

# Learning from the differing perspectives of families and clinicians to optimise recruitment to children's clinical trials

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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

- Audio recorded routine discussions about the clinical trial between recruiting practitioners and families
  - Examined percentage speech by each party, question counts, types of questions etc.
- Subsequent qualitative interviews with parents and with practitioners
  - Explored their experiences of the recruitment process

# 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 the trial discussions



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*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

- 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' experiences of the trial discussions

- 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  
*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' experiences of the trial discussions



# 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)*

- Ensuring sufficient understanding without forcing information on families

*The mere fact that **you insist on talking** about things [...] the fact that **they've said 'yes [...]'** and you somehow want to **argue with them** (P1)*

## 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

- 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
- Parents did not object to being asked about trials and many positively wanted to be approached
- By contrast, practitioners often saw research as a burden for families and some felt anxious about approaching them

# Implications

- Having an understanding of patient/family perspectives may help practitioners in recruiting vulnerable patients to clinical trials
- Question the assumption that inviting patients to join a trial necessarily burdens them
- Recruitment is not just about information – it also has important social dimensions
- Recruitment seemed an arduous process for some practitioners – need to improve their experience?

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