Research proposal

Parental misconceptions about pain medication, parental pain medication adherence and their child's pain at home after daycare surgery

A prospective observational cohort study

Misvattingen van ouders i.v.m. pijnmedicatie voor hun kind, therapietrouw en pijn van hun kind thuis na dagchirurgie

Een prospectieve observationele cohort studie.

Short title: Parental misconceptions about pain medication and their child's pain at home

Acronym-ID: MAQADHpred-stud version1

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Abbreviations

APAIS: Amsterdam Preoperative Anxiety and Information Scale

BMI: Body Mass Index

HBS : Health Beliefs Scale

NRS-P: Visual Analogue Scale – Pain

NRS-P-expected: Visual Analogue Scale expected Pain

SES: Socio-economic Status

ISRCTN: International Standard Registered Clinical/social sTudy Number

PCS-P trait: Parental Pain Catastrophizing Scale - Trait

PCS-P State: Parental Pain Catastrophizing Scale - State

NRS-sympathy:

ASA: American Society of Anesthesiologists

NSAID: Non-Steroidal Anti-Inflammatory Drugs

MAC: Minimum Alveolar Concentration

MAQ: Medication Attitude Questionnaire

ECG: Electrocardiogram

PACU: Post Anesthesia Care Unit

PRN: *Pro Re Nata* (“when needed”)

ICF: Informed Consent Form

GDPR: General Data Protection Regulation

1. Summary

Introduction & rationale

It has been observed that up to 80% of children undergoing day care surgery suffer a lot of pain at home . This might be the result of poor pain management but nevertheless the issue is a complex given with specific child, organizational system, medication and parental factors which should be taken into account. Parental related psychological determinants are considered to be very important.

Design

A prospective analytic observational cohort study up to three days postoperatively.

Setting

ZiekenhuisNetwerkAntwerpen (ZNA) Middelheim, Lindendreef 1, 2020 Antwerpen Belgium and ZNA Jan Palfijn, Lange Bremstraat 70, 2170 Merksem Belgium.

Aims of the study

1. Firstly, this study aims to assess parental misconceptions about the child's pain medication;
2. Secondly, to investigate possible associations between these misconceptions about pain medication and parental gender, education level, cultural / religious aspects, health beliefs mindset, level of expected pain, type of surgery, parental state anxiety / distress, need for information, parental sympathizing and pain catastrophizing thoughts (state / trait);
3. Thirdly, this study assesses: a) the level of postoperative pain and pain medication adherence at home in children aged 3 months - 15 years during the first three days after daycare surgery; b) to investigate possible associations between postoperative pain / pain medication adherence on the one hand and on the existing parental misconceptions, gender, education level, cultural / religious aspects, health beliefs mindset, level of expected pain, type of surgery, state anxiety / distress, need for information, sympathizing and pain catastrophizing thoughts (state / trait).

Inclusion criteria

1. Two hundred eighty-five parents who accompany their child aged between 3 months and 15 years old for a surgical intervention under anesthesia in day care;
2. The children undergo different kinds of surgery (general, orthopedic, urologic, maxillofacial and ear nose throat surgery);
3. Children with American Society of Anesthesiologists physical status (ASA I-II);
4. Parents with a good understanding of Dutch language;
5. Written informed consent.

Exclusion criteria

1. Parents of a child with a known mental / cognitive retardation;
2. Parents of children with an American Society Anesthesiologists ASA *physical status* > II;
3. When the parent no longer wishes to participate;
4. When a life-threatening situation occurs during the procedure (f.i. asystole);
5. When re-intervention is required as a result from f.i. a subsequent bleeding after a tonsillectomy;
6. When the child has to be admitted because of constant nausea / vomiting.

Primary endpoints

1. Medication Attitude Questionnaire (MAQ) – parental misconceptions about their child's pain medication;
2. Pain at home as assessed by the parents using: a) Parents' Postoperative Pain Measure (PPPM) and b) a Numerical Rating scale – Pain (NRS-P), both scales twice a day during the three consecutive postoperative days;
3. Parental adherence to pain management of their child at home.

Secondary endpoints

1. Amsterdam Preoperative Anxiety and Information Scale (APAIS)
2. Numerical Rating Scale (NRS-distress and NRS-sympathy)
3. Expected Numerical Rating Scale postoperative pain (NRS-P-expected)
4. Parental Health Beliefs scale (HBS)
5. Trait Pain Catastrophizing Scale for parents – Trait (PCS-P-Trait)
6. State Pain Catastrophizing Scale for parents – State (PCS-P-State)

2. Introduction & rationale

Nowadays a lot of pediatric surgery under anesthesia is often performed on a day-case basis which offers to both the child and parents many advantages such as less disruption of family life and more cost-effective economic reasons[1].

This being the case however, it has been observed that postoperatively children still suffer a lot of pain at home after day-case surgery in up to 80%[2-6] and also show problematic behavior changes at home[7-9] up to 93%[3].

As far as the child's postoperative pain is concerned, specific child, organizational system, medication and parental factors should be taken into account[10]. Among specific child factors one can distinguish: 1. high levels of preoperative anxiety[7,11]; 2. the child's postoperative pain anxiety[12]; 3. refusal to take medication[13]; 4. child pain catastrophizing[14-16]. Poor communication between health care professionals and insufficient provided information[8] can be categorized as hospital related organizational system factors[2]. Moreover insufficient or inadequate medication type and prescription might also contribute to higher levels of children's postoperative pain at home[10]. Finally parents become very important partners in postoperative care at home after surgery especially related to pain assessment and management[2,5,8].

This study is especially interested in the complex given of pain in children related to parental factors. Indeed parents were surprised or did not expect that their child could have a high level of persistent postoperative pain[8]. There seems to be a discrepancy between high postoperative pain ratings at home and the low dosing of analgesics provided by parents: both may point towards parents having no difficulty in recognizing and assessing their child's pain[4-6,8].

Several predictors can be distinguished that influence children's postoperative pain and parental pain management of their child[2]. Parents tend to undertreat their child's postoperative pain and the reasons why remain unclear and seem very complicated. Among described predictors are withheld: 1. parental personality[17]; 2. parental state / trait anxiety[3]; 3. their level of education[3]; 4. cultural / religious reasons[18,19]; 5. parental misconceptions about pain medication[17,18,20]. In this regard, Rony *et al.*[21] showed that parents do not adhere to the prescribed pain management[5,6] and that misconceptions about pain medication[20] might play an important role: a) 52% of parents believe that analgesics are addictive; b) 73% have concerns about side effects; c) 37% even believe that analgesics work better when children receive them less often. Zisk *et al.*[17] found that parental misconceptions about pain medication were associated with both parental and child personality characteristics. Parents who scored higher on conscientiousness and with more impulsive children were more likely to understand that analgesics were appropriate for their child. Also less educated parents

tended to avoid pain medication in their child[17]. To obtain this essential information is necessary to be able to identify more vulnerable parents in order to target parental preoperative preparation.

Furthermore in the context of parental pain management, parental pain catastrophizing which can be described as a tendency to exaggerate pain experiences is a strong predictor in pain related outcomes[22,23]. Parental catastrophizing explains parental behavioural tendencies in response to the child's pain[24,25]. Both child and parent state catastrophizing are associated with the child pain intensity, child state anxiety and parental distress[16]. High parental catastrophizing thoughts are related with prioritizing pain[26] and might have an influence on pain medication adherence.

Parental estimations of the child's pain has an important impact on pediatric pain management decisions[27]. Parental feelings of sympathy for the child and personal distress might be important when facing the child in pain. For this reason in this study we further want to investigate the differential influences of sympathy versus personal distress on pain estimation. Still it has been found that parental distress is related to the pain estimation of the child but feelings of sympathy were not associated with pain estimation[28].

Also the psychological mindset in which parents view a particular characteristic as fixed or changeable can have a profound influence on our reactions and perceptions in a variety of settings[29]. The original idea has been outlined by Dweck *et al.*[30] in a broad area of academic, professional and interpersonal settings. Interesting is the fact that this mindset could be altered and consequently improve both academic and interpersonal outcomes[30,31]. Furthermore health beliefs mindset appears to have an influence on the perception and reporting of postoperative pain[32]. A changeable (or growth) mindset could lower postoperative pain and is associated with more information seeking which can lead to less misconception about pain medication. Recent findings supported that parental mindset affects the assessment and management of their child[33] and the found growth mindset were seeking out more medical information and reported less misconception about pain medication. Furthermore in the assessing outcomes parents with a fixed mindset reported higher postoperative pain intensity scores in their children[33] and further supported the importance of a health beliefs mindset. Mindsets could be improved and so targeted interventions might be beneficial to attain a better pain management in children in the future.

3. Aims of the study

1. In the first part of this study we aim to assess parental misconceptions about their child's pain medication and to investigate possible associations between these misconceptions and parental gender, education level, cultural / religious aspects, health beliefs mindset, level of expected pain, type of surgery state anxiety / distress, need for information, sympathizing and pain catastrophizing thoughts (state / trait).
2. The second part of this study assesses: a) the level of postoperative pain in hospital, pain and pain medication adherence at home in children aged 3 months - 15 years during the first five days after day care surgery, and investigates b) possible associations between postoperative pain / pain medication adherence on the one hand and on the other parental misconceptions, gender, education level, cultural / religious aspects, health beliefs mindset, level of expected pain, type of surgery, state anxiety / distress, need for information, sympathizing and pain catastrophizing thoughts (state / trait).

4. 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 International Standard Registered Clinical/soCial sTudy Number (ISRCTN) www.isrctn.com .

This study will be reported following STROBE statement of observational studies and according to the TIDieR checklist at http://www.equator-network.org/wp-content/uploads/2014/03/TIDieR-Checklist-PDF.pdf

Approval to translate the Medication Attitude Questionnaire (MAQ) was obtained from Prof. Dr. P.J. McGrath (Dalhousie University, Halifax-Nova Scotia) who developed the MAQ. Approval to translate the Health Beliefs Scale (HBS) was obtained from Prof. Dr. C. Dweck (Stanford University) who developed the HBS.

The original version of both scales has been translated using standard forward-back-forward translation technique[34,35] by two independent professional translators from Vadelingua VOF (Luikersteenweg 9, 3700 Tongeren, tel.: +32-12-210355). This was followed by an evaluation of this translation by an expert panel of one psychologist and one anesthesiologist.

Design and settings

This study is an analytic observational cohort study up to three days postoperatively which aims to include two hundred eighty-five parents whose children, aged between 3 months and 16 years old, will undergo different kinds of surgery (description see below) in daycare at the ZNA Queen Paola Children's Hospital and the ZNA Jan Palfijn Hospital in Antwerp, Belgium.

Inclusion criteria

1. Parents who company their child aged between 3 months and 15 years old for a surgical intervention under anesthesia in day care;
2. The children undergo different kinds of surgery (general, orthopedic, urologic, maxillofacial and ear nose throat surgery);
3. Children with American Society of Anesthesiologists physical status (ASA I-II);
4. Parents with a good understanding of Dutch language;
5. Written informed consent.

Exclusion criteria

1. Parents of a child with a known mental/cognitive retardation;
2. Parents of children with an American Society Anesthesiologists ASA *physical status* >II;
3. When the parent no longer wishes to participate;
4. When a life-threatening situation occurs during the procedure (f.i. asystole);

5. When re-intervention (or a complication occurs) is required as a result from f.i. a subsequent bleeding after a tonsillectomy;
6. 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 consulting hours and surgery is always longer than two days), 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 will not be adapted for this research. On the day of surgery prior to going to the operating theatre each child and parent watch a preoperative preparatory film showing – among other things - information about inhalation induction.

On the day of intervention the information and consent forms are signed by the parents. Parents who do not wish to participate are asked to give reasons for their refusal by answering specific questions about anxiety and socioeconomic status (SES) (to inquire about selection bias).

After inclusion the socio-demographic data are collected such as the age / gender of the accompanying parent, marital status, level of education of the parents as an indicator of SES – classified into three categories: I. no education, elementary school; II. secondary school; III. higher education or university[36], religion (Catholic, Islamic, atheist, other). Furthermore also data about age / gender of the child, type of surgery, previous admissions of the child to hospital and experience of the parents of previous admissions and surgery of their children are collected.

The accompanying parent also fills in the following preoperative questionnaires (for further information see below): 1. Medication Attitude Questionnaire (MAC); 2. Amsterdam Preoperative Anxiety and Information Scale (APAIS); 3. Parental personal distress and sympathy towards the child by an 11-point rating Numerical Rating Scale (NRS-distress and NRS-sympathy); 4. Expected postoperative pain – Numerical rating Scale expected pain (NRS-exp-Pain); 5. Health Beliefs Scale (HBS); 6. Trait / State Parental Pain Catastrophizing Scales (PCS-P-Trait, PCS-P-State); 7. Two additional questions.

After filling in the preoperative questionnaires the child will be brought to the surgical theatre accompanied with the parent.

For final analysis we distinguish three groups of surgery[37,38] and their 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. No specific stratification will be used.

Anesthesia procedure will be left to the discretion of the attending pediatric anesthesiologist but all inductions will be performed with: 1. sevoflurane 8 vol.% in a fresh gas flow of 6/8 liters/minute with a fractional inspired oxygen concentration (FiO_2) of 50% in air; 2. anesthesia maintenance with sevoflurane and a steady-state concentration of 2.5-3 vol.% in FiO_2 of 50%. If appropriate a laryngeal mask airway (LMA) or endotracheal tube (ETT) will be inserted and if necessary, children will receive regional anesthesia.

For intraoperative pain management opioids (fentanyl and / or pethidine) will be administered as required. When α_2 - adrenergic agonist clonidine, dexamethasone, ondansetron are used they will be noted. If appropriate locoregional anesthesia like a penile block, a caudal block or a nervus inguinal block might be performed and is noted.

For fluid administration of Ringer-lactate-solution (10 ml/kg/h, during surgery) will be used. If necessary a muscle relaxant can be administered.

During anesthesia the standard vital parameters are monitored: ECG, O_2-saturation, *end-tidal* CO2, inhalation gas concentration, non-invasive blood pressure measurement (5 min. interval).

Basis intra-hospital postoperative pain management consists of paracetamol and ketorolac. Intra-hospital postoperative rescue pain management consists of tramadol hydrochloride.

All children will be extubated while being awake, transferred to the Post Anesthesia Care Unit and thereafter to the ward before discharge home. The modified Aldrete scores above 8 are used to dismiss the children from the PACU[39].

Pain management at home

The parents will receive standardized pain management instructions in relation to the different types of surgery and with the recommendation to strictly adhere to prescribed regimen (at least for three days). The regimen consists of oral paracetamol and oral Ibuprofen ‘by the clock’. Parents are asked to register medication adherence in a diary during three days. Pain medication adherence will be based on what is prescribed per individual case (f.i. only paracetamol for inguinal repair or both paracetamol and ibuprofen for an adenotonsillectomy). A good adherence is defined by 70% of prescribed pain medication given during the first three postoperative days.

On day 1 and day 3 a research nurse will contact the parents by phone and the parents will be encouraged to ask questions to the research nurse whenever they feel the need.

The accompanying parents will receive diaries to take home and complete the PPPM-D and NRS-Pain at two times each day (after breakfast and in the evening after dinner) during three consecutive days.

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

The estimated total inclusion period for 285 parents is estimated to be 10 months.

7. Research instruments

Predictor parameters

Medication Attitude Questionnaire (MAQ)[17,40,41]

The MAQ questionnaire has been developed to assess attitudes about using pain medication for treating children's pain. This instrument consists of 16 items each rated on a 7-point Likert scale ranging from 'strongly disagree' [1] to 'strongly agree' [7].
Parents will be instructed to consider their attitude regarding their child's pain management. Internal consistency (Cronbach's α) for the overall scale is reported between 0.68 and 0.73. For the four subscales the internal consistency coefficients are reported between 0.63 and 0.75. Factor analyses (Varimax rotation) revealed a three factor solution regarding parental pain medication perceptions[17] explaining 52% of MAQ variance. Conceptually, these factors represented: 1. appropriate use attitude of analgesics (items 8,12,13,16); 2. concerns about side effects (items 3,5,7,9,14); 3. avoidance of analgesia (items 1,2,4,6,10,11,15).
The original version has been translated using standard forward-back-forward translation technique[34,35] by two independent professional translators from Vadelingua VOF (Luikersteenweg 9, 3700 Tongeren, tel.: +32-12-210355). (Permission for translation has been obtained from PJ. McGrath). This was followed by an evaluation of this translation by an expert panel of one psychologist and one anesthesiologist.
(attachment 7.1 p.)

Amsterdam Preoperative Anxiety and Information Scale (APAIS)[42]

The APAIS is a reliable and validated Dutch self-report questionnaire comprising six questions that have been specifically developed to evaluate preoperative state anxiety and need for information requirement in patients undergoing surgery and anesthesia. Furthermore the APAIS has been validated for assessment of preoperative anxiety and need for information in parents[43].

The patients state anxiety (APAIS-state) is assessed by 4 questions: *1. I am worried about the anesthetic; 2. the anesthetic is on my mind continually; 3. I am worried about the procedure; 4. the procedure is on my mind continually.* The patients need for information (APAIS-information) is assessed by 2 questions: 1*. I would like to know as much as possible about the anesthetic; 2. I would like to know as much as possible about the procedure.* The anxiety part correlates strongly (r = 0.74) with the state part Spielberger State-Trait Anxiety

Inventory (STAI)[44] and the correlation with the information items and the State-STAIC was low (r = 0.16). The APAIS will be filled in only once preoperatively on the day of surgery.

Assessment of both parental personal distress and sympathy towards the child by an 11-point rating Numerical Rating Scale NRS-distress and NRS-sympathy[27]

Parents rate their personal distress (defined as what parents experience as emotions / anxiety when their child undergoes a painful task) on an 11-point rating: *Specify how anxious you are at this moment*.

Parents rate their personal sympathy toward their child on an 11-point rating: *Specify to what extent you can sympathize with the feelings of the/your child at this moment*.

The 11-point rating scale ranges from 0 (not at all) to 10 (a lot).

Operationalization of sympathy and distress has been used in previous studies and in the context of pain and social psychology[27,45,46].

Both parental distress and sympathy will be rated preoperatively on the day of surgery.

Expected postoperative pain – Numerical rating Scale expected pain (NRS-exp-Pain)

During the preoperative period parents are asked to quantify the pain intensity they expect their child to suffer. In one study only 44% of parents declared that their child's recovery and pain met their expectations[8].

The 11-point rating scale with verbal descriptor anchors ranges from: 'the child will experience no pain (score 0) and ' the child will experience pain as bad as it could be' [or 'worst imaginable pain'].

The NRS-exp-Pain will be filled in only once preoperatively on the day of surgery.

Health Beliefs Scale (HBS)

The Health Beliefs Scale (HBS)[30,33] includes three items and uses a Likert-type scale ranging from 1 (strongly agree) to 6 (strongly disagree). Parents will be classified as having a fixed or growth mindset based on the following statements: *Your body has a certain amount of health, and you really can't do much to change it, Your health is something about you that you can't change very much, and You can try to make yourself feel better, but you can't really change your basic health*. A fixed mindset is defined when the average is below four, whereas scores of four and above represent a growth mindset.

The original version of the HBS has been translated using standard forward-back-forward translation technique[34,35] by two independent professional translators from Vadelingua VOF (Luikersteenweg 9, 3700 Tongeren, tel.: +32-12-210355). (Permission for translation has been obtained from Prof. Dr. C. Dweck). This was followed by an evaluation of this translation by an expert panel of one psychologist and one anesthesiologist.
Recent findings support the criterion validity[33].
The HBS will be filled in only once preoperatively on the day of surgery.

Pain Catastrophizing Scale for parents - Trait (PCS-P-Trait)[23]

Parental pain catastrophizing describes different thoughts / feelings that parents experience when their child is in pain. The PCS-P is a 13-item scale to assess parental catastrophic thinking about their child's pain. The PCP-P is an adaptation of the Adult Pain Catastrophizing Scale (PCS)[47] and the Pain Catastrophizing Scale for Children (PCS-C)[48]. Parents rate 13-items using a 5-point scale from 0 (not at all) to 4 (extremely). The PCS-P consists of three subscales: magnification, rumination and helplessness. All items are summed for a total score ranging from 0 to 52 with higher scores indicating higher levels of parent pain catastrophizing. Internal consistency for both the total PCS-P and the three subscales was good with Cronbach's α varying from a = .81 to a = .93.[23] The PCS-P has a good reliability and validity with parents of generally healthy children and children with chronic pain.

Parents will complete PCS-P at baseline preoperatively on the day of surgery.

Parental Catastrophizing scale – State (PCS-P-State)[16]

Durand *et al*.[16] offered preliminary support for the validity and reliability of a concise 3-item measure of state pain catastrophizing that can used in clinical and research settings. The underlying factor structure of the state versions of the PCS-P-State for parents was examined by exploratory factor analysis revealing a single factor solution that explained 49.72% of the variance for parents.
Parental state catastrophizing was significantly associated with child pain intensity, child state anxiety and parental distress and state catastrophizing scores were more strongly associated than trait catastrophizing scores.

Additional questions

Two additional questions to ask parental perceptions of the consequences of untreated pain in their child (cf. Zisk et al[17]):

1. Do you think that untreated pain can cause physical damage?
2. Do you think that untreated pain can cause psychological damage?

Outcome parameters

Pain at home

1. Parents' Postoperative Pain Measure (PPPM)[49]

The PPPM[19,49] is a 15-item questionnaire which assesses behavior changes and verbal pain behavior at home after surgery. Parents 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.

The PPPM was developed and preliminary validated for children aged 7-12 years by Christine Chambers *et al.* [49]. 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)[50] 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[19] 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[38].

Furthermore the PPPM is a proposed tool by PedIMMPACT recommendations [51] and has been used in several studies [4,37,52].

Parents will follow precise instructions to fill in the PPPM accordingly as suggested by Chambers *et al* [19]. 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.'

A validation study of the PPPM to support the validity and reliability of the Dutch version of the PPPM-D. ISCRTN number Results should be available soon https://www.isrctn.com/ISRCTN12813822 (March 2023).

2. **A Numerical Rating Scale – Pain (NRS-P)**[53]

Parents are 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[5,54] and gives a global impression of the child's pain[53,55]. Parents will be asked to use the scale twice a day at the same time as they fill in the PPPM-D.

Pain medication adherence at home

Pain medication adherence will be based on what is prescribed per individual case (f.i. only paracetamol for inguinal repair or both paracetamol and ibuprofen for an adenotonsillectomy). The attending anesthesiologists will note the prescribed pain management per case in order to be able to analyse parental adherence to the prescribed analgesics.

A good adherence could be defined by 70% of prescribed pain medication given during the first five postoperative days.

Parents are asked to register medication adherence in their diary.

8. Statistical analysis

Power analysis

An a priori sample size calculation for multiple regression by G*Power 3.9.1.7 based on a fixed model (model parameters are fixed or non-random quantities) is performed[56]. Based on effect size obtained from literature[20] (F (*P*) = 18.27 (.001); adjusted R^2 0.38.), we assume that the final model will explain 30% of variability.

This analysis revealed that 171 patients are needed to detect a medium effect size (Cohen's $f^2 = 0,15$) with a probability of 0,05 and a power of 0,90 and using 15 predictors.

Allowing for a 35% loss to follow up, a sample size of 285 is considered large enough.

Statistics

Baseline / summary demographic and psychological data of the patients will be presented: 1. for continuous data as means ± standard deviation or as median with interquartile range; 2. for categorical items as frequencies and proportions. Normal distribution will be indicated by characteristics (skewness and kurtosis) and will be further checked by Shapiro-Wilk and Kolmogorov-Smirnov tests as well as with Q-Q plots. Numerical variables may have high skewed and non-normal distribution (Gaussian Distribution) caused by outliers, highly exponential distributions, etc. These distributions can be converted to normal by data transformation e.g. the log transformation, the square root transformation, the Box-Cox transformation.

Further analyses:

A. Firstly, **Principal components analysis of the MAQ questionnaire**

   The large volume of data resulting from current analysis is highly complex and multidimensional. Simple non-parametric methods like principal component analysis (PCA) may be valuable to examine the internal structure of such complicated datasets and to explore the interrelations among variables. PCA is a technique used to emphasize variation and bring out strong patterns in a large dataset. It is an exploratory tool favored to reduce redundancy in multivariate data and, as in the current study, is also useful to reveal measurements that best reflect the dynamics of a particular phenomenon; in this case, which traits contribute most of the variation in the development and expression of pain perception.

B. Regression analysis

Univariate analysis allows us to explore the impact of one covariable on the independent variable while multivariate analysis allows us to understand the relationship between several covariables and their association with the independent variable.

first an univariate regression will be conducted to identify variables who are individually associated with **parental misconceptions about pain medication (MAQ)** and some relevant predictors will be considered: parental age, parental gender, SES, child age, child gender, parental religion, surgical group characteristics (three groups related to their expected related pain in children at home -mild, moderate, severe), APAIS, parental NRS-distress and NRS-sympathy, NRS-exp-Pain, HBS, PCS-P-Trait, PCS-P-State. To avoid issues with multicollinearity, independent variables which correlate highly with other independent variables will be excluded for further analyses.

Secondly an univariate regression will be conducted to identify variables who are individually associated with **increased pain intensity scores (PPPM-D) at home** and pain medication adherence (% of a maximum prescribed pain medication – number during consecutive days) as outcome parameters. Relevant predictors will be considered: parental age, parental gender, SES, child age, child gender, parental religion, surgical group characteristics (three groups related to their expected related pain in children at home -mild, moderate, severe), MAQ, APAIS, parental NRS-distress and NRS-sympathy, NRS-exp-Pain, HBS, PCS-P-Trait, PCS-P-State. To avoid issues with multicollinearity, independent variables which correlate highly with other independent variables will be excluded for further analyses.

Several grouping variables (levels) sorting data into categories or groups can be defined.

Grouping variables can be: gender (i.e. male/female), level of education (grade I, grade II, grade III), surgical characteristics .

Principal Component Analysis (PCA)[57]

Furthermore we will use PCA to examine the internal structure of this complicated dataset and explore interrelations among variables.

Separate **multiple regression models (MLR)**[58] and a **Generalized Linear Mixed-Effects Model (GLMM)**[59] will be constructed to assess if, state anxiety / need for information, parental NRS-distress and NRS-sympathy, health beliefs, parental pain catastrophizing (trait and state) might explain PPPM-D scores at home and medication adherence after day care surgery in children.

'Longitudinal data have traditionally been analyzed using techniques like the paired t test or repeated measures analysis of variance (RM-ANOVA). In recent years, linear mixed-effects models—also referred to as multilevel models or hierarchical models—are becoming increasingly popular because they are much more flexible and overcome many of the limitations of more traditional methods.'[39,59,60]

Frequentist (traditional) analysis

The results will be reported as adjusted R^2 and standardized β.

All analyses will be performed with IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM. Corp.

Additional option: Bayesian approaches

Bayesian approaches to GLMM inference offer several advantages over frequentist (traditional) and information-theoretic Methods[61].

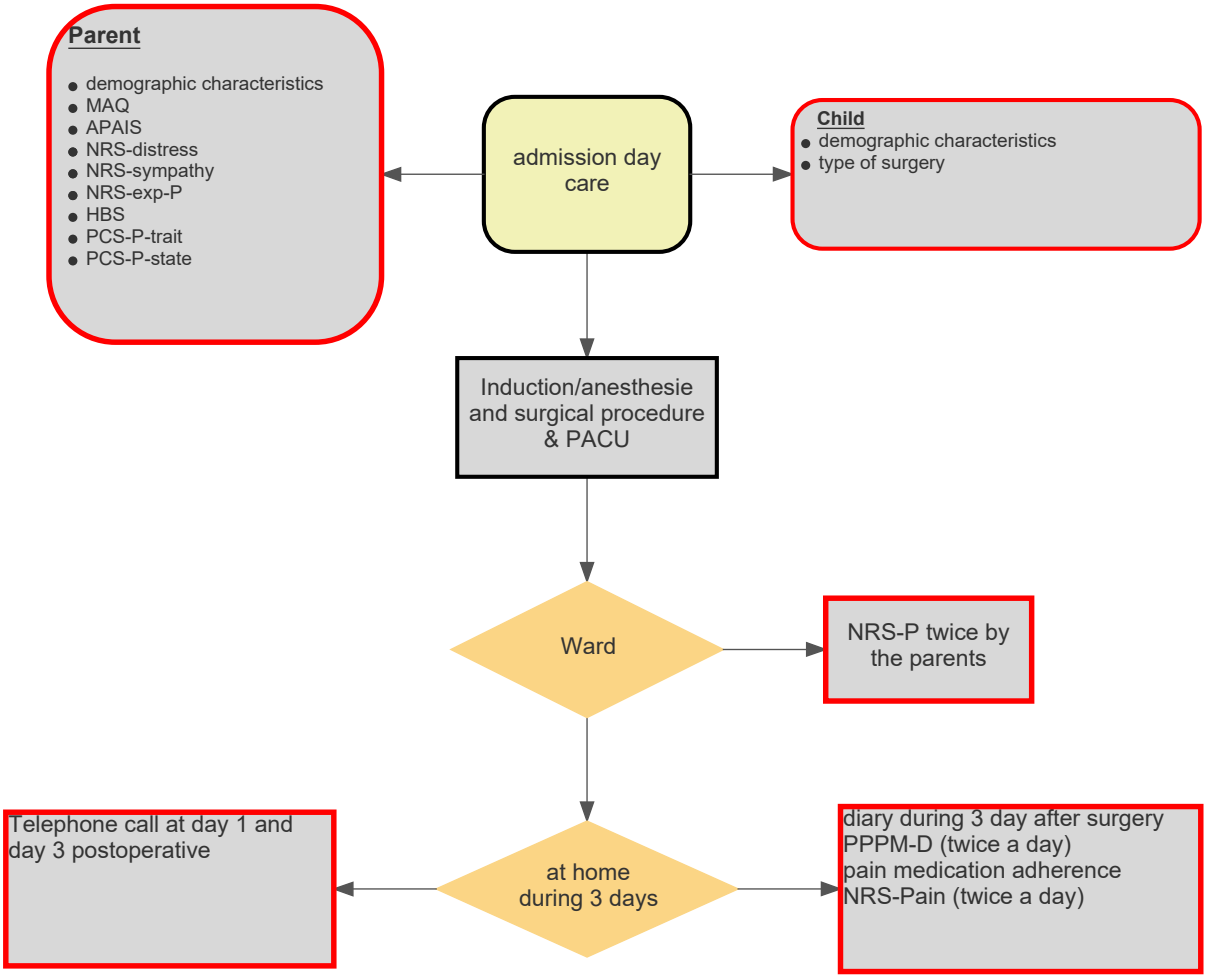
Bayesian modeling can be done in Winbugs[62].

Variables summary

1. parental age = years
2. parental gender = I or 0
3. SES classified into three categories: I. no education, elementary school; II. secondary school; III. higher education or university
4. child age = months
5. child gender = I or 0
6. parental religion: Catholic, Islamic, Atheist, other?
7. surgical group characteristics - three groups related to their expected related pain in children at home: mild, moderate, severe)
8. MAQ = % = numbers: A [strongly disagree - disagree - slightly disagree] B [uncertain] C [Strongly agree - agree - slightly agree][21]
9. APAIS – two subscale: state anxiety (score range 0 – 20) and need for information (score range 0 – 10)
10. parental NRS-distress – score range 0 - 10
11. parental NRS-sympathy – score range 0 - 10

12. NRS-exp-Pain – score range 0 - 10
13. HBS = dichotomy fixed vs growth mindset
14. PCS-P-Trait – score range 0 - 53
15. PCS-P-Stat - score range 0 - 30

9. Flowchart


Parent
demographic characteristics
MAQ
APAIS
NRS-distress
NRS-sympathy
NRS-exp-P
HBS
PCS-P-trait
PCS-P-state
admission day care
Child
demographic characteristics
type of surgery
Induction/anesthesie and surgical procedure & PACU
Ward
NRS-P twice by the parents
Telephone call at day 1 and day 3 postoperative
at home during 3 days
diary during 3 day after surgery
PPPM-D (twice a day)
pain medication adherence
NRS-Pain (twice a day)

10. Ethical considerations

This 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 ZiekenhuisNetwerkAntwerpen (ZNA) Institutional Review Board (IRB) (Chair: prof. Dr. P.P. De Deyn - ZNA Koningin Paola Kinderziekenhuis, P4, Route 34, Lindendreef 1, 2020 Antwerpen).

11. Administrative aspects, monitoring and publication

1. Handling and storage of data and documents

By answering the questions of the questionnaires, parents give consent to use these 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 according to the law: study data have to be stored for 20 years. Anonymous data will be analysed in SPSS and MedCalc.

2. Monitoring and Quality Assurance

Not applicable.

3. Amendments

All amendments will be notified to the accredited IRB which will give its opinion. When favourable, amendments can be made to the research.
All substantial amendments will be notified to the IRB and to the competent authority.
Non-substantial amendments will not be notified to the accredited IRB and the competent authority, but will be recorded and filed by the sponsor.

4. Temporary halt and (prematurely) end of study report

Not applicable.

5. Public disclosure and publication policy

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

6. Structured risk analysis

Not applicable.

7. Attachments

a. Medication Attitude Questionnaire (MAQ)

De volgende vragenlijst informeert specifiek uw kennis en houding ten aanzien van het geven van pijnmedicatie aan uw kind

1. Kinderen zouden zo weinig mogelijk pijnmedicatie moeten krijgen vanwege bijwerkingen.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

2. Kinderen die pijnstillers gebruiken tegen pijn zouden hierdoor leren drugs te gebruiken om andere problemen op te lossen.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

3. Pijnstillers werken altijd hetzelfde ongeacht hoe vaak ze gebruikt worden.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

4. Pijnstillers werken het best wanneer ze zo weinig mogelijk toegediend worden.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

5. Pijnstillers hebben vele bijwerkingen.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

6. Kinderen zullen verslaafd geraken aan pijnstillers als zij ze gebruiken tegen pijn.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

7. We moeten ons weinig zorgen maken over de bijwerkingen van pijnstillers

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

8. Het is onwaarschijnlijk dat een kind verslaafd zal geraken aan pijnstillers wanneer ze ingenomen worden tegen pijn.

□ Helemaal oneens	□ Oneens	□ Een beetje oneens	□ Onzeker	□ Een beetje eens	□ Eens	□ Helemaal eens

9. Pijnstillers werken/zijn verslavend.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

10. Pijnstillers werken het best als men ze houdt voor wanneer de pijn vrij erg is.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

11. Pijnstillers gebruiken voor pijn bij kinderen leidt later tot druggebruik.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

12. Er is weinig risico op verslaving wanneer pijnstillers worden gegeven tegen pijn.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

13. Kinderen leren hoe ze pijnstillers verantwoord moeten gebruiken wanneer ze tegen pijn worden gegeven.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

14. Bijwerkingen zijn iets waarover we ons zorgen moeten maken wanneer we kinderen pijnstillers geven.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

15. Hoe minder kinderen pijnstillers gebruiken tegen pijn, hoe beter het medicijn werkt.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

16. Pijnstillers geven aan kinderen leert hen op een geschikte manier met medicijnen om te gaan.

□	Helemaal oneens	□	Oneens	□	Een beetje oneens	□	Onzeker	□	Een beetje eens	□	Eens	□	Helemaal eens

b. Amsterdam Preoperative Anxiety and Information Scale (APAIS)

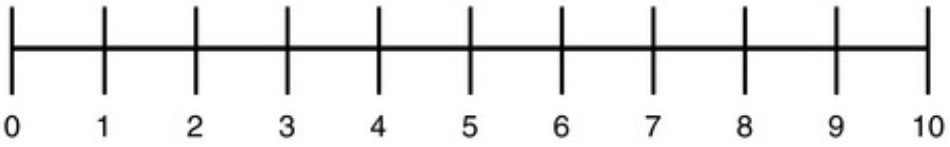
Kan u voor alle onderstaande uitspraken aangeven in hoeverre die op u van toepassing zijn. Kruis het juiste antwoord aan.

	Helemaal niet	Niet erg	Enigszins	Nogal	Zeer
Ik zie erg op tegen de anesthesie.	☐	☐	☐	☐	☐
Ik moet voortdurend denken aan de anesthesie.	☐	☐	☐	☐	☐
Ik zou zoveel mogelijk willen weten over de anesthesie.	☐	☐	☐	☐	☐
Ik zie erg op tegen de ingreep.	☐	☐	☐	☐	☐
Ik moet voortdurend denken aan de ingreep.	☐	☐	☐	☐	☐
Ik zou zoveel mogelijk willen weten over de ingreep.	☐	☐	☐	☐	☐

c. Assessment of both parental personal distress and sympathy towards the child by an 11-point rating Numerical Rating Scale NRS-distress and NRS-sympathy

Angst ouder voor de ingreep (NRS-11)

Omcirkel het cijfer dat weergeeft hoeveel angst u heeft:



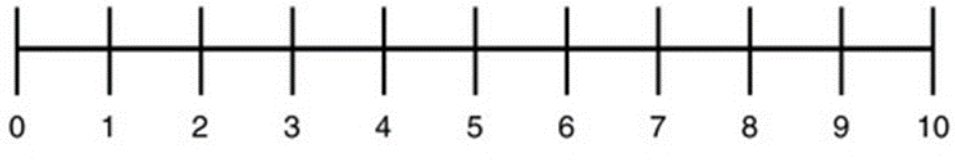
Schaal i.v.m. het meevoelen van de ouder (NRS-11)

Omcirkel het cijfer dat weergeeft hoeveel u meevoelt met uw kind op dit moment:

d. Expected postoperative pain – Numerical rating Scale expected pain (NRS-exp-Pain)

Verwachtte pijn (NRS 11)

Omcirkel het cijfer dat uw voorspelling weergeeft van de verwachtte pijn van uw kind na de ingreep:



Geen pijn ergste pijn

e. Health Beliefs Scale (HBS)

Gezondheidsschaal

Duid aan in welke mate u akkoord bent met de volgende stellingen:

1. Je lichaam heeft een welbepaalde mate aan gezondheid en je kan er echt niet veel aan doen om het te veranderen.

Helemaal eens	Eens	Een beetje eens	Een beetje oneens	Oneens	Helemaal oneens

2. Je gezondheid is iets in jezelf waaraan je niet veel kan veranderen.

Helemaal eens	Eens	Een beetje eens	Een beetje oneens	Oneens	Helemaal oneens

3. Je kan proberen om jezelf beter te laten voelen, maar je kan je basisgezondheid niet echt veranderen.

Helemaal eens	Eens	Een beetje eens	Een beetje oneens	Oneens	Helemaal oneens

f. Trait Pain Catastrophizing Scale for parents (PCS-P)

Vragenlijst Gedachten en Gevoelens wanneer je Kind Pijn heeft

Elk kind ervaart wel eens pijn, zoals hoofdpijn, tandpijn, gewrichts- of spierpijn. Kinderen kunnen ook in situaties terechtkomen die pijn veroorzaken zoals een behandeling bij de tandarts of een chirurgische ingreep.

Wij zijn geïnteresseerd in de soort gedachten en gevoelens die u ervaart als uw kind pijn heeft. In de onderstaande lijst staan dertien beweringen die verschillende gedachten en gevoelens beschrijven. Probeer aan te geven in welke mate deze gedachten en gevoelens weergeven wat u denkt en voelt als uw kind pijn heeft door onder elke zin het best passende te omcirkelen.

1. Als mijn kind pijn heeft, vraag ik mij voortdurend af of de pijn wel zal ophouden.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

2. Als mijn kind pijn heeft, voel ik dat het zo niet verder kan.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

3. Als mijn kind pijn heeft, is dat verschrikkelijk en denk ik dat het nooit beter zal worden.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

4. Als mijn kind pijn heeft, is dat afschuwelijk en voel ik dat het me overweldigt.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

5. Als mijn kind pijn heeft, voel ik dat ik het niet meer uithoud.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

6. Als mijn kind pijn heeft, word ik bang dat de pijn erger zal worden.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

7. Als mijn kind pijn heeft, blijf ik denken aan andere pijnlijke gebeurtenissen.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

8. Als mijn kind pijn heeft, verlang ik hevig dat de pijn weggaat.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

9. Als mijn kind pijn heeft, kan ik het niet uit mijn gedachten zetten.
   HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

10. Als mijn kind pijn heeft, blijf ik denken hoeveel mijn kind eronder lijdt.
    HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

11. Als mijn kind pijn heeft, blijf ik denken hoe graag ik zou willen dat de pijn ophoudt.
    HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

12. Als mijn kind pijn heeft, is er niets dat ik kan doen om de pijn te stoppen.
    HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

13. Als mijn kind pijn heeft, vraag ik mij af of er iets ernstigs kan gebeuren.
    HELEMAAL NIET EEN BEETJE NOGAL ERG HEEL ERG

g. State Pain Catastrophizing Scale for parents (PCS-P-state)

In welke mate blijft u nu denken aan hoeveel pijn uw kind zal hebben tijdens en na de operatieve ingreep?

0 1 2 3 4 5 6 7 8 9 10

Helemaal niet Heel veel

In welke mate denkt u nu dat er, omwille van de pijn, iets ernstigs zou kunnen gebeuren met uw kind?

0 1 2 3 4 5 6 7 8 9 10

Helemaal niet Heel veel

In welke mate denkt u dat u, omwille van de pijn bij uw kind, het niet zal kunnen uithouden tijdens en na de operatieve ingreep?

0 1 2 3 4 5 6 7 8 9 10

Helemaal niet Heel veel

Bijkomende vragen

h. Duid aan of u al dan niet akkoord bent met de volgende stellingen

1. Denkt u dat onbehandelde pijn fysieke/lichamelijke schade kan veroorzaken? Ja/neen
2. Denkt u dat onbehandelde pijn psychologische schade kan veroorzaken? Ja/neen

i. Parent's Postoperative Pain Measure (PPPM)

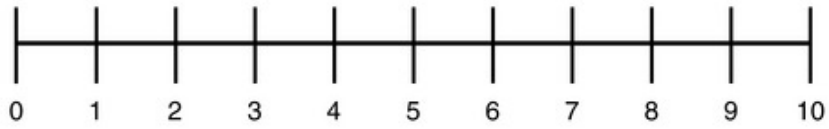
Soms zien we gedragsveranderingen bij kinderen die herstellen van een operatieve ingreep.
De onderstaande lijst is een lijst van gedragingen die uw kind al dan niet heeft getoond tijdens het herstel van de operatie. Omcirkel voor iedere gedraging hieronder het juiste antwoord, ja of nee.

Hoe reageert je kind vandaag?

17. Zeurt of klaagt meer dan gebruikelijk?	Ja	Nee
18. Huilt gemakkelijker dan gebruikelijk?	Ja	Nee
19. Speelt minder dan gebruikelijk?	Ja	Nee
20. Hij/zij doet de dingen niet die hij/zij normaal doet?	Ja	Nee
21. Gedraagt zich meer bezorgd dan gebruikelijk?	Ja	Nee
22. Gedraagt zich stiller dan gebruikelijk?	Ja	Nee
23. Heeft minder energie dan gebruikelijk?	Ja	Nee
24. Weigert te eten?	Ja	Nee
25. Eet minder dan gebruikelijk?	Ja	Nee
26. Houdt het pijnlijke deel van zijn/haar lichaam vast?	Ja	Nee
27. Probeert zich niet te stoten tegen het pijnlijke deel van zijn/haar lichaam?	Ja	Nee
28. Kreunt of kermt meer dan gebruikelijk?	Ja	Nee
29. Zijn/haar gezicht ziet er roder uit dan gebruikelijk?	Ja	Nee
30. Wil dichter bij je zijn dan gewoonlijk?	Ja	Nee
31. Neemt medicijnen in op momenten wanneer hij/zij dit normaal weigert?	Ja	Nee

j. Numerical Rating Scale (NRS-11)

Omcirkel het cijfer dat weergeeft hoeveel pijn uw kind op dit moment heeft.



k. Pijnmedicatie

Noteer hier alle pijnmedicatie die uw kind innam, alsook op welk tijdstip.

AARD PIJNSTILLER	TIJDSTIP INNAME	
Paracetamol, zoals bv. Dafalgan, Perdolan. Max. 4x/dag, om de 6 uur.		
Ibuprofen, zoals bv. Nurofen, Perdophen. Max 3x/dag, om de 8 uur.		

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