Lay public's understanding of equipoise and randomisation in randomised controlled trials

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Executive summary

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Executive summary

Objectives

- To understand why, despite efforts to make trial information clear, participants in RCTs are at risk of failing to take in or remember information about random allocation and equipoise.
- To investigate the background knowledge about randomisation and equipoise that members of the public are likely to bring to bear if invited to take part in an RCT.
- To explore in the context of hypothetical trials the effects of providing information designed to overcome barriers to understanding and recall of randomisation and equipoise.

Methods

Reviews

The investigations were informed by an update of an earlier systematic review on patients' understanding of consent information in clinical trials, and by relevant theory and evidence from experimental psychology.

Investigations

Nine investigations were conducted, involving healthy adult participants with a wide range of educational backgrounds and ages. Use of hypothetical scenarios allowed precise comparisons to be made between conditions in ways that would be both impractical and unethical in real clinical settings, but which could produce results relevant to real trial consent procedures. Investigations 1–6 (n between 67 and 130) examined participants' background assumptions concerning equipoise and randomisation. Investigations 7–9 (n = 128) explored ways of helping participants to recognise the scientific benefits of randomisation.

Results

Reviews

Recent literature continues to report trial participants' failure to understand or remember information about randomisation and equipoise, despite the provision of clear and readable trial information leaflets. Within the context of research in experimental psychology this is unsurprising. Patients' expectations about normal treatment decisions may make it hard for them to take in information about randomisation and equipoise. Even if patients realise that normal treatment decision-making is not going to take place, they may lack appropriate scientific background knowledge to interpret trial information as intended. In current best practice, written trial information describes what will happen without offering accessible explanations. As a consequence, patients may create their own incorrect interpretations and consent or refusal may be inadequately informed.

Investigations

Investigations 1–6 addressed the following questions.

- *Do members of the public understand and accept randomisation?*
  In investigation 1, participants judged which methods of allocation were random. The majority judged correctly. However, most judged the random allocation methods to be unacceptable in a trial context.

- *Do members of the public assume that new treatments are better?*
  In investigation 2, the mere description of a treatment as new was insufficient to engender a preference for it over a standard treatment.

- *Do they accept doctors' individual equipoise?*
  In investigations 3 and 6 around half of the participants denied that a doctor could be completely unsure about the best treatment.

- *Do they accept doctors' suggestions of random allocation given equipoise?*
  In investigations 3 and 6, a majority of participants judged it unacceptable for a doctor to suggest letting chance decide when uncertain of the best treatment. Randomising for research purposes may be judged less unacceptable.

- *Do they believe that random allocation has scientific benefits?*
  In investigations 4–6, in the absence of a justification for random allocation (none is

currently recommended for real trial information leaflets), participants did not recognise scientific benefits of random allocation over normal treatment allocation methods: they failed to judge that doctors would be more sure about which of two treatments was better when allocation was at random rather than by doctor/patient choice.

Investigations 7–9 examined the consequences of explaining the reasons for randomising. In investigation 7 a pre-existing brief justification for randomisation did not help participants to recognise the scientific benefits of random allocation. With more demanding procedures used in investigations 8 and 9, both this brief justification and an extended explanation led participants to recognise that more certain knowledge would arise with random allocation than with doctor/patient choice. The pattern of results across investigations 7–9 suggests that merely supplementing written trial information with an explanation is unlikely to be helpful. However, when people manage to focus on the trial's aim of increasing knowledge (as opposed to making treatment decisions about individuals), and process an explanation actively by answering test questions, they may be helped to understand the scientific reasons for random allocation.

Conclusions

This research was not carried out in real healthcare settings. However, participants who could correctly identify random allocation methods, yet judged random allocation unacceptable, doubted the possibility of individual equipoise and saw no scientific benefits of random allocation over doctor/patient choice, are unlikely to draw upon contrasting views if invited to enter a real clinical trial. This suggests that many potential trial participants may have difficulty understanding and remembering trial information that conforms to current best practice in its descriptions of randomisation and equipoise.

Given the extent of the disparity between the assumptions underlying trial design and the assumptions held by the lay public, the solution is unlikely to be simple. Nevertheless, the results suggest that including an accessible explanation of the scientific benefits of randomisation may be beneficial provided potential participants are also enabled to reflect on the trial's aim of advancing knowledge, and to think actively about the information presented.

Recommendations for research

The findings of this study raise the following questions:

- How is participants' understanding of written trial information influenced by different forms of oral accompaniment? A leaflet may be understood and remembered more or less well depending on what is said during recruitment. Effective combinations of written and oral information need to be identified.
- How can potential trial participants be helped to take a research perspective and thereby improve their chances of understanding about random allocation and equipoise? Participants tend to construe a trial as aiming to identify the best treatment for each recruit. Informed decision-making may be more likely if participants can reflect on the aim of advancing knowledge.
- 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.

Publication

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NHS R&D HTA Programme

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