

FOCUS ON RESEARCH

PATIENTS' PERSPECTIVES ON PARTICIPATION IN RANDOMISED CONTROLLED TRIALS

Researchers

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Aim

The study sought to improve understanding about the range of views people have about participation in RCTs, and specifically to explore those factors impacting on participation in the REFLUX trial (a UK multicentre RCT assessing the effectiveness and cost effectiveness of minimal access surgery compared with long term medical management amongst people with gastro-oesophageal REFLUX disease). A subsidiary aim was to develop recommendations about approaches to trial design and conduct that may improve the future experiences of participants involved in clinical trials.

Project Outline/Methodology

The study had three components:

(a) Review of the literature on (potential) participants' views of RCTs; (b) Synthesis of previous qualitative research on participant participation in RCTs; and (c) Case study of recruitment and participation within an ongoing UK multi centre RCT [the REFLUX trial]. Potential trial participants were recruited using purposive sampling in two recruitment centres with varying recruitment procedures and accrual rates. Non-participant observation and in-depth interviews were used to explore patients' experiences of recruitment and participation in the trial.

Key Results

Rather than people simply focusing on aspects of a trial *per se* when deciding whether or not to participate in a trial, decision-making took place in a broader personal context, such as people's past and present medical experiences; perceptions of treatment and levels of symptom control; and prior experience of interventions. Views about the trial procedures, treatment interventions, and impressions of recruiting staff were also found to be important as people decided whether or not to take part in a trial.

Although altruism was identified as a factor impacting on trial participation, this tended to be 'conditional' on expectations of personally benefiting from participating in a trial.

Being able to see some direct personal benefit from joining a trial was found to be closely associated with a willingness to participate in a trial. Perceptions of self-benefit were linked directly both to the trial intervention(s) and trial processes. For example, being able to speak to an "expert"; being considered for an 'alternative' treatment; and potentially having access to 'quicker' treatment or a higher standard of care than might otherwise be available all appeared salient.

Experiences of trial participation were generally found to be positive. Perceptions of trial involvement, and having directly benefited from trial participation seemed particularly dependent on which treatment people were subsequently allocated to.

Conclusions

By examining RCTs from participants' perspectives, this study has identified a number of issues relating to trial participation that have implications for those recruiting for future trials.

What does this study add to the field?

The findings from this study have illustrated that trials are not simply an experimental tool operating in a vacuum, independent of the views and experiences of participants.

Implications for Practice or Policy

The findings offer some valuable insights into people's experiences of trial recruitment and participation, and suggest a number of lessons for trialists undertaking future trials, and recommendations for future research.

Where to next?

Dissemination of the results to trialists is required. Further in-depth qualitative studies embedding qualitative methods into ongoing trials, to explore patients' experiences in other trial settings and with different kinds of health issues.

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