

Why don't they just tell me straight, why allocate it? The struggle to make sense of participating in a randomised controlled trial.

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“Why don't they just tell me straight, why allocate it?”  
The struggle to make sense of participating in a randomised  
controlled trial

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### Abstract

Randomised controlled trials are the acknowledged “gold standard” method of evaluating the effectiveness of treatments, but little is known about how and why patients decide to participate in trials nor how much they understand about trial design. In this study, in-depth, semi-structured interviews were carried out with 33 middle aged and older men with lower urinary tract symptoms related to benign prostatic disease, 22 of whom had consented to participate and 11 refused to take part in a randomised trial. The trial was evaluating the effectiveness of a new technology (laser therapy) compared with standard surgery (transurethral resection of the prostate) and conservative management (monitoring without active intervention) (the *CLasP* study). Purposive sampling was used to include participants from different centres, each treatment arm

sampling was used to include participants from different centres, each treatment arm, and at different stages in participation, as well as those indicated to have refused participation. Interviews explored their recall and understanding of trial information, and their reasoning about how they were allocated to a treatment. Data were analysed thematically according to the methods of constant comparison, and by examining each participant's narrative of their experiences.

Most participants recalled major aspects of trial design, including the involvement of chance, but the case studies showed that most also held other co-existing (and sometimes contradictory) views about their treatment allocation. The key to understanding their experiences was their engagement in a struggle to understand the trial in the context of their own beliefs, their recall of the study information and their actual experiences of the trial. The outcome of the struggle was the placing of trust in clinicians or the development of distrust. Non-participants made sense of their experiences in similar ways, but gave different reasons for non-participation than indicated by recruiters.

This study shows that most eligible patients, whatever their level of knowledge, will struggle to make sense of their participation in randomised trials. The provision of clearer written information or time to discuss the trial with particular individuals might be beneficial, although greater public understanding of trials is also needed.



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## Keywords

Randomised controlled trials; Trial participation; Patient understandings; Prostatic disease

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The goal: a process of ongoing improvement, inheritance, as follows from the system of equations, chooses the social cult of personality.