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Hearing the voices of children: self-reported information on children's experiences during research procedures: a study protocol

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ABSTRACT

Introduction: In paediatric research, there is a tension between what you can ask from a child and what is needed for the development of evidence-based treatments. To find an optimal balance in conducting clinical research and protecting the child, it is necessary to have empirical data on children's experiences. Until now, there are scarce empirical data on the experiences from the perspective of the child. In this manuscript, we describe the protocol of a two-phase study measuring children's self-reported experiences during research procedures.

Methods and analysis: In the first phase of our study, we aim to interview approximately 40 children (6–18 years) about their self-reported experiences during research procedures. In the second phase, we will develop a questionnaire to measure children's experiences during research procedures in a quantitative way. We will use the interview outcomes for the development of this questionnaire. Next, we will measure the experiences of children during seven research procedures with this questionnaire. A one-month follow-up is conducted to investigate the emotional impact of the research procedures on the children. Children will be recruited from different research studies in three academic children's hospitals in the Netherlands.

Ethics and dissemination: The ethics committee of the VU University medical center evaluated both studies and indicated that there was no risk/discomfort associated, stating that both phases are exempt from getting approval under the Dutch Law. Dissemination of results will occur by conference presentations and peer-reviewed publications. The findings of our project can help Institutional Review Boards and paediatric researchers when evaluating the discomforts of research procedures described in study protocols or when designing a study. Information on experiences of children involved in previous studies may also help children and parents in future research with their decision-making about participation in clinical research, or parts thereof.

Strengths and limitations of this study

- This study gives insight into children's experiences during research procedures, as seen from the perspective of children themselves.
- This study provides suggestions of children to reduce discomforts related to research procedures.
- This study provides an instrument to measure children's self-reported experiences during research procedures.
- This study explores whether certain children experience more discomfort during research based on age, health condition and anxiety-proneness.
- We study children's experiences during a limited number of research procedures as well as a limited number of medical conditions of the children. Future research is needed to study the experiences of other research procedures, and with children from all kinds of medical backgrounds.

INTRODUCTION

In paediatric research, there is a tension between what is needed for the development of evidence-based drugs and treatments for children and what is ethically acceptable concerning the involvement of children in research, given that they are (legally) unable to give informed consent. For instance, there are scarce data about the dosage and effect of medicines for children, which amount to 65% of all prescribed drugs. More paediatric research is therefore needed.[1] While children are rightly considered to be vulnerable and in need of protection against risky and burdensome research procedures, withholding children from participation in clinical research might be considered unethical as well; children deserve to get access to the benefits of clinical research.

Institutional Review Boards

The balance between the burdens and risks of clinical research and its benefits for the

child plays an important role in the decision-making of Institutional Review Boards (IRBs). Since little is known about children's self-reported experiences of discomfort in clinical research,[2] IRBs have limited empirical evidence to guide their decision-making, which is why they often rely on observations and assumptions of other persons (eg, paediatricians, paediatric nurses, ethicists). Literature shows, however, that paediatric nurses, paediatricians, psychologists and parents are likely to overestimate, for example,[3 4] or underestimate, for example,[4 5] children's discomfort in medical settings. It is therefore crucial to also take children's *own* perspectives into account when evaluating discomfort of research procedures. This argument is also reflected by an advisory council of the Dutch government, Committee Doek, that proposed that one of the conditions for clinical research in children is to define and permanently monitor children's discomforts during research procedures.[6]

The measurement of children's experiences in paediatric research

Hunfeld and Passchier reviewed the literature on discomfort of paediatric research a few years ago.[7] They concluded: "Several limitations of the present body of knowledge on the burden of child participants in medical research can be mentioned. So far no systematic research has been conducted covering and comparing the amount and different aspects of perceived burden and risks in children, like regular hospital visits, the time needed to undergo the medical procedure or the unpleasantness of particular procedures". In addition, they mentioned that there is scarce information on the experiences of research procedures based on the perspectives of the children themselves.

The need to have empirical data about the experiences of children in clinical research on an international level is seen, for instance, by the development of two questionnaires about this topic: the Reactions to Research Participation Questionnaire for Children (RRPQ-C)[8] and the Pediatric Research Participation Questionnaire (PRPQ).[9] The PRPQ concerns perceived benefits and barriers to paediatric clinical trials participation. The RRPQ-C concerns children's experiences with research studies in general. Since research studies vary in the procedures involved and often involve a combination of procedures, the outcomes of these questionnaires are difficult to generalise. It is therefore important to have additional information about the experiences of the individual research procedures as well as an instrument to measure this.

Current study

In this manuscript, we describe the protocols of a two-phase study: an interview study and a questionnaire study. The primary aim of this project is to get insight into the self-reported experiences of children when undergoing research procedures, in particular in relation to discomfort, and the emotional impact of the procedure for the child. Secondary aims are to get insight into children's suggestions to reduce possible discomforts of research procedures and whether there are differences in experiences between subgroups of children (age, anxiety-proneness and health condition).

Since there is limited information about this topic, the first phase of our project is a qualitative study to explore the experiences of children in clinical research in particular related to discomfort. We will use the outcomes of the interviews (ie, the different experiences of the children) for the development of a questionnaire to measure children's experiences in a quantitative way. In the second phase, we will use this questionnaire to measure children's experiences during research procedures in order to get insight into the percentages of children who experience certain discomforts and to what extent.

Research questions

Primary research questions:

1. What are children's experiences during (common) research procedures, and do these differ between different procedures?
2. What is the emotional impact of research procedures for children after 1 month?

Secondary research questions:

1. Are there differences in experiences and emotional impact of research procedures between (a) healthy children and children with a chronic condition, (b) young (<12 years) and older children (≥12 years) and (c) between anxiety-prone versus not anxiety-prone children?
2. Are there differences in experiences between medical procedures that are conducted for research purposes or routine clinical care?
3. What are children's suggestions to decrease discomfort related to research procedures?

METHODS AND ANALYSIS—INTERVIEW STUDY

Design

In the first phase of our study, we will interview a group of children who participate in clinical research studies to explore their experiences during research procedures and their suggestions to reduce potential discomfort caused by the procedures. The primary outcomes of this interview study are the different discomforting aspects during research procedures that children experience. These aspects will be categorised into themes. Secondary outcomes are children's positive experiences and their suggestions to reduce discomfort.

In addition, for the development of the questionnaire in the second phase of our project, children will answer some written questions about their experiences with the research procedures. We will ask children to fill in each question on three different response options and will ask them which of these options they prefer. The reason

why we will investigate this is because there is discussion about what the most suitable response option is for children. We will use the response option that is most often preferred by the children for the questionnaire in the second phase of our project.

Population

The focus of the interviews is to explore the experiences of a diverse group of children. We will purposefully select a wide range of children (ages and medical conditions) undergoing various types of clinical research procedures to ensure a wide range of experiences, influences and attitudes. In qualitative research, this is called a maximum variation sample.[10] This method is designed to represent a wide range of experiences, rather than aiming at numerical representativeness. We will interview children from 6 years of age because the literature shows that children aged 6 years and older are cognitively capable and have language capacities to accurately verbalise their experiences.[11] We aim to include approximately 40 children, or until saturation is reached. In qualitative research, this is the point when additional interviews do not provide new information.[12] The point of saturation will determined by the interviewer (MSS) in consultation with other members of the project group (JAMH and JP). Children are eligible to be interviewed if they meet the following criteria: (1) aged between 6 and 18 years, (2) fluent in Dutch, (3) no current psychological treatment for pain or anxiety disorders, (4) no severe psychosocial problems (such as anxiety disorders and depression), (5) accompanied by at least one parent or caretaker and (6) able to express themselves verbally. These inclusion criteria will be determined by asking the parent(s) of the children and/or by consulting the child's medical record.

The children will be recruited from research studies at three academic hospitals in the Netherlands: Sophia children's hospital (Erasmus University Medical Center) in Rotterdam, the department of Paediatrics of the VU Medical Center in Amsterdam and Emma children's hospital (Academic Medical Center) in Amsterdam. We aim to include children from four different paediatric departments: gastroenterology, pulmonology, nephrology and oncology, to cover a large variety of research procedures and to include children from a broad range of diseases. We will also include healthy children who participate in research studies at these departments.

Procedure

The children and their parents will be approached by the researchers of the studies we will cooperate with. If interested, parents and children will receive an information letter, which will be adapted for children (6–11 years) and adolescents (12–18 years). Parents and children will also have an opportunity to ask the interviewer questions about the interview in a face-to-face conversation, which will probably take place on the day of the child's research visit. After agreement, written parent consent and child assent (children ≥12 years) will be obtained. Children younger than 12 years have to verbally agree to participate.

The interviews will be conducted by the PhD student of the project (MS, a health psychologist) who will receive specific training in interview skills by experts in the field of medical and paediatric psychology. Children will receive a gift card (€7.50) for being interviewed. Interviews will be conducted in a private room at the hospital, directly after the child's participation in a research study. Parents are allowed to be in the room during the interview but will be asked not to intervene as the focus is on the child's perspective. During the interviews, parents will fill in some questions about the child's demographics and medical history. After the interview, children will fill in some written questions about their experiences with the research procedures.

Instruments

Demographics

We will collect demographics by asking the parent of the child to fill in some questions about the child's gender, date of birth, ethnicity, educational level, paediatric disease and medical history. If the parent does not know this information, we will collect the data from the child's medical record.

Interview

The interviews about children's experiences in clinical research will be semistructured and will focus on the discomforts the child experienced in relation to research procedures. Children will also be asked about positive experiences and suggestions to decrease possible discomfort. The interview questions are based on the literature, a review about the discomfort of children in clinical research,[7] and input from several paediatricians, psychologists and paediatric nurses. The interview will contain questions about children's experiences during participation, in particular related to discomfort, future research participation, preparation for the study and suggestions to reduce discomforts.

Written questions

To find out the most preferred response option, children will fill in five questions about their experiences with the research procedures. These questions will be based on input from the project group and the literature. We will ask the children to fill in each question on three response options: a 5-point Likert scale, a 100 mm coloured visual analogue scale (VAS) and a simple 100 mm VAS. Children will be asked which of the three response options they prefer.

Analyses

Interview

The interviews will be audio recorded and transcribed verbatim. The transcripts will be analysed using 'thematic analysis' in QSR NVivo V.10 to identify themes related to

children's experiences and their suggestions to reduce discomforts.[13] Thematic analysis is a method to interpret the findings of qualitative research, in which the transcripts will first be coded using open coding. The codes obtained during open coding will then be divided into categories covering all relevant information. Finally, the categories will be merged into main themes. Two researchers (a PhD student and a supervisor) will independently analyse the interviews to ensure inter-rater agreement on the relevance of the themes derived from the interviews. In case of disagreement, the researchers will discuss until consensus about the themes is reached.

Written questions

We will investigate which response option is most frequently preferred by the children.

METHODS AND ANALYSIS—QUESTIONNAIRE STUDY

Design

In the second phase of our study, we will first develop a questionnaire based on the information gathered in the interview study (ie, the themes/categories on children's experiences during research procedures) as well as in expert meetings with different healthcare professionals involved in paediatric research (paediatricians, paediatric nurses, ethicists, psychologists, pedagogics and parents). This draft questionnaire will be pretested in a sample of 25 children. The final questionnaire will be used to measure children's experiences during several research procedures. At two time points, we will ask children to fill in questionnaires: directly after undergoing a research procedure and 1 month later.

The primary outcomes of this questionnaire study are children's experiences, in particular related to discomfort, during research procedures and the emotional impact of the research procedures on them. Secondary outcomes will be their suggestions to reduce discomfort, and possible factors that influence children's experiences.

Population

Since this study is a first step in systematically investigating children's experiences during research procedures, we cannot say beforehand how many children are needed to be included. We plan to include a sample of 50 children for each research procedure. We think this number will be reasonable given the duration of our study, and the availability of children undergoing the research procedures at the different locations during the inclusion period of our study. Recruitment is based on the same criteria as previously mentioned for the interview study, except that the lower age limit will be 8 years instead of six because we will use two questionnaires that are suitable for children aged eight and older. Again, we aim to recruit children from the same three academic children's hospitals in the Netherlands.

In addition, 50 healthy children (8–18 years) will be included to measure their experiences after a check-up visit at the dentist. With this group of children, we aim to measure the experiences of a common medical procedure in a child's 'daily life'. We will compare this outcome with the experiences during the other research procedures.

Procedure

Parents and children will be recruited in the same way as for the interview study. Directly after undergoing the research procedure, the child will complete the '*What do you think of …?'-questionnaire*, which is the questionnaire we will develop to measure children's experiences during a research procedure. Children also fill in the '*Zelfbeoordelings Vragenlijst voor Kinderen*' (ZBV-K) to measure anxiety-proneness. After 1 month, the child receives an email with the link to fill in the two questionnaires online: the '*What do you think of …?'-questionnaire* again to investigate whether the moment of measuring may influence children's answers and the Child Revised Impact of Event Scale (CRIES-13) for the assessment of the emotional impact of the clinical research procedure. After having completed all questionnaires, children will be sent a gift card (€7.50) to their home as a token of appreciation for their participation in our study. To send the gift card to the children, it is necessary to ask for their addresses. We will delete this information directly after sending the gift card.

Instruments

Discomfort -'What do you think of …?'-questionnaire

Children's experiences during research procedures, in particular related to discomfort, will be measured using the questionnaire we developed (*What do you think of …?'*-questionnaire). This questionnaire will contain questions about: (1) experiences during a clinical research procedure, both positive and negative experiences; (2) the most burdensome part of the research study in which the child participates; (3) whether the child would undergo the research procedure again in the future; (4) the child's experiences with the same medical procedure in routine clinical care and (5) an open question to ask children about suggestions for decreasing discomfort of the research procedures. The specific questions of the '*What do you think of …?'*-questionnaire will be based on the topics on children's experiences from the interviews and on input from professionals during the expert meetings. The method of answering the questions is based on the children's preferences for response options on the written questions in the first phase of the study (ie, five-point Likert scale, 100 mm coloured VAS or 100 mm simple VAS).

Emotional impact—Child's Revised Impact of Event Scale

The emotional (traumatic) impact of the research procedures will be measured by the Dutch version of the

Child's Revised Impact of Event Scale (CRIES-13).[14] The CRIES-13 is a child self-report scale about the frequency of event-related (traumatic) distress (in our study, we measure the distress caused by the research procedures). The questionnaire consists of 13 items which are divided into three subscales: avoidance, intrusion or re-experiencing and arousal. Children have to rate each question on a 4-point Likert scale, with the following categories: 0='not at all', 1='rarely', 3='sometimes', 5='often'. The CRIES-13 demonstrates satisfactory to good psychometric characteristics.[15] It has good internal consistency for the total scale (Cronbach's α=0.80) and satisfactory internal consistency for the three subscales: intrusions or re-experiencing (Cronbach's α=0.70), avoidance (Cronbach's α=0.73) and arousal (Cronbach's α=0.60), for example, when a child has a total score of 30 or above on the CRIES-13, he or she is considered to have clinically elevated stress response symptoms.[16]

Anxiety-proneness—Zelfbeoordelings Vragenlijst voor Kinderen

Anxiety-proneness of the children will be measured by the *Zelfbeoordelings Vragenlijst voor Kinderen* (ZBV–K).[17] The ZBV-K is a Dutch translation of the State Trait Anxiety Inventory for Children (STAI-C)[18] and consists of two scales: state and trait anxiety. Each scale consists of 20 items. For this study, the trait scale was used, which addresses the frequency and intensity of general anxious symptoms. The child was instructed to rate the frequency with which he or she experiences anxiety symptoms in general (ie, anxiety-prone) on a three-point Likert scale (eg, 'I worry about school'), with the following categories: 1='almost never', 2='sometimes', 3='often'. Individuals scoring high on this scale tend to interpret situations as more threatening than do individuals with lower scores. The trait scale demonstrates good internal consistency in a Dutch norm population (Cronbach's α>0.80).[17] The total ZBV-K score for trait anxiety ranges between 20 and 60. Test–retest reliability for both children and adolescents has been found to be acceptable (Dutch norm population: r>0.65).[17] Since the manual of the ZBV-K does not mention a clinical cut-off score, based on previous studies with the ZBV-K, we consider children as anxiety-prone when they have a total score of at least 38 on the ZBV-K.

The ZBV-K is used for children aged between 8 and 15 years. However, it has been suggested that the child version of ZBV (ZBV-K) may be more useful for adolescent populations than the adult version (ZBV), given that even older adolescents may have difficulty understanding some of the vocabulary in the adult version.[19] Kirisci *et al*[20] studied whether the ZBV-K was also reliable and valid for adolescents (12–18 years) and indicated that it was applicable to this age group. We therefore decided to also use the ZBV-K for children between 16 and 18 years.

Demographics

Demographics that we will collect include the child's age, gender, health status, ethnicity and previous experiences with the medical procedure. Since we will include children from different hospitals, the research procedures may not be conducted in an identical way between those hospitals. Therefore, we will also collect data about how the child is prepared for the study, who performed the procedure (eg, paediatrician, lab worker, PhD student), the duration of the procedure and whether the child had local anaesthetics. This information will be asked from the parents, from the researchers of the studies and/or derived from the child's medical record.

Research procedures

We will measure children's experiences during several research procedures: echoscopy, faeces testing, MRI, pulmonary function test, buccal swab, skin prick test (allergy test) and venipuncture. The research procedures are selected on the basis of an expert meeting with paediatricians, paediatric nurses, ethicists, psychologists, pedagogics and parents, and on which research procedures are conducted during the time frame of our study at the departments of the three hospitals we cooperate with.

Analyses

Primary outcomes

Discomfort

Depending on the response option (VAS or Likert scale) of the questionnaire, parametric or non-parametric tests will be used. The mean (or median) of each question on the '*What do you think of…?*' -questionnaire will be calculated. Differences in outcomes between baseline and 1-month follow-up on the '*What do you think of…?*' -questionnaire will be tested using paired t tests (or Wilcoxon matched-pairs tests). Differences in experiences on the different research procedures will be tested by one-way between groups analysis of variances (ANOVAs) (or Kruskal-Wallis tests). For each research procedure, the percentage will be calculated of children willing to undergo a similar procedure again in the future.

Emotional impact

We will measure the percentage of children who have elevated stress symptoms caused by the research procedure after 1 month (ie, a total CRIES-13 score of 30 or more). We will also study whether there is a relation between emotional impact and the type of research procedure by one-way between groups ANOVAs.

Secondary outcomes

Suggestions

Suggestions for reducing discomforts of the research procedures will be coded into categories, and frequencies on each category will be measured.

Influencing factors on children's experiences and emotional impact

Depending on the response option (VAS or Likert scale) of the '*What do you think of…?*' questionnaire, parametric (independent-samples t test) or non-parametric (Mann-Whitney U test) tests will be used to study possible differences in experiences between anxiety-prone children (children with a score of 38 or higher on the ZBV-K trait scale) and nonanxious children (children who score 37 or lower on the ZBV-K trait scale). The same tests will be used to study the differences between young children (<12 years) and older children (≥12 years), and between healthy children and children with a chronic condition.

To measure if there are differences on emotional impact between (1) anxiety-prone versus non-anxiety-prone children, (2) young children (<12 years) versus older children (≥12 years) and (3) healthy children versus children with a chronic condition, we will perform independent-samples t tests.

ETHICS AND DISSEMINATION

The IRB of the VU Medical Center in Amsterdam (the Netherlands) evaluated both studies described in this manuscript and indicated that there was no risk or discomfort associated either with the interview study (2012/279) or the questionnaire study (2014/010), stating that both phases are exempt from getting approval under the Dutch Law.

Dissemination of results will occur by conference presentations and peer-reviewed publications. No identifying participant information will be made available. Only investigators will have access to the raw data of the studies. The outcomes on children's discomfort during research procedures will be available for IRBs and paediatric researchers in an online database. These outcomes will not include identifying participant information.

DISCUSSION

In this manuscript, we describe the protocol of a two-phase study to measure children's experiences during research procedures. The findings of this study give insight into children's experiences during some common research procedures, the emotional impact of these procedures and suggestions to reduce discomforts of research procedures, as seen from the perspective of children themselves. This study also explores whether age, health condition and/or anxiety-proneness influence children's experiences. Finally, this study provides an instrument to measure children's self-reported experiences of research procedures.

We will provide the findings of this study on a website which will be accessible for parents, children, IRBs, researchers and others who are interested. The findings of our project can help IRBs and paediatric researchers when evaluating the discomforts of research procedures or when designing a study. Information on experiences of children involved in previous studies may also help children and parents in future research with their decision-making concerning participation in clinical research, or parts thereof.

Limitations

A limitation of our study is that we cannot acquire a complete overview of the experiences of all research procedures, subgroups of children and all factors influencing their experiences given the limited time and funding.

Future research

A future aim is to use our questionnaire to obtain empirical data from other research procedures than the ones we investigated in our study. This requires the development of a network in which physicians, researchers, IRBs, parents and children are involved. We are currently working on the development of this network.

Next to age, medical condition and anxiety-proneness, other variables may have an impact on children's experiences, such as the interaction of the child, parent and researcher during research procedures. Since children's age, health condition and anxiety-proneness are important factors for IRBs to take into account when evaluating the discomfort in paediatric study protocols, we decided to focus on these three factors.

Contributors MSS is responsible for the data collection and analysis of both studies. She drafted the initial manuscript of this study protocol and approved the final version of it. JAMH conceptualised and designed both studies from a psychological/pedagogical perspective, and supervises the data collection at the different hospitals. She critically reviewed and revised the manuscript, and approved the final version of this study protocol. RT supported with the methodological and statistical aspects of the study protocol. He approved the final version of this study protocol. JP conceptualised and designed both studies from a psychological perspective. He critically reviewed and revised the manuscript and approved the final version of this study protocol. JBvG conceptualised and designed both studies from a medical/paediatric perspective. He critically reviewed and revised the manuscript and approved the final version of this study protocol.

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