Targeted Informed consent : empowering young participants in medical-scientific research

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CHAPTER 4

Comic Strips Help Children Understand Medical Research. Targeting the Informed Consent Procedure to Children's Needs

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Abstract

Objective: Children involved in medical research often fail to comprehend essential research aspects. In order to improve information provision, a participatory approach was used to develop new information material explaining essential concepts of medical research.
Methods: A draft of a comic strip was developed by a science communicator in collaboration with pediatricians. The draft was presented to children participating in a clinical trial and to two school classes. Children were consulted for further development in surveys and interviews. Subsequently, the material was revised and re-evaluated in four school classes with children of varying ages and educational levels.
Results: In the first evaluation, children provided feedback on the storyline, wording and layout. Children thought the comic strip was 'fun' and 'informative'. Understanding of 8 basic research aspects was on average 83% and all above 65%, illustrating that children understood and remembered key messages.
Conclusion: A comic strip was developed to support the informed consent process. Children were consulted and provided feedback. The resulting material was well understood and accepted.
Practice Implications: Involving children in the development of information material can substantially contribute to the quality of the material. Children were excited to participate and to 'be a part of science'.

Introduction

The recent update of the WHO report on Priority Medicines for Children pleads for more scientific research in children, as 45-60 % of medication currently used for children is prescribed off-label (WHO, 2013). This plea holds an implicit duty to inform society in general and parents in particular about what medical research entails and why it is important to also involve children in research. In most circumstances, children do not have the legal right to provide consent for research participation. As children age, their mental capacity and autonomy to make decisions develops. Therefore, various rules and regulations require children to assent to research participation when they are capable of making a decision (Jaspan, Cunningham, & Tucker, 2008; Office for Human Research Protections, 2009). Offering children the possibility to assent assumes that children possess sufficient and adequate information to make a decision.

However, research has shown that disclosure to children is seldom adequate, due to the use of too difficult language or due to a general absence of information material specifically designed for children (Chappuy et al., 2008; De Vries et al., 2010; Falagas et al., 2009; Unguru et al., 2010). A number of studies indicate that children do not understand basic aspects of the research they are participating in (Barrett, 2005; Burke et al., 2005; Hunfeld & Passchier, 2012; Ondrusek et al., 1998; Swartling et al., 2011; Tait et al., 2003). For example, research among children in a clinical trial showed that 76% did not understand the risks associated with participation (O'Lonergan & Forster-Harwood, 2011). In another study, 79% did not understand the right to withdraw (Chappuy et al., 2008), and in yet another, 51% of children were unaware that their treatment was in fact a clinical trial (Unguru et al., 2010). A major obstacle for comprehension is the lack of ‘plain simple language’ in consent forms (Falagas et al., 2009; J. B. Green, Duncan, Barnes, & Oberklaid, 2003; Gribble, 1999). The use of simplified consent forms has been shown to improve comprehension in children (Tait et al., 2007).

Textual information provided to children thus requires substantial improvement to increase understanding (Menoni et al., 2011; Tarnowski et al., 1990). To this aim, we developed new information material for children involved in research. In this new material, the basic aspects of scientific medical research are explained, such as the goal of scientific research, and the right to withdraw. The information material can be used to support children in the informed consent/assent procedure.

The new information material is designed in the format of a comic book. Comic books combine written text with pictures and a story-line, which makes them ideally suited for education of young patients (M. J. Green & Myers, 2010). Pictures supporting written information are a powerful tool to increase comprehension (Mayer, 2001). They have been shown to improve comprehension, attention, recall and adherence in health care (Houts et al., 2006). Considering the story-line, Barnett observed that the use of a story-format for children significantly improves comprehension when compared to a standard text-format (Barnett et al., 2005). Comics have already shown their potential as a useful medium in school education and can improve patient education as well (M. J. Green & Myers, 2010; Tjiam et al., 2013). For example, in a study among 14 year-olds, a comic book on disease information was shown to succesfully improve understanding of the material (Gillies et al., 1990).

Participatory design

The new information material should optimally connect to the target group and lead to increased understanding. In order to achieve this, a participatory approach was adopted (Lee, Yoon, Chen, & Juon, 2013; Rudd & Comings, 1994). Children are the experts on their own preferences, experiences and situation. This implies that they can provide a unique insight in their information needs and appreciation of the material that could not be achieved without their participation (Dedding et al., 2015; C. Hart & Chesson, 1998; Lansdown, 2001). There are different levels of participation, as described by the 8-stage participatory ladder of Hart (R. A. Hart, 1992). Level 1-3 reflect non-participation, i.e. children do not have a significant role. An often encountered form of non-participation is ‘tokenism’ (level 3), when researchers or decision-makers pretend to consult children, but in reality have established plans (R. A. Hart, 1992). Level 4 is informing children, and at level 5 children are consulted about their perspective and experiences. Levels 6-8 reflect research in which children are in increasing levels involved in formulating the research question and study design. Our study takes place at level 5: children were consulted about their information needs and preferences, and their input was implemented in the product. Due to the legal requirements of research information, it was not possible to involve children in the research question or execution of decisions.

Methods

Development of the comic strip

The comic strip was developed as a joint project of a science communicator (LvD) and the professional artist Irene Cécile. This initial top-down approach (i.e. without involving the target group) was chosen in order to ensure that all the required information would be present. The content of the comic strip was based on the national brochure for adults 'Research Participant Information' from the Dutch Ministry of Health, Welfare and Sports (Ministerie van Volksgezondheid, Welzijn en Sport 2012). A storyline was developed about a young school girl called Anne, who has a rare disease. A non-existing disease, the green-nose flu, was chosen to make the story appealing to children with various diseases and to soften the tone of voice. Anne is asked to participate in a research project, and during the conversations with the doctor and her parents, all essential aspects of research are discussed.

The script was written by the science communicator and the pictures were subsequently drawn by the artist, as recommended by Houts (Houts et al., 2006). An example of the final design of the comic strip (translated version) is shown in figure 1. At the end of every chapter an exercise is presented, called *let's repeat!*, to repeat the explained information, see for an example figure 2.

This initial top-down development resulted in a comic strip of 40 pages, containing the topics: diagnostic testing vs. scientific research, institutional review boards, drug research, placebo, why it is necessary to do research with children, side effects, informed consent procedure, right of withdrawal, and privacy. The information is primarily aimed at children 10-14 years old. This target group was chosen as research has shown that children under the age of 9 hardly understand research-related information, and children over the age of 14 have an understanding similar to adults (Ondrusek et al., 1998; Weithorn & Campbell, 1982).

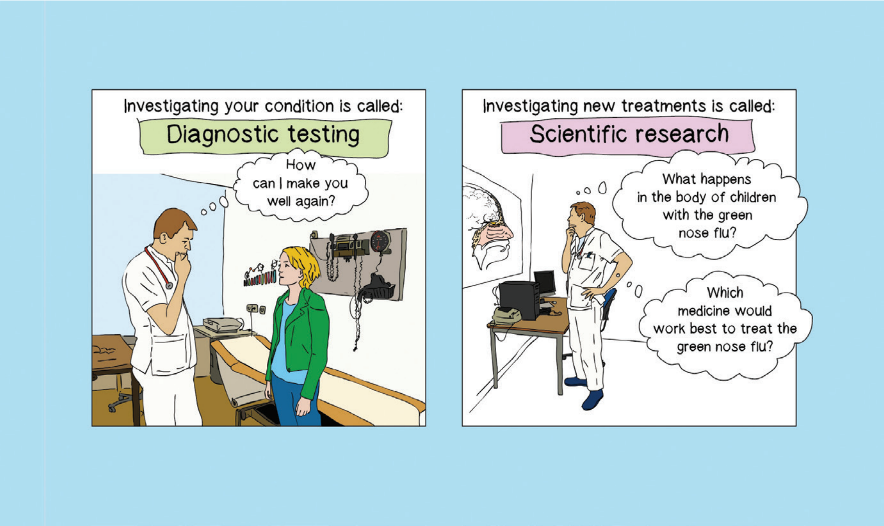
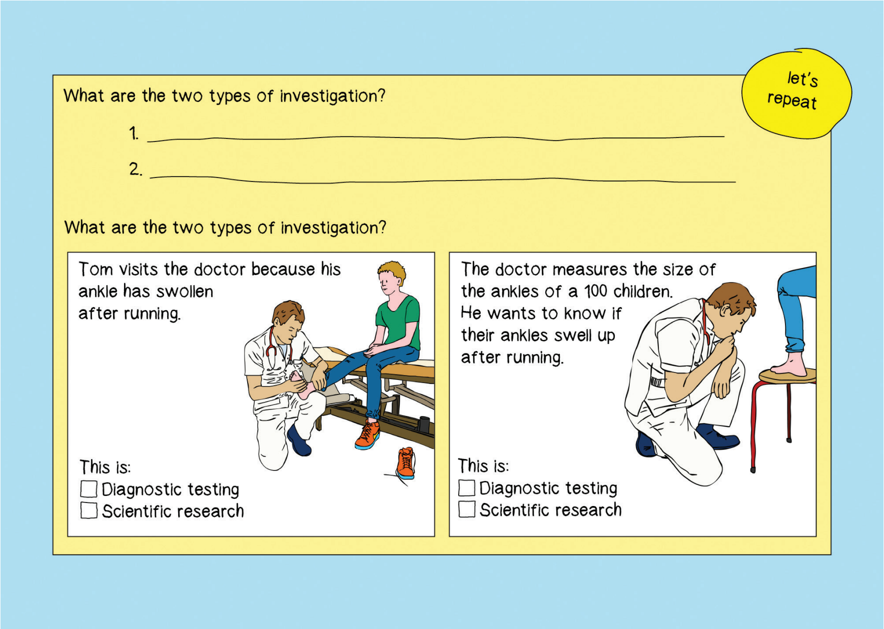


Figure 1. Picture from the comic strip ©Irene Cécile (original version in Dutch).

NB: In Dutch, the word 'onderzoek' describes both scientific research and the process of diagnostic testing and deciding upon treatment. Therefore the distinction between these two types of 'onderzoek' is given special attention.



What are the two types of investigation?

1. ______________________________
2. ______________________________

What are the two types of investigation?

Tom visits the doctor because his ankle has swollen after running.

This is:
☐ Diagnostic testing
☐ Scientific research

The doctor measures the size of the ankles of a 100 children. He wants to know if their ankles swell up after running.

This is:
☐ Diagnostic testing
☐ Scientific research

Figure 2. Exampe of a Let's repeat exercise ©Irene Cécile (original version in Dutch).

Initial feedback

An initial feedback round was performed with six children (age 8-12) and their parents participating in a clinical trial for a chronic disease in a large academic hospital in the Netherlands. The received the comic strips during a regular hospital visit. Children and their parents left sticky notes in the comic strips to indicate specific things they liked or points of improvement, such as complicated words.

After several weeks, the comic strips and feedback were collected and children and their parents were interviewed over phone or at home. Children and parents indicated that they liked reading the comic strip; however, they thought it was very long, and that the end was boring.

Participatory testing in school classes

Set-up

In order to consult more children, a first evaluation was performed in two school classes. Feedback was collected by surveys and interviews, in order to identify problematic topics and whether the material appeals to children. Based on the feedback, the comic strip was adapted and re-evaluated by four more school classes, with the same methods. Participation was anonymous; no names or other personal details were recorded. A week before performing testing, the children were handed a letter for their parents about the test. This letter served as an opt-out consent: parents who did not want their child to be involved in our test could sign the letter.

Survey

A survey was used to consult children on user satisfaction and understanding. It was explained that no wrong answers could be given, since everything that the children would write or tell would help us in developing the comic strip.

User satisfaction was assessed with closed questions (how much did you read) and open questions (is there anything you would like to change about the comic strip: color/text/length/story/other + explanation).

In addition, 8 multiple choice questions were asked on key concepts of research that are legally mandatory to be included in consent information, as presented in table 1.

Table 1 Multiple choice questions on 8 basic research aspects

Research aspect	Question
Voluntary	When you are asked for research, you cannot say no (false)
Best meds	When you participate in a study, you will always receive the best drug (false)
Withdraw	When you participate in a study, you can quit halfway, if you don't want anymore (true)
Randomization	Who determines which treatment you will receive in research? (The doctor, you or the computer)
Placebo	When you receive a placebo, you will get well again (always, sometimes, never)
Side effects	Sometimes drugs in research can give nasty side effects (true)
Anonymity	In research, your name is always stored (false)
Therapeutic misunderstanding	If you are ill, and you participate in research, you will get well again (false)

Interviews

Children were asked for an interview at the end of the survey. The children who volunteered were interviewed after finishing the survey, either in an individual interview, or in a group of 2-4 children. The interview started with the open question: Tell what you think of the comic strip – you can say anything that comes to your mind. The interviews took approximately two to six minutes and were recorded with a voice recorder. In addition to the open question on the comic strip, children were asked to explain specific research concepts (e.g. *could you explain to me what a biobank is?*), in order to assess understanding in a deeper way than possible with the survey.

Results

Evaluation in school classes

Initially, two classes were tested as a pilot: a primary school ‘group 7’ with 28 children from ages 10 and 11, and a high school first year ‘vmbo’ (preparatory middle-level vocational education) with 15 children ages 12 to 13 (1 non-responder). We interviewed a total of 16 children in individual interviews (8 boys, 8 girls). The feedback from these children led to a number of modifications of the comic strip, a selection of which is demonstrated in table 2.

As biobank research is increasingly used among children, we added a six-page chapter on this topic. Since children only need to read chapters relevant to their situation (i.e. either biobank or drug trial), the extra chapter does not increase the total amount that has to be read by research participants. Compressing the strip further would reduce the amount of information given, and therefore we aimed to improve the structure of the comic strip to enhance the reading experience.

Re-evaluation in school classes

Participants

In total 101 children from 4 new school classes participated. Class 1 was a primary school class ‘group 7’, with 28 children aged 10-11. Class 2 was primary school ‘group 7/8’, with 22 children age 10-12. Class 3 was a high school first year ‘vwo’ (pre-university secondary education) with 25 children age 12/13. Class 4 a high school first year ‘vmbo’ (preparatory middle-level vocational education) with 26 children aged 12-13. We interviewed a total of 16 children, in 7 individual interviews (5 girls, 2 boys) and 3 focus groups with 2 (boys), 3 (boys) and 4 children (2 boys, 2 girls).

User satisfaction

Number of pages read was measured to identify whether children liked the material enough to keep reading, a condition for user satisfaction. Table 3 indicates how many pages children did read per school class. In class 1 and class 3, the majority of children read the entire comic strip (89.3% and 92.0%). In class 2 and class 4, the majority of children read at least 30 pages (77.3% and 80.0% respectively).

Table 2 Common feedback from the children in the survey and interviews, and the reflection of this input in the subsequent revision of the comic strip

Input children	Quotes	Reflection in revision
Children indicated that the comic strip was too long and there was too much repetition. A number of children told that this ultimately made them stop reading before the end.	'It is too long, some things can be left out' 'Too much repetition' 'I thought it was a little bit too long' 'I would make the story less tedious'	We removed pictures in which nothing was added to the storyline, and repetitive parts. All changes together reduced the length from 40 to 34 pages In order to reduce the feeling that it was a lot to read, the format was altered from one page per A4 to 2 pages per A4, leading to a more compact product.
	'There are maybe too many examples, that might be a little too much […] the ones with the medication, for people who eat unhealthy or do not exercise […] there were a lot of examples'	We removed the multiple examples in the explanations of differences in study participants and also in the chapter about side effects.
	'It took a long time to discuss one topic sometimes, for example that she has to choose and he explains a lot and becomes very repetitive'	At the end of the explanation about drug trials, there is a one-page recap of the consequences of participation. This page was eliminated, as it did not add any information to the story.
	'Less questions!'	The drug study chapter had over 1 page with 8 personal questions, this was reduced to two core questions
Many children complained about an intermezzo at the beginning of the story in which the difference between observational and interventional research was explained. Children thought it was complicated and confusing because it was not part of the story itself.	'It was too complicated so I thought 'what is this' and stopped reading.' 'It should be more a real storyline' 'In the beginning it was a little bit complicated, because someone was introducing himself and then a lot of things came and then suddenly the story started again'	This explanation was separated as a special chapter, clearly different from the storyline. The words used were simplified in order to aid understanding, based on suggestions from the children. After re-evaluation it was decided that this chapter should be eliminated from the comic strip.
Children indicated that the story was boring because of its wordiness and the lack of color. Also, there should be more jokes to keep them reading	'First it was exciting […] but at some point I did not like it anymore, because it took too long and was not interesting anymore'	The script of the story was shortened, involving specific comments by the children, to reduce wordiness and making the story more interesting.
	'It is boring if there is no color' 'More color, but on the pictures that were already drawn, I thought it looked nice'	The comic strip will be developed in color, as in the example pages valued positively by the children. This might improve reading experience and interest as well
	'The end is boring, we want more humor'	We were hesitant to add more jokes to the story, as we did not want to undermine the serious tone of the information. We assumed that shortening the story could reduce boredom as well.

Input children	Quotes	Reflection in revision
Children indicated to be confused about the structure of the story and the alternating reading direction on two pages	'Sometimes it is difficult to switch between topics'	The story was divided into separate chapters for each topic, which were color-coded at the top of the page. An explanation of how to read the comic strip, as well as a colored index was added on the first page
	'What is the next image?'	Addition of reading arrows and clearer lines to indicate two pages should be read from top to bottom
	'After a while I figured out that these people were her parents, but it was unclear, maybe you should add arrows with father and mother'	In the first appearance of the parents, arrows were added with 'father' and 'mother'
Many children were positive about the *let's repeat* exercises and indicated it could help in understanding the information	'I think the *let's repeat* exercises are good when you are participating in a research […] you are more involved and can understand it better'	For continuity and structure, we decided to add the *let's repeat* exercises to the end of all the chapters

Table 3 Amount of pages read, per school class

	Class 1		Class 2		Class 3		Class 4	
Complete	25	89.3%	8	36.4%	23	92.0%	9	36.0%
30-39 pages	2	7.1%	9	40.9%	1	4.0%	11	44.0%
20-29 pages	1	3.6%	3	13.6%	1	4.0%	5	20.0%
0-19 pages	0	0.0%	2	9.1%	0	0.0%	0	0.0%
Total	28	100%	22	100%	25	100%	25	100%

(1 person missing, as this person did not fill in how many pages he had read)

All interviewed children responded that they liked the comic book and thought it was '*fun*'. Some children said the comic strip was very informative and there is '*really a lot in it*'; '*I liked it because it is very interesting*'; '*you now know new things and that is really interesting*'. About the length, children said: *'I thought it was too long, because for this long, some people cannot keep their head to it, you could better divide it into pieces and read one piece each day*'. One boy said '*I thought it was a bit boring, but when you're ill, maybe you don't think about that*'.

One girl thought the comic strip was '*well thought-off*', because '*for children it is much more fun to read a comic strip instead of a story*'. Another boy said '*it is more fun than very lengthy texts, and then you are very easily distracted*'. One girl told '*I understood it* *well, and it looked nice, it was clear […] if it would have been shorter, then you would not understand it, because there would be less information in it'.*

The children thought the comic strip was funny, and they especially liked the 'green-nose flu'. Some children pointed out that there should be more humor or jokes in the story, '*because now it is […] a bit too serious, and we still like some jokes*'.

The children expressed that the design should be more appealing, because it was still a draft with simple sketches. One girl said that she really liked the pages that were already in color as an example of the final product. Two other girls indicated together that they enjoyed the *let's repeat* exercises in between the chapters.

Understanding

Understanding of 8 key concepts was assessed in order to obtain an indication of how well the information connected to the target group after the revision, and to identify topics that needed extra attention. As reflected in table 4, classes 1 and 3 achieved high average scores (86% and 95%) and performance of classes 2 and 4 was substantially lower (77% and 72%). Especially troublesome for class 2 and 4 was anonymity (54% and 42% respectively). As the chapter on privacy is at the end of the comic strip, it is likely that the lower score for this topic is partly due to the fact that not all children read it. In table 5 the scores for privacy are related to whether the child read the chapter, a X^2-test indicated a significant association between answer (correct/incorrect) and having read the chapter on privacy ($p<0.01$).

Table 4 Percentages of correct (+), incorrect (-) and blank (O) answers, per multiple choice question

Research aspect	**Class 1**			**Class 2**			**Class 3**			**Class 4**			**Total**
	+	-	O	+	-	O	+	-	O	+	-	O	+
Voluntary	78.6	21.4	0	77.3	22.7	0	96.0	4.0	0	69.2	26.9	3.8	80.2%
Best meds	92.9	7.1	0	95.5	0	4.5	100	0	0	80.8	15.4	3.8	92.1%
Withdraw	78.6	21.4	0	81.8	18.2	0	96.0	4.0	0	57.7	38.5	3.8	78.2%
Randomization	89.3	3.6	7.2	77.3	22.7	0	96.0	4.0	0	84.6	11.5	3.8	87.1%
Placebo	89.3	10.7	0	63.6	36.4	0	96.0	4.0	0	69.2	30.8	0	80.2%
Side effects	100	0	0	100	0	0	100	0	0	96.2	3.8	0	99.0%
Anonymity	82.1	17.9	0	54.5	40.9	4.5	80.0	20.0	0	42.3	57.7	0	65.3%
Therapeutic misunderstanding	82.1	14.3	3.6	68.2	31.8	0	96.0	4.0	0	76.9	23.1	0	82%
Average	86.6	12.0	1.4	77.3	21.6	1.1	95.0	5.0	0	72.1	26.0	1.9	83.0

Table 5 Percentage of correct answers, for children who reported to read the chapter on privacy

Privacy	Read chapter		Did not read chapter	
Correct answer	53	81.5%	13	37.1%
Incorrect answer	12	18.5%	22	62.9%
Total	65	100%	35	100%

(1 person missing, as this person did not fill in how many pages he had read)

Benefits and risks The majority of children (68.2-96.0%) understood that participation does not always benefit the child itself, that a participant does not necessarily receive the best medication (80.8-100%), and that there are risks involved, such as side effects of a drug (96.2-100%). This understanding was confirmed in the interviews, in which children answered that they would not necessarily have benefit or get well due to research participation. Explanations were given: '*the medicines might not work, so it might take longer before you are well again*' and '*I don't think so, because they don't know yet what the drug does*'.

Children were asked whether a drug could give side effects and they answered correctly that this is possible. When asked whether you always receive the best drug, children responded '*No, because they need to know which drug works best*; '*No, because there are different drugs and I think they don't know which one is the best, because they have not tested that*'.

Rights Children demonstrated a good understanding of the voluntary nature of research participation (69.2-96.0%), and of the right to withdraw (57.7-96.0%). When children were asked to explain 'informed consent' they were unable to provide an answer. However when asked '*if they ask you to participate in a study, do you have to do so?*' children answered '*you can choose whether you want to or not*'; '*no, you decide that yourself, because it would be quite unfair if you had to*'. Two boys together explained that you can decide upon participation on your own when you are over 18, and between 12 and 17, you decide together with your parents (as is the present situation in the Netherlands). In addition, children spontaneously pointed out that you can quit whenever you want.

The subject of privacy was less well understood (42.3-82.1%). Children indicated that their name would not be recorded for the research, but one boy thought that participation is not anonymous. There was some confusion as to how researchers would be able to contact you years after the research, after permission for follow-up. Three boys discussed '*in ten years, they want to know how you are doing, then they can always check that,* *I thought that was strange […] that they can know that in ten years, how it happens automatically, from a distance'*. Upon further inquiry, the boys had not understood that you could indicate whether you wanted to be contacted or not.

Procedures One of the chapters in the comic strip explained why research with children is necessary. Children were asked if they knew why children are involved in research. They demonstrated a clear understanding and gave explanations such as '*to look for better drugs […] so children can get well sooner*'; '*for diseases for which there is no drug, to make drugs […] and study those*'. When asked why we could not just use drugs that were already tested on adults, children answered that '*they have another body'*; '*from the inside it is very different*'; '*if you have something bad and you give the same [drugs] for adults to children, you never really know the outcome*', '*it could be very bad, or maybe not*'.

The concept of a placebo was well understood (63.6-96.0%). All interviewed children, except for one could explain it. One girl did not know, but said she thought she had not read that chapter. Only half of the children were able to give a correct explanation as to why you would use a placebo, e.g. '*if you have the real drug, and you get well just as much as when you had the placebo, then the drug does not work, it happens on its own*'.

In the comic strip, the concept of randomization is explained as a computer that picks the treatments, instead of the doctor or the child. The survey question on this complicated topic was answered correctly by the majority of children (77.3-96.0). When children were asked who determines which treatment you receive, most answered '*the computer*'. One girl however answered '*I did not know that one, I think the computer, but then it can be entered in the computer*'. This indicates confusion about the role of the computer, which plays a role in the explanation of random treatment assignment, as well as in the concept of a biobank ('a freezer for samples and a computer for data'). This confusion also becomes apparent in the answer of one boy to the question if he knows what a biobank is: '*I think it was something with a freezer and a computer. Then you can do research there, and pills are being prescribed, if I'm right, and that is done by the computer, if I'm right, I don't know for sure*'.

Discussion and Conclusion

Discussion

Understanding of current pediatric consent/assent material is often poor, due to complex language and long documents (J. B. Green et al., 2003; Hunfeld & Passchier, 2012). The use of plain language and pictures, such as in a comic strip, is a promising strategy to increase understanding (J. B. Green et al., 2003; M. J. Green & Myers, 2010; Mayer, 2001). Therefore, a comic strip was developed and the target group was consulted in the process. As children are the experts regarding their information needs and preferences, they need to be consulted in order to optimize understanding and user satisfaction of the information. A total of 148 children of various ages and educational level were consulted in our study and provided feedback for the further development of the information material. A mixed-methods design consisting of both a survey and qualitative interviews was used to collect feedback. This design enabled us to triangulate the data and gain more insight in the perspectives, understanding and opinions of the children.

User satisfaction

Children enjoyed reading the material and liked it that the information was provided as a comic story format instead of plain text. Many children commented that the color in the comic strip should be improved, which is a valid suggestion as it was only a draft. In the final version, more color will be used. In addition, more humor will be added at the end of the story, as recommended by the children.

The length of the story already has been reduced based on first evaluations. In the re-evaluation, a number of children still indicated that the comics strip was too long. This is reflected in the data on how many pages children had read. However, the majority of children would read at least 30 pages. This is sufficient, as in an actual trial, children will only need to read the chapters applicable to their situation. We therefore intend to instruct providers of the comic strip to indicate which chapters are relevant for the child. For example, when there is no randomization in a trial, this chapter needs not to be read.

Understanding

Understanding measurements can indicate how well the material connected to the children. The combined data of the survey and the interviews indicate that children have a good to reasonable understanding of the basic aspects of research after reading the comic strip. Understanding of key research concepts in the survey ranged from 65.3% to 99.0%, with an average of 83.0%.

There was variation between school classes; class 1 and 3 outperformed class 2 and 4. This is partly explained by class 3 being of a higher educational level than class 4, although class 1 and 2 are of mixed educational level and we cannot draw such a conclusion. The variation is thus possibly showing that the information connects better to certain educational levels in the target group than others, indicating room for improvement in order to connect better to the varied target group.

The main points for improvement, as indicated by the children, are the chapters on privacy, placebo and randomization. Additionally, children did not understand the term 'informed consent', but were aware of their rights to be involved in consent and to withdraw during research. Therefore, the specific term should be replaced with a more common term, such as 'permission'.

Evaluation of participatory design

The participation of children in our research offered us valuable insights that we could not have achieved without their involvement. Children are the experts on what they like and what they can understand, and therefore, we could not have developed the comic strip in the same way without their input (C. Hart & Chesson, 1998; Lansdown, 2001). Most children spontaneously told us that they were excited to participate in our research and that they 'could be a part of science'. Most children were enthusiastic to participate and also wanted to be interviewed. Due to time constraints (school hours), we could not even interview all children who wanted to be interviewed. Involving children in research is thus not only interesting and valuable for the scientist, but also for the children.

Limitations

Feedback was collected among healthy school children, although the target group of the comic strip consists for a major part of ill children, who might have less energy or concentration than their healthy peers. Therefore, more research is required to adapt the material for ill children in the more stressful hospital context.

The interviews were conducted on a voluntary basis: children, who indicated that they did not want to be interviewed, were not interviewed. This might have led to a response bias: it is likely that children interviewed were either very interested in giving their opinion, or had a strong opinion.

Understanding was measured with a non-validated questionnaire and only one question was asked per research aspect. Therefore, measured understanding cannot be generalized outside of this research. The results serve only as an indication of the clarity of the comic strip at this stage. Rigorous testing is necessary to be able to draw more generalized conclusions. A randomized controlled trial with a validated instrument in a clinical situation will be performed in further research.

Conclusion

Information provided to children in the informed consent process should optimally reach the target group. To this aim, a participatory development of pediatric consent material was set up. Participating children were enthusiastic about their input in the development and offered useful feedback and new perspectives. The comic strip was much appreciated and indications of understanding suggest the material has the potential to improve understanding of research information in the clinic.

Practice Implications

In order to improve information provision for children in medical scientific research, material should be developed together with these children. Such a participatory development process yields information material that optimally appeals and connects to the target group. Moreover, it could possibly lead to increased understanding and can greatly support children in the decision-making process. Ideally, children should be involved in the development of medical information on a regular basis, such as is being done in the MCRN Children & Young Persons' Advisory Group in England, where children can express their views on medical research (NIHR, 2014).