



Title	Lay Public's Understanding of Equipoise and Randomization in Randomized Controlled Trials (RCTs)
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Aim

1. To learn why participants in RCTs are at risk of failing to understand or remember about randomization and equipoise.
2. To investigate the background knowledge about randomization and equipoise which members of the public are likely to have if invited to participate in an RCT.
3. To explore, in the context of hypothetical trials, the effects of providing information designed to overcome barriers to understanding and recall of randomization and equipoise.

Conclusions and results

Trial participants, despite being informed, often fail to understand or remember about randomization and equipoise. Patients' expectations about treatment decisions may make it hard for them to understand information about randomization and equipoise. Hence, consent or refusal might be inadequately informed.

Investigations 1 to 6 addressed the following questions: *Do members of the public understand and accept randomization?* Most participants correctly judged which methods of allocation were random, but judged random allocation methods in RCTs to be unacceptable. *Do members of the public assume new treatments are better?* Merely describing a treatment as new was insufficient to engender a preference for it over a standard treatment. *Do they accept doctors' individual equipoise?* Around half the participants denied that a doctor could be completely unsure about the best treatment. *Do they accept doctors' suggestions of random allocation given equipoise?* Most participants judged it unacceptable for a doctor to suggest letting chance decide when uncertain of the best treatment. A research context may render randomizing less unacceptable. *Do they believe random allocation has scientific benefits?* Participants did not recognize scientific benefits of random allocation over normal treatment allocation methods. Investigations 7 to 9 examined the consequences of explaining the reasons for randomizing.

In Investigation 7, a brief justification for randomization was not helpful. In Investigations 8 and 9, this brief justification and an extended explanation enabled participants to recognize the scientific benefits of random allocation. The results from Investigations 7 to 9 suggest that merely supplementing written trial information with an explanation is unlikely to be helpful. However, when people focus on the trial's aim of increasing knowledge, and process an explanation actively by answering test questions, they may be helped to understand the scientific reasons for random allocation.

Recommendations

Results highlight the disparity between assumptions underlying trial design and those the lay public may draw on if invited into an RCT. Many potential trial participants know what random allocation is, but find it unacceptable, find equipoise unbelievable, and see no reason to randomize. They are likely to have difficulty understanding and remembering trial information about randomization and equipoise. Explaining the scientific benefits of randomization may be helpful if participants can reflect on the trial's aim of advancing knowledge and think actively about the information presented.

Methods

Please refer to the NCCHTA website – via the Executive Summary link above.

Further research/reviews required

How do different forms of oral accompaniment influence participants' understanding of written trial information? We need to identify effective combinations of written and oral information. How can potential trial participants be helped to take a research perspective and thereby improve their understanding of random allocation and equipoise? Can (and should) research ethics committees expect trialists to have evaluated information leaflets on relevant patient groups? The current emphasis is on leaflets' adherence to national guidelines. An evidence based approach to leaflet construction may be valuable.