

Self-reported experiences of children during medical research procedures: an explorative study

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CONCLUSION

Most interviewed children considered physical, mental and logistical discomfort of the medical research procedures as acceptable, and viewed their participation in clinical research as a positive experience.

Background

Little is known about children's experiences in clinical research → parents, children, researchers and Institutional Review Boards have no or limited empirical evidence to guide their decision-making for participating in pediatric research or for evaluating discomfort described in study protocols.

Aim

To explore children's self-reported experiences during medical research procedures as well as their suggestions to reduce discomfort.

Methods & Participants

Design. Face-to-face interview study.

Setting. Children were recruited from **8 studies** conducted at two academic hospitals.

Participants. We purposefully selected **46 children** (aged 6-18) participating in clinical research studies.

Medical research procedures. The procedures in the studies included invasive procedures (e.g. needle procedures, MRI-scans, provocation tests) and several non-invasive procedures (e.g. taking medical history, questionnaires).

Data analysis. The interviews were independently analyzed by 2 researchers (thematic analysis).



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Results

Age	Years
Range	6.3-17.8
Mean±standard deviation	11.9±3.8
Gender	# children
Boy	24
Girl	22
Health condition:	# children
Chronic condition (cystic fibrosis, inflammatory bowel disease, asthma, cashew allergy)	34
Healthy	12

"You get a nose clip and you can't swallow and you almost have no air and you get a dry throat" boy, 11 yrs

We identified 3 themes related to discomfort: **physical discomfort**, **mental discomfort**, and discomfort related to logistic aspects of a study (**logistic discomfort**). Another theme concerned **positive experiences**.

Physical discomfort

The majority of children experienced some but no excessive physical discomfort, e.g. pain, shortness of breath, nausea → caused by needle related procedures, pulmonary tests, cashew provocation test.

Mental discomfort

- Some children felt anxious or tense (especially the first time they underwent a procedure) → mainly caused by needle procedures.
- Some children got bored because of longlasting procedures → MRI, provocation test, questionnaires.

"For me a MRI is quite normal. The first time I was a little scared but now I'm used to it." boy, 15 yrs

Logistical discomfort

Frequently mentioned as burdensome were the logistical aspects of the study → duration of the study and waiting times.

"I think the study took too long" girl, 8 yrs

Positive experiences

Almost all children were happy because they could help other children by their participation. Other positive experiences included learning about their physical/cognitive capacities and getting a present.

"The test has a scientific aim, but it was really fun to do!" boy, 12 yrs

Suggestions to reduce discomfort

Suggestions to make medical research procedures less burdensome included providing distraction, providing information on expected physical sensations and shortening the duration of some procedures.

"I would make it a bit more of a game" boy, 11 yrs

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