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Commentary: an imperfect compromise

Martin Dennis

Boter and colleagues have proposed a compromise to obtaining fully informed consent before enrolment for randomised trials that have primary outcomes based on a subjective measure, which makes blinding impossible and bias likely. This compromise aims to involve the patient and show them as much respect as possible. As with all compromises it is imperfect. From the trials’ point of view it still has several drawbacks compared with obtaining consent only for follow up.

Telling patients that there is a secret additional research question is likely to reduce the proportion of patients who agree to participate and thus the generalisability of the trial’s results. The number of patients who refused to participate in the study, and their characteristics compared with participants, would indicate the size of this problem.

The wording of the patient information is bound to raise curiosity about the nature of the additional questions. Some participants may make the link between the intervention they receive and the questions asked at follow up. This would introduce an unknown amount of bias, although it is likely to be small.

The reassurance given to patients that the “additional question entails no risk” is potentially misleading. Firstly, if the intervention improves outcome then those in the control group will have a risk of a worse outcome. This statement could therefore be used only when the patient would have access to the intervention only within the trial and where the control arm would receive normal care. Also, in our trial, those allocated a stroke family care worker judged themselves more helpless than controls at follow up. We have subsequently shown that helplessness in these stroke patients was associated with poorer long term survival, even after we adjusted for important prognostic factors. No treatment should be assumed to be free of adverse effects. Perhaps the reassurance should read that there are no likely adverse effects.

No doubt the ethicists, who focus mainly on the rights of the individual, will see this compromise as unacceptable. They do not have to struggle with the everyday double standards applied to consent procedures in research compared with those in routine care and audit. We have no universally accepted solution to the clinical trialists’ dilemma that to provide treatments of proved benefit to many future patients (and to avoid putting them at risk) we may sometimes have to compromise the rights of current patients to be fully informed in advance about treatment options and research methods.

Of course, we shouldn’t have to rely on what the ethicists or the trialists think. Surely, we should involve potential participants in the design of the consent procedure. We should ask the patients who were enrolled in this study for their views. Did they feel, once they had been informed, that they had been treated with respect? Was the approach taken in this case acceptable to them?

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