E&HR

The Importance of Engaging Children in Research Decision-Making: *A Preliminary Mixed-Methods Study*

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Table 1.
Participant Characteristics

Variable	*Mean ± SD/N(%)*		
	Total sample	*Ill child dyad*[1]	*Healthy control dyad*
	N = 31	*N = 20*	*N = 11*
Child			
Age, years	11.7 ± 3.1	12.4 ± 2.9	10.5 ± 3.1
Female sex	15 (48%)	4 (36%)	11 (55%)
White, non-Hispanic	24/30 (80%)	13/19 (68%)	11/11 (100%)
Participation in prior study	16 (52%)	10 (50%)	6 (55%)
Parent			
Age, in years	43.3 ± 7.4	43.5 ± 8.2	42.8 ± 6
Female sex	29 (94%)	18 (90%)	11 (100%)
Married	23 (74%)	12 (60%)	11 (100%)
Education			
High school	4 (13%)	3 (15%)	1 (9%)
Up to two years of college	8 (26%)	6 (30%)	2 (18%)
Four years of college	6 (19%)	3 (15%)	3 (27%)
Graduate or doctoral	13 (42%)	8 (40%)	5 (45%)

[1] Of the 31 children interviewed, 11 were enrolled in their research study as healthy controls, while 20 were enrolled due to illness. Illnesses included spinal muscular atrophy, endometriosis, short stature, asthma, autistic spectrum disorder, and sickle cell disease.

Table 2.
Factors Related to the Child's Actual Decision-Making Role

Variable[1]	*Spearman correlation r (p-value)*	*Effect*	*Possible implication*
SSCI	r = 0.35 (p = 0.005)	Greater decision-making role for higher comprehension score	Understanding information is a key component of participating in decision-making.
Child or parent read information they received	0.005	Greater decision-making role if read information	Study team-participant interaction is important for decision-making.
Child was asked by doctor about participation	0.01	Greater decision-making role if study doctor asked about participation	Study team-participant interaction is important for decision-making.
Child's race	0.03	Greater decision-making role for children of white race compared to African-American children	Awareness of potential for differential involvement for different races may help study teams in communicating with families; family decision style may play a role.
Parental marital status	0.02	Greater decision-making role for children of married parents	Comprehension of information and support for decision-making may vary by family structure.

[1] Fisher's exact tests (effect size N/A) were used to evaluate the association between the child's actual role in decision-making and categorical covariates. Spearman correlation coefficients (effect size noted as r in table above; positive values correlate with greater child involvement) were used to evaluate the association between the child's actual role in decision-making and continuous covariates (SSCI for comprehension). We evaluated several other potential predictors of decision-making role including comprehension (MISQ), verbal and similarities scores on the WASI, age, prospect of direct benefit, education level, the amount of information given to the child, family decision preferences, prior research participation, sex, whether the child was asked by the parent about participation; these were not associated with decision-making role (data not shown).

Table 3.
Factors Related to Child Comprehension

Variable[1]	χ^2	*p-value*	*Effect*	*Possible implication*
WASI verbal	0.73	<0.0001	Higher score on verbal subscale related to greater comprehension.	Assessing verbal comprehension may illuminate opportunities to improve comprehension.
WASI similarities	0.61	0.0003	Higher score on similarities subscale related to greater comprehension.	Assessing ability to manipulate information may illuminate opportunities to improve comprehension.
Child age	0.57	0.001	Higher age related to greater comprehension.	Age-related materials are important.
Child education	0.62	0.0003	Higher education related to greater comprehension.	Assessing education level or deviation from level expected for age may provide opportunities to improve comprehension.
Whether child or parent read information they received	8.5	0.003	Reading information led to greater comprehension.	Written materials provide important media for information sharing with children.

[1] Kruskal Wallis tests (effect size noted as χ^2) were used to evaluate the association between comprehension and categorical covariates. Spearman correlation coefficients (effect size noted by r) were used to evaluate the association between comprehension and continuous covariates. We evaluated several other potential predictors of comprehension, including prospect of direct benefit, the amount of information given to the child, family decision preferences, prior research participation, sex, child's race, parental marital status, whether the child was asked by the study doctor about participation, whether the child was asked by the parent about participation; these were not associated with comprehension (data not shown).

Table 4.
Representative Reasons for Preferred Decision-Making Role

Theme	*Code*	*Excerpt*	*Respondent ID, child's age*
Greater parent involvement	Age	"At this age, I think it is probably the most appropriate for me to identify opportunities."	Parent #17 7 years old
	Parental responsibility is primary	"But then my parents are my parents so they kind of control . . ."	Child #7a 14 years old
	Child lacks understanding	"Because basically she doesn't really understand what is in there and what is going to be done. Because you can explain to her, but she doesn't really know, like when we're talking to her about a study, she didn't really understand."	Parent #16 11 years old
	Parent understands	"I would have a better understanding of what it entails, and the benefits, and then just inform him of what it's all about. But just in terms of the decision, I would understand better."	Parent #34 12 years old
	Parent responsibility to ensure study completed	"Because they have to be there, and it's like an hour drive in."	Child #6 17 years old
Relational involvement	Shared responsibility	"They know a lot more about, like, what I should be doing or shouldn't be doing, but I also think that I should have some opinion in what I'm going to be doing."	Child #18 12 years old
	Parent helps child understand	"But she's only seven, so, you know, she needs help from us sort of explaining this is what it's about."	Parent #10 7 years old
	Parent imparts altruism	"But if I can help him understand why it would be potentially useful to other people, then I can tell him those things, and then he can tell me whether he objects to it."	Parent #11 9 years old
Greater child involvement	Child preferences or wishes	"I didn't want her to participate in something that she didn't want to participate in."	Parent #31 11 years old
	Child experiences study burden	"Because I'm doing the work of getting poked and having to do all of the hard stuff."	Child #4 11 years old
	Child's body	"Because I think it's my body . . . so I think I should be able to make the final decision."	Child #27 16 years old
	Maturity	"I would say depending on the maturity of the child, given my background and how I can explain this to my kids, then I would let them equally make the decision."	Parent #7 14 years old
	Child's decision in the absence of direct benefit	"Because there is no direct benefit to my daughter in terms of her physical health, emotional health, mental health, um, she needs to have as much of a buy-in in wanting to help others in this study as I do."	Parent #14 11 years old

Table 5.
Representative Excerpts for Reasons for Child Satisfaction

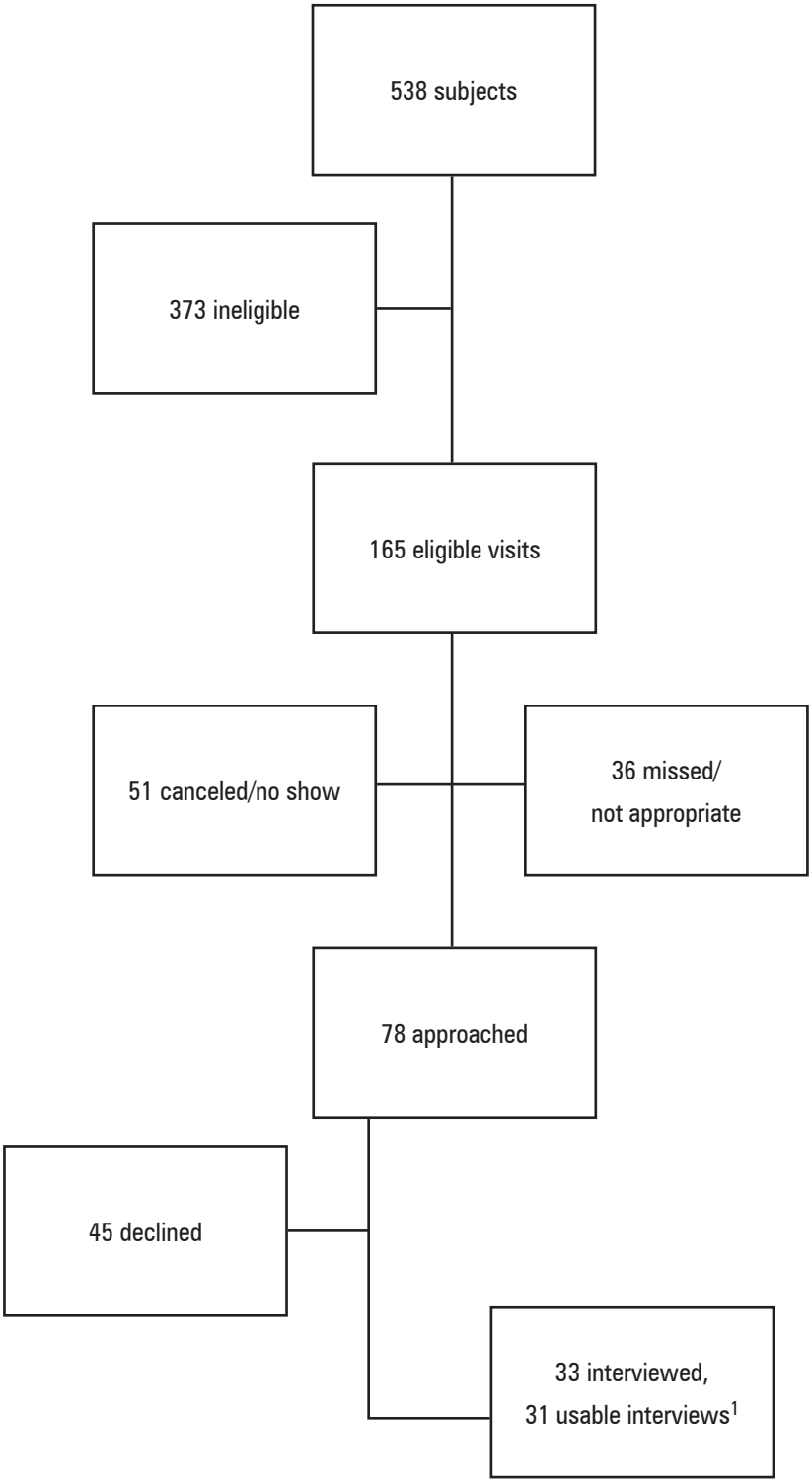
Theme	*Code*	*Excerpt*	*Respondent ID, child's age*
Process-related factors	Autonomy	"I was happy that my parents actually wanted to know what I thought first, because if I didn't want to do it, they weren't going to do it at all."	Child #18 12 years old
	Parent encouraged	"We got a letter. And my parents read it, and then they told me. And that was about it."	Child #7b 13 years old
	Shared responsibility	"I was satisfied because I got my say in it and my parents got a say in it. So, I was satisfied."	Child #14 11 years old
Research-related factors	Experience	"I was because, like, well, I was satisfied with it because I thought it would be like just boring test studies, but we ended up doing a lot of things to test for, and it was exciting."	Child #23 12 years old
	Altruism	"Because if we help other children, we'll get something out of it. Like when you have asthma and the people have asthma and the doctors don't know how to treat it. That's how you can help them."	Child #20 9 years old
	Low burden	"I guess just it didn't seem like it was really that much of a bother to do, so may as well."	Child #6 17 years old
	Incentive	"And then they told me about the $40, so I said yes."	Child #12 8 years old
	Belief in benefit	"Because I had been in pain for a long time, and it was finally going to get better, and I was going to be able to basically do the exact same thing that I would have on my own, but it was actually going to help someone else too."	Child #21 17 years old

Appendix.
Shared Decision-Making Scale

- When thinking about being in a research study, who in your family should make the decision about whether or not you participate?
  [Options included "parent alone," "mostly parent," "parent and child equally," "mostly child," and "child alone."]
- Why do you think that [INSERT ANSWER] should make the decision about whether or not you participate?[1]
- When you joined the research study, who in your family actually decided that you would participate?
  [Options included "parent alone," "mostly parent," "parent and child equally," "mostly child," and "child alone."]
- How much say did you have in the decision to join the research study?
- How much information were you given about the research study?
- Did the study doctor include you in the discussion about the study?
- Did the study doctor ask you whether or not you wanted to be in the study?
- Did your parents ask you whether or not you wanted to be in the study?
- Were you satisfied with how the decision about being in the study was made? Why, or why not? What do you remember most about the experience?[1]
- Did you read the informed consent form for the research study?
- Did you read any other information about the research study?

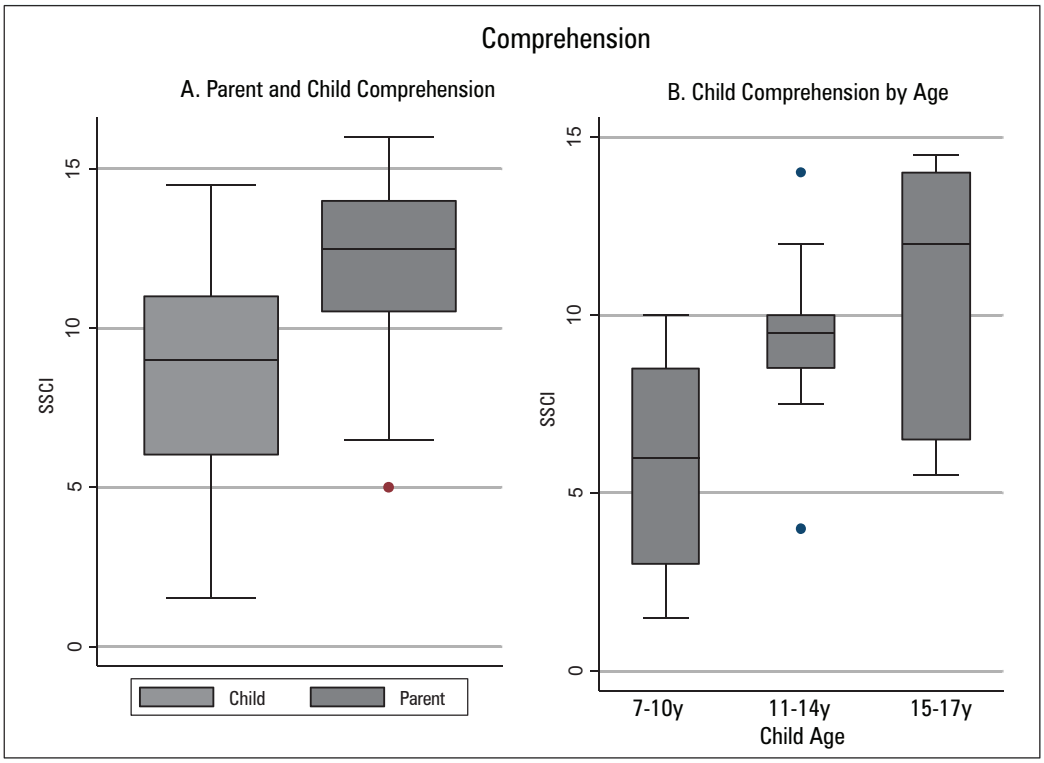
[1] These questions underwent qualitative analysis.

Figure 1.
Enrollment of Parent-Child Dyads



[1] The response rate was 31/76 (41%), excluding unusable interviews. Subjects were enrolled from seven protocols.

Figure 2.
Comprehension of Parent and Child Subjects



A. Median parent SSCI = 12.5, interquartile range (IQR) = 10.5, 14; median child SSCI = 9, IQR = 6, 11.
Wilcoxon signed rank z = -4.2 ($p<0.00001$).
B. Kruskal Wallis for child comprehension by age group = 9.6 ($p = 0.008$).