

The potential benefit of the placebo effect in sham-controlled trials: implications for risk-benefit assessments and informed consent

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ABSTRACT

There has been considerable debate surrounding the ethics of sham-controlled trials of procedures and interventions. Critics argue that these trials are unethical because participants assigned to the control group have no prospect of benefit from the trial, yet they are exposed to all the risks of the sham intervention.

However, the placebo effect associated with sham procedures can often be substantial and has been well documented in the scientific literature. We argue that, in light of the scientific evidence supporting the benefits of sham interventions for pain and Parkinson's disease that stem from the placebo effect, these sham-controlled trials should be considered as offering potential direct benefit to participants. If scientific evidence demonstrates the positive effect of placebo from sham interventions on other conditions, sham-controlled trials of interventions for the treatment of these conditions should be considered to have prospects of benefit as well. This potential benefit should be taken into account by research ethics committees in risk-benefit analyses, and be included in informed consent documents.