



Paediatric Clinical Research Infrastructure Network

PedCRIN Patient Consultation Tool

Format PedCRIN Patient meeting guide for children

Description

This tool is a basic guide about the way children/youth can be 'consulted' about a paediatric clinical study. 'Consultation' is asking children/youth for input about the study. The tool describes a specific way of consultations: a 'focus group', a face-to-face meeting. There are other ways to ask patients for input. For example, by means of interviews or questionnaires. These means of consultations are not described in this tool.

Key words

Patient involvement, patient engagement, focus group, clinical research, paediatric research

Disclaimer: The meeting guides are formats and need to be adapted for the local circumstances. If a researcher wants to organize a patient consultation focus group for parents about their trials please consult the patient consultation experts.

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Abbreviations

PedCRIN	Paediatric Clinical Research Infrastructure Network
YPAG	Young person advisory group
FSJD	Fundacio Sant Joan de Deu
VSOP	Patient Alliance for Rare and Genetic Diseases

Keynotes

Why we need to use it in neonatal/paediatric studies?

Consultations of children/youth about clinical trials concerning their age group are important because children/youth can advise investigators about their needs and priorities. That way the researchers can adapt information about the study or study design/procedures that can enhance inclusion and retention as well as use relevant outcome measures.

What kind of information it provides?

It gives a basic guidance for the organization of face-to-face meetings with children/youth. The different phases of the meeting are described and topics for discussion are listed.

How this document is useful and at which stage of the trial it should be used?

This document describes the consultation in basic terms. If the researcher follows this procedure, she will obtain useful information of children about a prospective clinical trial. It should be used because it is important to consult the trial target group in order to enhance the chances to organise a successful and relevant clinical trial.

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1. Consultation tool children

1.1. Introduction

The objective of this tool is to support consultations, with children, about the three clinical trials that are supported by PedCRIN. This tool specifically focusses on consultations with children that have the specific disease the trial is focussing on or have experience with the conditions/circumstances of the clinical trial.

The goal of the consultations is to explore and assess how the children can be involved in the design, execution and finalization of clinical trials in paediatrics.

Involvement of children in clinical research is needed to increase trial success, for example on account of recruitment rates or outcome measures.

PedCRIN develops tools for these consultations. The experiences with and evaluation of this tool will be used to evaluate existing tools and to create a tool that can be widely used in future research.

This tool offers specific examples of meeting guides:

Format meeting guide children (face to face groups with children)

The meeting guides are formats and need to be adapted for the local circumstances. If a partner wants to organise a patient consultation focus group for children about their trials please contact Eric Vermeulen VSOP (e.vermeulen@vsop.nl) further detailed information on how to use these materials, experiences with and evaluations of the tools

2. Format PedCRIN meeting guide children

This meeting guide consist of activities that should be performed before, during and after a consultation with children.

3. Preparation

- Contact patient organisation / interest group;
- Explain the purpose of the consultation to the contact person of the patient organisation / interest group and ask them if they want to cooperate and what role they can play (for example: contact and invite their members/children for the consultation, share information about other research projects they are involved in etc.);
- If children are willing to participate, contact their parents and set a date and time for the consultation (aim for 6 participants/children for a consultation, make sure the age difference between children is not too big and depending on the age of the children their parents can also be involved in the consultation);
- Organise a venue/location/meeting room;
- If not available, write a summary of the clinical trial;
- Share relevant information with the participant about the clinical trial, for example: Trial protocol, summary of the clinical trial, informed consent material / procedure, (information about) questionnaires/tools used in the trial, etc.;
- If not available, make a reimbursement form for travel expenses of participants.

4. Consultation

The consultation can last a maximum of 2 hours, also depending on the age of the children

4.1. Welcome and introduction (15 min)

- Getting to know each other;
- Explaining the plan for the consultation (for example: recording of the consultation and their permission, topics being discussed, etc.);
- If parents are present and involved during the consultation, make sure you explain their role and position (for example: this meeting focusses on the input / feedback of the children. The parents can give additional information if needed, or supplement the information given by their children) etc.

4.2. Discussion session I (45 min)

During this session, the first topic(s) will be discussed with the children. This can be done just face-to-face and in discussion, but can also be guided by innovative tools like Kahoot.

Depending on the number and type of topic(s) the organisers and/or the clinical researchers want to receive feedback on this part of the consultation can contain one or more topics. For example:

- Informed consent material
- Informed consent procedure
- Trial protocol (randomisation, type of design, etc.)
- Logistics of the clinical trial
- Outcome measures of the clinical trial
- Communication about the trial results.

Break (10 min)

4.3. Discussion session II (40 min)

During this session, topics about the clinical trial that were not discussed during the first session can be discussed. Another option for this session is to discuss with the children how they would like to be involved in research and research design. Topics that can be discussed:

- At what point in research design would they want to be involved? (for example: setting the research agenda; when designing the research design, or the logistic, or the type of outcome measures; when developing the informed consent material or procedure; or when they develop the communication plan, etc.)
- How would they want to be involved? (for example: via questionnaires, email, interviews, meetings with researchers, etc.)

4.4. Closure (5 min)

- Thank everybody
- Hand out reimbursement form for travel expenses (if not done already)

- Explain procedure after this consultation

5. After the consultation

The organisers of the consultation will make a report of the consultation that will be shared with the participants. In addition to giving feedback to the report, the participants can also give additional information regarding the topics discussed. Maybe, after they went home, they thought of things regarding the topics that were not discussed during the sessions, but are valuable.

