
Sir,
The study by Bernateck et al. [1] was aimed at comparing two treatments. This aim is best reached with a non-superiority design but the study seems to be conceived as a superiority trial. Discussing their result, the authors state that ‘using a placebo or sham control ... may have generated a false negative result’. I would argue not using a sham might produce a false positive result: both groups improved because of non-specific effects and, as these may well be greater with a slightly invasive intervention [2], the effects of acupuncture were quicker and slightly more pronounced. The point I am trying to make is simple: if the study design cannot answer the study question, even a randomized trial will fail to produce meaningful information.

E. Ernst, Universities of Exeter & Plymouth

References

Authors’ Reply
Dear Sir,
We would totally agree with Prof. Ernst’s notion that not using sham controls may have produced false positive results if we had done a drug trial in which incidental (placebo) factors could have been separated from characteristic drug effects. However, we compared two complex procedures which are not based on biomedical theory and in which incidental factors and specific factors are inseparably interwoven. In other words: factors which are incidental to a biomedical approach may be characteristic to a biopsychosocial one [1]. Therefore, a comparative trial of similar procedures which are based on the same theory may even produce clinically more meaningful information than the inclusion of a sham control which is based on an invalid theory. Certainly, the addition of a no-treatment group would have provided more information about the size of the observed treatment effects. However, from other studies it is well known that less ‘intervention’ is associated with significantly less efficacy [2, 3], but such a design would not be any better to discriminate incidental from specific effects, anyway. In the light of understanding placebo as a measurable correlate of a psychoneurobiological reaction of the organism, focusing on the overall effect of a treatment may become more important [4]. Interestingly, in drug trials the significance of head-to-head comparisons is currently being rediscovered: The Committee for Medicinal Products for Human Use (CHMP)’s ‘Guideline in clinical medicinal products intended for the treatment of neuropathic pain’ states that a 3-armed study (study drug – comparator – placebo) should be provided in order to allow the assessment of comparative efficacy and safety of a new product [5].

M. Karst, M. Fink, and M. Bernateck, for all authors
Hannover Medical School

References