatively (longitudinal sensitivity) of the Dutch version of the PPPM-D among children aged between 2 and 12 years.

3. Methods

After approval by the IRB, this study will be conducted in accordance with the Declaration of Helsinki, the APA ethical standards and this study will be registered at https://www.isrctn.com International Standard Registered Clinical/soCial sTudy Number (ISRCTN).

This study will be reported following STROBE statement of observational studies. Approval to translate of the PPPM was obtained from C. Chambers (Centre for Pediatric Pain Research - IWK Health Centre | Dalhousie University, Canada) who developed the PPPM. The original version of the PPPM will be translated using standard forward-back-forward translation technique (27) (28) which will be done by two independent professional translators from Vadelingua VOF (Luikersteenweg 9, 3700 Tongeren, tel.: +32-12-210355). This followed by an evaluation of this translation by an expert panel of 2 psychologists and two anesthesiologists (attachment 2).

This study is a stratified observational cohort study which aims to include 120 children aged between 2 and 12 years old who undergo different kinds of surgery in day care at the ZNA Queen Paola Children's Hospital in Antwerp.

Stratification will be used to ensure equal allocation of subgroups of children and is based on: 1. child's age - age between 2-5 and between 6-12 years of age; 2. distribution of different kinds of surgery related to their expected level of pain intensity at home (20, 22). We distinguish three groups of surgery and there expected related pain in children at home: a) mild pain – inguinal hernia repair, myringotomy, adenoidectomy, gastroscopy, dental surgery; b) moderate pain – orchidopexy, strabismus, circumcision; c) severe pain – adenotonsillectomy, orthopedic osteosyntheses.

As usual care will be provided for both the surgical and anesthetic procedures and also instruction for pain management at home will be the same as usual.

Inclusion and exclusion criteria

Inclusion criteria

a) age of children 2 – 12 years old;
b) information and consent forms for parents and *an assent* form explained to the child aged 6 – 12 years;
c) different surgical procedures: a) inguinal hernia repair, myringotomy, adenoidectomy, gastroscopy, dental surgery; b) orchidopexy, strabismus, circumcision; c) adenotonsillectomy, orthopedic osteosyntheses;
d) one accompanying parent present at induction;
e) parents who speak and understand Dutch;
f) no premedication (the norm in Queen Paola Children's Hospital).

Exclusion criteria

a) known mental/cognitive retardation;
b) American Society Anesthesiologists ASA *physical status* > II;

Secondary exclusion criteria

a) when parent or child no longer wish to participate;
b) when a life-threatening situation occurs during the procedure (f.i. asystole);
c) when re-intervention is required as a result from f.i. a subsequent bleeding after tonsillectomy;
d) when the child has to be admitted because of constant nausea/vomiting.

During the consulting-hours prior to surgery an information brochure is handed out about the course of research (the time interval between the consulting-hours and the surgery will always be longer than two days) is handed out, so that parents have sufficient time to consider whether or not they will participate in the research. Parents are also given a general brochure concerning pain management after surgery in children. The psychological preparation is standard practice for everyone and it has not been adapted for this research.

On the day of surgery prior to going to the operating theatre each child and parent get to watch a preoperative preparatory film which gives them – among other things - information about inhalation induction.

On the day of intervention the information and consent forms are signed by the parents.

After inclusion the socio-demographic data are collected such as the age of the parents, marital status, level of education of the parents as a surrogate for socio-economic status (SES), religion, previous admissions of the child to hospital and experience of the parents of previous admissions and surgery of their children (attachment 3)**.** Parents who do not wish to participate are asked to give reasons for their refusal by answering specific questions about anxiety and SES (to inquire about selection bias).

The accompanying parents will receive diaries to take home and complete the PPPM-D and NRS at two times each day (after breakfast and in the evening after dinner) during five consecutive days. Parents will also fill in the PPPM-D on the day of surgery before the intervention as basic assessment.

Also children ≥ 6 years of age will receive a diary and will be asked to provide rating of FPS-R is two times each day. The burden to do this is very limited and it only takes a few seconds.

Both parents will be instructed on how to fill in the PPPM-D (see below) and children (≥ 6 years) will be instructed/trained to use the FPS-R.

After five days the parents will be asked to send the diaries back by using a provided self-addressed stamped provided envelope.

Telephone calls will be made by a research nurse at day 1 postoperative and between day 3 and 5.

The estimated total inclusion period for 120 children is estimated to be 6 to 8 months.

4. Research instruments

Parental pain assessment tools

Parents' Postoperative Pain Measure (PPPM)(17).

The PPPM (10, 17) is a 15-item questionnaire which assesses behavior changes and verbal pain behavior at home after surgery (attachment 1). Parents should answer each question by using a simple yes or no. Other options are not possible and positive answers (yes) are added up. A total score ranges from 0 to 15 and a PPPM score ≥ 6 is defined as a child with clinical significant pain which should be treated.

The PPPM was developed and preliminary validated for children aged 7-12 years by Christine Chambers *et al.* (17). Both internal consistency reliability (Cronbach's α's = .87 -.88) and convergent validity with child-related pain was high (Spearman rho =.60 on Day 1 and 2 postoperatively). There was also a positive correlation between the PPPM and emotional distress on Day 1 (Spearman rho =.39) and on Day 2 (Spearman rho =.27). No significant interactions were found between the child's age and sex or main effect for the child's age or sex. Child related pain decreased from Day 1 to Day 2 and the same pattern was found for the PPPM. The discriminative validity (reference Faces Pain Scale 3-6)(19) of the PPPM to distinguish between children who underwent no/low pain surgery or moderate to high pain surgery, a cut-off PPPM score ≥ 6 showed good sensitivity (Day 1: 88%; Day 2: 80%) and specificity (Day 1: 80%; Day 2: 84%).

Furthermore also the reliability and validity of the PPPM was extended to 2-6 year old children (10) showing good internal consistency (Cronbach's α's = .81 -.88) and good correlations between the PPPM scores and the child related pain intensity FPS in older children (≥ 6 years) (Spearman rho Day 1 =.64; Day 2 =.53) and parental global pain ratings (FPS) in young children (< 6 years) (Spearman rho Day 1 =.72; Day 2=.62). However, construct validity has never been established beyond day 3 postoperative. A further study

revealed that the PPPM scores followed the pattern of children's self-reported pain intensity but was not related to state-anxiety (20).

Furthermore the PPPM is a proposed tool by PedIMMPACT recommendations (21) and has been used in several studies (3, 22, 23).

The PPPM has been translated into German (24), Finish (25), Swedish (Ljungman, 2002 unpublished data), Thai and Korean.

Parents will follow precise instructions to fill in the PPPM accordingly as suggested by Chambers *et al* (10). Parents who will complete the PPPM receive the following instruction: '*Children sometimes have changes in behavior when recovering from surgery. The following is a specific list of behaviors that your child may or may not have had when recovering from surgery between … and … today. For each of the behaviors below circle the appropriate response, yes or no.'*

Numerical Rating Scale (NRS-11)*(18)*

Parents were asked to assess the child's global pain at home by using an NRS-11 – 'how much pain do you think your child feels right now?' – score range 0-10 and NRS-11 scores < 4 indicate no or mild pain; scores ≥ 4 indicate moderate to serious pain. The endpoints of the scale represent the extremes of pain experience (0 = no pain to 10 = worst possible pain). An NRS-11 has been used in several studies (4, 29) and gives a global impression of the child's pain (18, 30). Parents will be asked to use the scale two times a day at the same times as they fill in the PPPM-D.

Child pain assessment tools

The Faces Pain Scale-Revised FPS-R (31, 32)

Children between 6 - 12 years of age will be asked to fill in a diary (2 times/day) during 5 postoperative days for self-report of their pain using the Faces Pain Scale-Revised (FPS-R).

The FPS-R (31) was developed as a self-report measure of pain intensity for children and is the recommended tool by the International Association for the Study of Pain (IASP) (www.iasp-pain.org/Education/Content.aspx). For research the FPS-R is the recommended tool based on the psychometric feature and is easy to use (32, 33). *Originally it has been adapted from the Faces Pain Scale (19) to make it possible to score the sensation of pain on the widely accepted 0 - to -10 metric. This scale shows a close linear relationship with visual analog pain scales across the age range of 4-16 years. It is easy to administer and requires no equipment except for the photocopied faces* (http://www.usask.ca/childpain/NRS). (von Baeyer CL. Numerical Rating Scale (NRS) or Verbal Numerical Scale (VNS) for self-report of pain intensity in children)

The absence of smiles and tears in this scale may be advantageous. It is particularly recommended for use with very young children. Numerical self-rating scales (0-10) can be used with most children older than 8 years of age, and behavioral observation scales are required for those unable to provide a self-report.

From the website www.iasp-pain.org/Education/Content.aspx , we downloaded the instructions to use the Dutch version (see attachment X) and we use the following instructions, say "Hurt" or "Pain," whichever seems right for a particular child:

"These faces show how much something can hurt. This face *[point to left-most face]* **shows no pain. The faces show more and more pain** *[point to each from left to right]* **up to *this* one.** *[point to right-most face]* **It shows very much pain. Point to the face that shows how much you hurt** *[right now]***."**

Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so "0" equals "No pain" and "10" equals "Very much pain." Do not use words like "happy" and "'sad." This scale is intended to measure how children feel inside, not how their face looks.

5. Statistical Analysis

Power calculation/sample size

In this study, the sample size calculation was based on the analysis internal consistency reliability, namely Cronbach alpha (34) and we used to this aim Bonett's formula (35). By taking the assumption of a minimal acceptable level Cronbach alpha .7 (H0), an expected Cronbach's alpha of .8 (H1) (10), significance level (α) .05 (two tailed), power (1 – β) = 80%; 15 items (k), expected drop out of 10%, we calculated a sample size of 104 or a sample size with ± 15% dropout , n_{drop} = 120 children to be included.

$$n = \frac{2k}{k-1} \cdot \left[\frac{Z_\alpha + Z_\beta}{\ln(\delta)}\right]^2 + 2 \qquad \delta = \frac{1 - C\alpha(H_0)}{1 - C\alpha(H_1)} \qquad n = \frac{2 \cdot 15}{15-1} \cdot \left[\frac{1.96 + 0.842}{\ln(1.5)}\right]^2 + 2 \qquad \delta = \frac{1-0.7}{1-0.8} = 1.5$$

n = 104.335 ≈ 104

Demographic and psychometric data of children and parents will be presented as means ± SD (continuous data) or median with IQR or as percentages for categorical data. Normal distribution will be indicated by skewness and kurtosis and further confirmed by Kolmogorov-Smirnov tests.

The reliability and validity will be investigated at different levels:

1 Internal consistency reliability: Cronbach's alpha at the consecutive 5 postoperative days of the PPPM-D;

2 Convergent validity (a type of construct validity): a) correlation between PPPM-D with both NRS-11 and FPS-R by means of Spearman Rank correlation or Pearson correlation (additionally also Principal Component Analysis); b) comparison based on the different used cut-off values related to the respectively used scales the PPPM-D (≥ 6), NRS-11(≥ 4) and FPS-R (≥ 4) by means of a Chi-square test and receiver operating characteristics (ROC) analysis using cut-off values at the NRS-11 as reference;

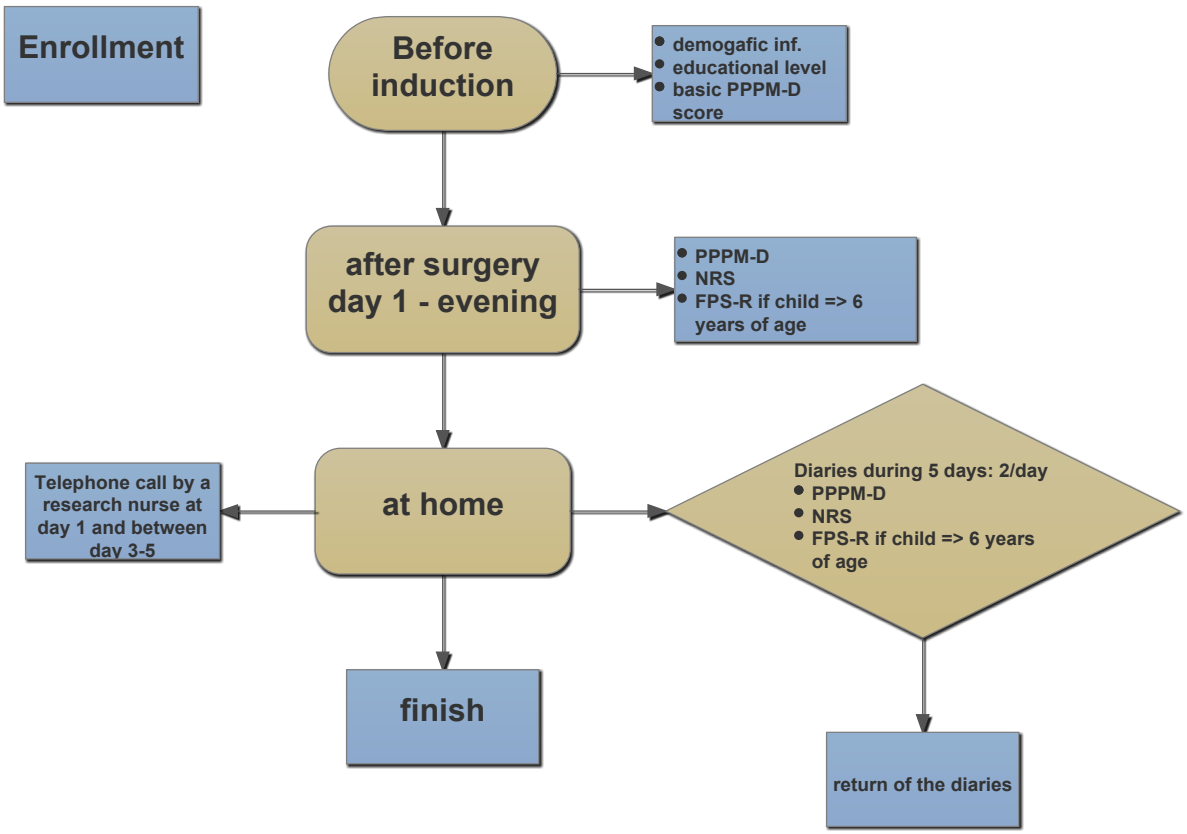
3 Known-groups validity (a type of construct validity): by assessing different kind of surgeries and their expected postoperative pain levels at home (mild, moderate, severe) using: 1. multiple Mann-Whitney U tests or T-tests; 2. General Estimating Equations (GEE) and post-hoc pairwise comparisons between the means of the severity groups (mild, moderate, severe) at each of the assessment times;

4 To study the sensitivity to change over time of the PPPM-D (up until day 5) using: 1. Friedman ANOVA or repeated measures ANOVA; 2. GEE to examine differences in each of these scores during the days for self-report NRS-11 and PPPM scores corrected by the child's age, gender and parental educational level.

P-values of < .05 will be considered statistically significant.

All data will be analyzed using IBM SPSS Statistics for Windows, Version 25.0 Armonk, NY: IBM Corp and MedCalc Software, Mariakerke, Belgium; http://medcalc.org).

6. Flowchart


Enrollment
Before induction
demogafic inf.
educational level
basic PPPM-D score
after surgery day 1 - evening
PPPM-D
NRS
FPS-R if child => 6 years of age
at home
Telephone call by a research nurse at day 1 and between day 3-5
Diaries during 5 days: 2/day
PPPM-D
NRS
FPS-R if child => 6 years of age
finish
return of the diaries

7. Ethical considerations

The study will be conducted according to the principles of the Declaration of Helsinki (version of 2008, updated 23/11/2017). Prior to patient enrolment, the protocol must be approved by the IRB of de ZNA ZiekenhuisNetwerkAntwerpen (EC).

8. Administrative aspects, monitoring and publication

Handling and storage of data and documents

By answering the questions of the questionnaires, parents give consent to use this data for the study. Participants data will be handled anonymously, using coding for each individual participant of the study. Each participant will have their own CRF number. The key to the code for each participant will be held by the investigator. Only study personnel involved with the specific parent will have access to the anonymous personal data. We will store data following the law: study data have to be stored for 20 years. Anonymous data will be analysed in SPSS and MedCalc.

Monitoring and Quality Assurance

Not applicable.

Amendments

Amendments are changes made to the research after a favourable opinion by the accredited IRB has been given. All amendments will be notified to the IRB that gave a favourable opinion.

All substantial amendments will be notified to the IRB and to the competent authority.

Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

Temporary halt and (prematurely) end of study report

Not applicable.

Public disclosure and publication policy

The results of the study will be published in a medical journal.

Structured risk analysis

Not applicable.

9. Attachments

Attachment 1

Attachment 1

Parents' Postoperative Pain Measure (PPPM)

It Doesn't Have to Hurt™
Proven Pain Control for Children

Children sometimes have changes in behavior when recovering from surgery. The following is a list of behaviors that your child may or may not have exhibited while recovering from surgery.

For each of the behaviors below, circle the appropriate response, yes or no.
When your child was recovering from surgery between

_____ **and** _____ **today, did she/he:**

1.	Whine or complain more than usual?	Yes	☐	No ☐
2.	Cry more easily than usual?	Yes	☐	No ☐
3.	Play less than usual?	Yes	☐	No ☐
4.	Not do the things s/he normally does?	Yes	☐	No ☐
5.	Act more worried than usual?	Yes	☐	No ☐
6.	Act more quiet than usual?	Yes	☐	No ☐
7.	Have less energy than usual?	Yes	☐	No ☐
8.	Refuse to eat?	Yes	☐	No ☐
9.	Eat less than usual?	Yes	☐	No ☐
10.	Hold the sore part of his/her body?	Yes	☐	No ☐
11.	Try not to bump the sore part of his/her body?	Yes	☐	No ☐
12.	Groan or moan more than usual?	Yes	☐	No ☐
13.	Look more flushed than usual?	Yes	☐	No ☐
14.	Want to be close to you more than usual?	Yes	☐	No ☐
15.	Take medication when s/he normally refuses?	Yes	☐	No ☐

Note on Administration and Scoring: Parents are asked to complete the measure between a specific time period (i.e., between breakfast and lunch, between lunch and supper, or supper and bedtime). The number of items parents have circled "Yes" are summed for a total score out of 15. A score of at least 6 out of 15 signifies clinically significant pain.

Reference: Chambers, C.T., Reid, G.J., McGrath, P.J., & Finley, G.A. (1996). Development and preliminary validation of a postoperative pain measure for parents. Pain, 68, 307-313.

Attachment 2

PPPM Backward translation

1. Zeurt of klaagt meer dan gebruikelijk?
1. Whines or complains more than usual?

2. Huilt makkelijker dan gebruikelijk?
2. Cries easier [more easily] than usual?

3. Speelt minder dan gebruikelijk?
3. Plays less than usual?

4. Hij/zij doet andere dingen dan gebruikelijk?
4. He/she does other things than usual? [Not do the things s/he normally does?]

5. Gedraagt zich meer bezorgd dan gebruikelijk?
5. Behaves less quietly than usual? [Act more worried than usual?]

6. Gedraagt zich rustiger dan gebruikelijk?
6. Behaves more quietly than usual? [Act more quiet than usual?]

7. Heeft minder energie dan gebruikelijk?
7. Has less energy than usual?

8. Weigert te eten?
8. Refuses to eat?

9. Eet minder dan gebruikelijk?
9. Eats less than usual?

10. Houdt de pijnlijke plek van zijn/haar lichaam vast?
10. Holds the painful spot [sore part] of his/her body?

11. Probeert zich niet te stoten tegen het pijnlijke deel van zijn/haar lichaam?
11. Tries not to bump the painful [sore] part of his/her body?

12. Kreunt of kermt meer dan gebruikelijk?
12. Groans or moans more than usual?

13. Zijn/haar gezicht ziet er roder uit dan gebruikelijk?
13. His/her face looks redder [more flushed] than usual?

14. Wil dichter bij je zijn dan gewoonlijk?
14. Wants to be closer [close] to you more than usual?

15. Neemt medicijnen in wanneer hij/zij gewoonlijk weigert?
15. Takes medicine [medication] when s/he normally refuses?

Definitive consensus translation

1. Zeurt of klaagt meer dan gebruikelijk?
2. Huilt gemakkelijker dan gebruikelijk?
3. Speelt minder dan gebruikelijk?
4. Hij/zij doet de dingen niet die hij/zij normaal doet.
5. Gedraagt zich meer bezorgd dan gebruikelijk?
6. Gedraagt zich stiller dan gebruikelijk?
7. Heeft minder energie dan gebruikelijk?
8. Weigert te eten?
9. Eet minder dan gebruikelijk?
10. Houdt het pijnlijke deel van zijn/haar lichaam vast?
11. Probeert zich niet te stoten tegen het pijnlijke deel van zijn/haar lichaam?
12. Kreunt of kermt meer dan gebruikelijk?
13. Zijn/haar gezicht ziet er roder uit dan gebruikelijk?
14. Wilt dichter bij je zijn dan gewoonlijk?
15. Neemt medicijnen in op momenten wanneer hij/zij dit normaal weigert?

Attachment 3 - Questionnaire (socio-demographic data and previous admissions and surgery of the child)

Geslacht	Jongen	Meisje
Gewicht		
Lengte		
Geboortedatum		
Aantal broers en/of zussen	Broers	Zussen
Nationaliteit kind		
Moedertaal kind		
Ontwikkelingsachterstand	Ja	Neen
Aandoeningen/gekende medische problemen		
Voorgaande ingrepen en hospitalisaties		
Wie zal het kind begeleiden in de operatiezaal bij de inductie?	Moeder Andere?	Vader
Is het de eerste keer dat uw kind onder narcose gaat?	Ja	Neen
Is de persoon die het kind zal begeleiden in de operatiezaal vroeger al eens aanwezig geweest bij de inductie van dit kind of van een broer of een zus?	Ja	Neen

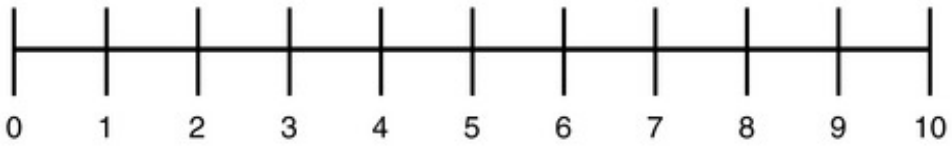
Gegevens ouders

MAMA		**PAPA**	
Leeftijd		Leeftijd	
Nationaliteit		Nationaliteit	
Religie		Religie	
Hoe lang bent u naar school geweest? O Minder dan 10 jaar? O Handel/Leercontract O Tussen 10 en 11 jaar O Hogeschool O 12 jaar O Universitair		Hoe lang bent u naar school geweest? O Minder dan 10 jaar? O Handel/Leercontract O Tussen 10 en 11 jaar O Hogeschool O 12 jaar O Universitair	
Hebt u momenteel een betaalde job? Ja Neen		Hebt u momenteel een betaalde job? Ja Neen	
Huidige job?		Huidige job?	
Uren/week?		Uren/week?	

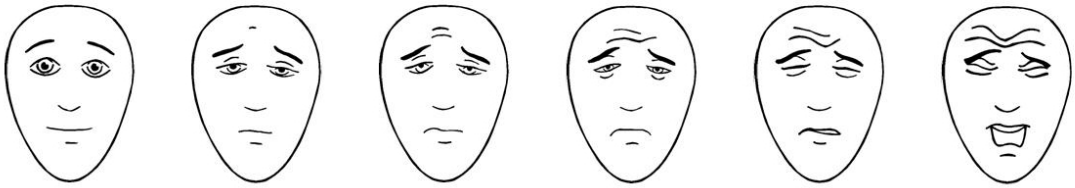
Gegevens gezin - Burgerlijke staat ouders?

O Gehuwd	O Uit elkaar	O Alleenstaand
O Samenwonend	O Nooit gehuwd/samenwonend	O Weduwe/Weduwenaar
O Gescheiden		

Attachment 4 - Numerical Rating Scale – pain (NRS-11)



Attachment 5 - The Faces Pain Scale-Revised (FPS-R)



Pijnschaal gezichtjes – herzien (FPS-R)

Zeg in de volgende instructies 'zeer' of 'pijn', naargelang wat het beste past bij een bepaald kind.

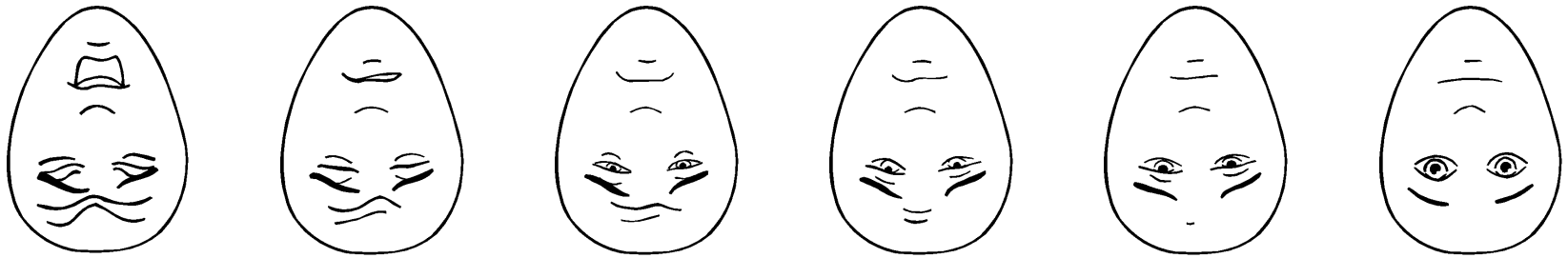
"Deze gezichtjes tonen hoeveel pijn het kindje heeft. Dit kindje *[wijs naar het uiterst linkse gezichtje]* **heeft geen pijn [zeer]. De gezichtjes laten altijd maar meer pijn zien** *[wijs naar elk gezichtje van links naar rechts]* **tot dit gezichtje** *[wijs naar het uiterst rechtse gezichtje]***, dit kindje heeft heel veel pijn [zeer]. Wijs het gezichtje aan dat zegt hoeveel pijn je** [nu] **hebt.**"

*Geef het gekozen gezichtje een score van **0**, **2**, **4**, **6**, **8** of **10** en tel daarbij van links naar rechts, dus '0' = 'geen pijn' en '10' = 'heel veel pijn'. Gebruik geen woorden als 'blij' en 'verdrietig'. Deze schaal is bedoeld om te meten hoe kinderen zich vanbinnen voelen, niet hoe hun gezicht eruitziet.*

Bronnen. Hicks CL, von Baeyer CL, Spafford P, van Korlaar I, Goodenough B. The Faces Pain Scale – Revised: Toward a common metric in pediatric pain measurement. Pain 2001;93:173-183. Bieri D, Reeve R, Champion GD, Addicoat L, Ziegler J. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: Development, initial validation and preliminary investigation for ratio scale properties. Pain 1990;41:139-150.

(vouwen langs de stippellijn)

10 **8** **6** **4** **2** **0**



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