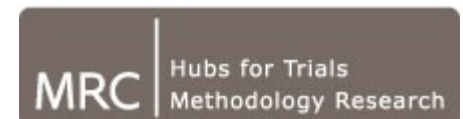


What parents think about being approached about children's trials, how this differs from what practitioners expect, and what this tells us about enhancing recruitment

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The RECRUIT study

- Qualitative study of recruitment to clinical trials of medicines for children
- Aimed to identify ways to optimise recruitment and its conduct



Participating trials

4 double-blind randomised placebo controlled trials

- MASCOT – Management of asthma in school age children on therapy
- MENDS - Use of melatonin in children with neurodevelopmental disorders and impaired sleep
- POP – Prevention and treatment of steroid induced osteopaenia in children and adolescents with rheumatology diseases
- TIPIT – Thyroxine in preterm infants trial

Method and analysis

- Practitioners audio-recorded trial discussions with families
 - Examined percentage speech by each party, question counts, types of questions etc
- Interviewed parents and practitioners about their experiences of recruitment
 - Analysis followed the principles of the constant comparative method

Sample

- Sampled from 11 research sites
- Audio-recorded 41 trial discussions
- Interviewed parents from 59 families
 - 10 families had declined a trial, 3 withdrew, 8 were ineligible and 38 were randomised
- Interviewed 31 practitioners (12 research nurses and 19 doctors)

Audio-recorded trial discussions

- Parents' median percentage speech was 16% of total words spoken
- Practitioners tended to use closed questions:
- *Does that make sense? (TD3); Are you with me so far? (TD2)*
- Parents asked few questions (median=1)

Parents' experiences of trial discussions

*I thought it was perfect and I don't think there is any room for improvement, to be honest
(F35)*

Parents' experiences of the trial discussions

- Parents emphasised the social aspects of the trial discussion

*Lovely people, they were really, really nice and **made us feel really welcome and really comfortable** (F1)*

- Confidence in practitioners

*You could see **he was passionate** about [...] the trial [...] that just, just **aids things. It makes it more comfortable** (F51)*

- Child's safety and needs were central

*I know it's not harming him [...] I was like **"Go ahead with it 100%"** (F41)*

Parents did not mind being asked about trials

- Parents told us that the timing of the approach was sometimes difficult

*It went sort of like **in one ear and out the other** [...] she was so small and so poorly (F46)*

- But when asked if the approach could have been improved said

***No, I don't think so. The doctor was really nice, he was nice and clear** (F46)*

Parents did not mind being asked about trials

- Parents accepted that practitioners needed to ask them about trials

Doctors definitely [should] feel [...] able to approach the parents. I definitely think that because without approaching them obviously they won't be able to do the trials (F40)

- Some indicated that they were “excited” to be approached or would have been disappointed if they had not been asked

You don't want to think [...] there's [...] a trial that could improve your child's <condition> and your child hasn't been offered that [...] I would like to be asked (F50)

Practitioners were concerned with information and understanding

- Difficult balance between informing but not overwhelming

I worry about [...] the families that just say, '[...] it's all right, I don't need to read the information sheet. I'm happy, whatever you say (P5)

Practitioners were concerned for families

*These are **very, very sick kids** [...] you're going up to them and this is **yet another consideration for them** (P2)*

- Some questioned whether it was appropriate to discuss research at all

*This **family is at a terrible time** and really, **is it right to be asking them to do this?** (P19)*

Some practitioners were apprehensive

I will go and approach them but I feel, I feel very uncomfortable doing it every single time (P18)

Each parent is different and causes me great anxiety (P16)

Stressful for the family [...] stressful for you (P12)

Conclusions and implications

- Despite saying little during trial discussions parents described feeling comfortable and involved and they valued the way that practitioners explained the trials
- But practitioners were often concerned that families were overwhelmed with information

Conclusions and implications

- Parents did not object to being asked about trials and many positively wanted to be approached
- By contrast, practitioners saw research as a potential burden for families and some felt anxious about approaching them
- Understanding patient/family perspectives may help practitioners in recruiting vulnerable patients to clinical trials

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