References


In Reply:—We are pleased that our study has generated further discussion of informed consent and participation in clinical research. Erb and Sugarman state that prerrandomized consent (whereby patients are randomized to a treatment group before they provide consent) may be unnecessary or unethical. Prerandomization is not new and has been used in anesthesia research; although not without controversy. Its success, at least as measured by the recruitment rate, has also been previously tested in a volunteer study. We acknowledge that prerandomization is contentious and should be subject to scrutiny and debate. We did not set out to test its validity, but instead to measure its efficacy in improving recruitment rates in the preoperative period. We found no such benefit; therefore, given the ethical concerns raised by others, we recommended its abandonment.

Erb and Sugarman ask what we would have done if prerandomization had resulted in a better recruitment rate. In response, we would have accepted the trial evidence and concluded that it was an effective method of improving recruitment rates. The ethical considerations are a separate, albeit important, issue. These considerations have been the subject of discussion and debate in the past and should remain so. We do not pretend to have all the answers regarding ethical decision making, and would support the usual process based on the Declaration of Helsinki. Final approval of a research project should be left to a properly constituted ethics committee consisting of persons from a variety of backgrounds who can offer a range of views.

The Explanatory Statement used in our study was developed in consultation with our hospital Ethics Committee, and considered the need to include as much information as possible versus the need for brevity and clarity. Naturally, this balance will differ according to the nature of any proposed trial. Our Committee has been established according to the guidelines of the Australian National Health and Medical Research Council Health Ethics Committee (equivalent body to the US National Institutes of Health Ethics Program). Patient autonomy was respected; they were able to withdraw consent at any time during the trial.

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