



Children's self reported discomforts as participants in clinical research



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ABSTRACT

Introduction: There is little empirical evidence on children's subjective experiences of discomfort during clinical research procedures. Therefore, Institutional Review Boards have limited empirical information to guide their decision-making on discomforts for children in clinical research. To get more insight into what children's discomforts are during clinical research procedures, we interviewed a group of children on this topic and also asked for suggestions to reduce possible discomforts.

Materials and methods: Forty-six children (aged 6–18) participating in clinical research studies (including needle-related procedures, food provocation tests, MRI scans, pulmonary function tests, questionnaires) were interviewed about their experiences during the research procedures. Thematic analysis was used to analyze the interviews.

Results: The discomforts of the interviewed children could be divided into two main groups: physical and mental discomforts. The majority experienced physical discomforts during the research procedures: pain, shortness of breath, nausea, itchiness, and feeling hungry, which were often caused by needle procedures, some pulmonary procedures, and food provocation tests. Mental discomforts included anxiousness because of anticipated pain and not knowing what to expect from a research procedure, boredom and tiredness during lengthy research procedures and waiting, and embarrassment during Tanner staging. Children's suggestions to reduce the discomforts of the research procedures were providing distraction (e.g. watching a movie or listening to music), providing age-appropriate information and shortening the duration of lengthy procedures.

Discussion: Our study shows that children can experience various discomforts during research procedures, and it provides information about how these discomforts can be reduced according to them. Further research is needed with larger samples to study the number of children that experience these mentioned discomforts during research procedures in a quantitative way.

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1. Introduction

1.1. Clinical research in children

Pediatric research is necessary to develop safe and effective

treatments for children. However, children are vulnerable and need to be protected against high levels of risk and burden in clinical research. It is an ethical and legal requirement for pediatric research that the risks and burdens of research participation are proportionate to the expected benefits of participation (WMA General Assembly, 2013). It is the responsibility of Institutional Review Boards (IRBs) to weigh these burdens and risks to establish whether they are acceptable. To be able to properly conduct this responsibility, research on the possible discomforts of research procedures is required, which involves knowing the perspectives of the participating children. For an overview of the terminology used in this article, we refer to Table 1.

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1.2. Children's experiences in clinical research

Since little is known about children's subjective experiences of discomfort during clinical research procedures (Hunfeld and Passchier, 2012; Ondrusek et al., 1998), IRBs have limited empirical information to guide their decision-making, which is why they often have to rely on the observations and assumptions of others. Literature shows, however, that pediatric nurses, pediatricians, psychologists and parents are likely to overestimate (Chambers et al., 1999; McCarthy et al., 2010) or sometimes underestimate (McCarthy et al., 2010; Romsing et al., 1996) children's discomfort in medical settings. It is therefore crucial to also take children's own perspectives into account when evaluating the discomforts of clinical research procedures. This position is reflected in Article 12.1 of the Convention on the Rights of the Child (United Nations, 1989) "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child" as well as Article 3.2.a of the EU Clinical Trials Directive (2001/20/EC) (European Parliament, 2001).

1.3. Empirical data on children's experiences in clinical research

The experiences of children who participated in research were studied in few studies. In two of these studies, children were asked about the worst (and best) parts of the study they participated in. Most frequently mentioned were blood work and needles because of pain or unpleasantness (Ondrusek et al., 1998; Wagner et al., 2006). In another study children were asked to rate their level of comfort in relation to IV insertion, Tanner stage assessment, blood draws and staying overnight in the hospital after their participation in a research study (McCarthy et al., 2001). The results indicated low levels of discomfort, although Tanner staging and IV insertion were perceived as more discomforting than the other procedures. Some other studies in trauma-focused research investigated children's experiences by using the Reactions to Research Participation Questionnaire for Children (RRPQ-C) (Kassam-Adams and Newman, 2002), which includes three questions on children's discomforts: feeling bored during the study, feeling upset or sad during the study, and feeling sorry for having taken part in the study. Studies that used this questionnaire for investigating the discomforts of trauma-focused research showed that the majority of the children was not bored, upset/sad or felt sorry about participating in these research studies (Chu et al., 2008; Kassam-Adams and Newman, 2005; Seedat et al., 2004). There is also some literature on the (expected) discomforts that children mention in hypothetical research situations, e.g. (Bernhardt et al., 2003; Brody et al., 2003). In these studies discomforts mentioned by the children were concerns and worries (e.g. about the safety of the procedures or uncertainty that comes with test results), and pain.

Prior literature gives us some insight into discomforts children experience during clinical research procedures. Limitations are that

these studies focused on the experiences of a homogenous group of children (e.g. only children with asthma or children from a limited age-range) during a small number of research procedures, or did not distinguish between different kinds of discomforts. In addition, the experiences of children in hypothetical situations may not be totally generalizable to the actual experience of children because children undergoing a painful procedure often expect to experience higher levels of discomfort than they actually experienced (Cohen et al., 2001; Spafford et al., 2002).

1.4. Purpose of this study

To get a more complete picture of children's discomforts during clinical research procedures as described in their own words, we interviewed a diverse group of children about the discomforts they experience during a wide range of clinical research procedures. In addition, we asked the children for their views on reducing discomfort of the research procedures, which as far as we know has not been done in prior research.

2. Materials and methods

2.1. Subjects

Children (6–18 years) who participated in clinical research studies at two academic pediatric hospitals in the Netherlands (Sophia Children's Hospital in Rotterdam and Emma Children's Hospital in Amsterdam) were interviewed between November 2012 and June 2013. We purposefully selected 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 (Marshall, 1996). This method is designed to represent a wide range of experiences, rather than to aim for numerical representativeness. The age of six was chosen as lower age limit because literature shows that children from six years onwards are cognitively capable and have language capacities to accurately verbalize their experiences (Rich, 1968).

Children were enrolled in one of the outpatient pediatric studies described in Table 2. The children we interviewed all participated in clinical research studies: in either experimental or observational/follow-up studies. We enrolled children until saturation was reached. In qualitative research, this is the point when additional interviews do not provide new information (Glaser and Strauss, 1967). The point of saturation was determined by the interviewer (MS) in consultation with other members of the project group (JH and JP).

Exclusion criteria were 1) children with mental health issues (such as anxiety disorders and depression) to avoid information being biased by their mental condition, 2) children who underwent research procedures that are used for both clinical and research

Table 1
Terminology.

Term	Description
Medical research	The over-arching term for all types of medical research, which can be divided into primary research and secondary research. <i>Primary research</i> includes basic research, clinical research (experimental and observational research) and epidemiological research. <i>Secondary research</i> includes meta-analyses and systematic reviews (Rohrig et al., 2009).
Clinical research procedures	Medical procedures that are used for clinical research purposes.
Therapeutic research	Therapeutic research is clinical research that is likely to directly benefit the participant.
Non-therapeutic research	Non-therapeutic research is clinical research that is not likely to directly benefit the participant but may benefit future patients.
Discomfort	Something that causes one to feel uncomfortable (Simpson et al., 1989).

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