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Title **Processes in Recruitment to Randomized Controlled Trials of Medicines for Children (RECRUIT): A Qualitative Study**

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Aim

To investigate clinical trial recruitment processes from the perspective of parents, young people, and practitioners to identify strategies to improve recruitment and its conduct across the spectrum of trials of medicines for children.

Conclusions and results

Practitioners were concerned to avoid overburdening parents, and some indicated that they found approaching families about trials to be aversive. By contrast, parents did not mind being asked about trials and did not describe the approach as burdensome. Some parents viewed the trial approach as a positive opportunity. Parents and young people took little active part in the trial discussions and asked few questions. They were satisfied with how they had been approached, and spoke of how they had felt involved, valued, cared for, and comfortable to interject during the discussion. Yet, we identified several parents who had important misunderstandings about the trial. We found few differences between parents who consented and those who declined a trial. Parents' trial decisions were influenced by their perceptions of the trial in relation to their child's safety and well-being, potential benefits to the child and family, potential benefits to others, and the practicality of participation. Of these, parents' main consideration was safety. Parents', young people's and practitioners' views of what was important when considering a trial were broadly convergent, but families gave greater importance than practitioners to the trial's practical requirements. All parties highly valued the face-to-face trial discussion and wanted shorter, less complex, written information. Parents did not feel pressured by the trial team to participate, but some described how their personal values made them reluctant to decline. Several parents who declined described a passing sense of discomfort with the decision. Concerns of some practitioners that families would be overburdened were unfounded; parents did not object to being asked about research. Practitioners may benefit from support that helps them feel personally more at ease in approaching families about trials. Parents and young people often described the trial discussions in strongly positive terms and emphasized the importance of the social and emotional aspects of these encounters. Informed consent training could be enhanced if it similarly emphasized these aspects of recruitment; the misunderstandings we identified indicate how this training could help practitioners improve the clarity of their trial discussions with families. Guidelines on informed consent documents should note that all groups thought that these documents should be shorter and more straightforward.

Recommendations

See Executive Summary www.hta.ac.uk/project/1530.asp.

Methods

This qualitative interview and observational study (RECRUIT) ran alongside 4 diverse trials of medicines for children. Data were verbatim transcripts of (1) audio-recorded trial recruitment discussions between practitioners and families (n=41) and (2) semistructured interviews exploring the experience of trial recruitment from the perspective of parents (62 individuals from 60 families), young people (n=22), and recruiting practitioners (19 doctors and 12 research nurses). Of the 60 families, 39 were randomized and on trial, 10 declined, 3 were randomized but withdrew, and 8 were ineligible. Interpretive analyses using the general principles of the constant comparative method were combined with descriptive summaries of recorded trial discussions comprising some quantitative measures.

Further research/reviews required

See Executive Summary www.hta.ac.uk/project/1530.asp.

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