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Measuring expectations of benefit from treatment in acupuncture trials: A systematic review☆

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Measurement

Summary
Objectives: We conducted a systematic review that aimed to document and describe how (1) expectation of benefit from treatment (response expectancies) were measured and reported in acupuncture trials, and (2) examine any effect on outcomes.
Design: We searched MEDLINE, EMBASE, AMED, CIHAHL, CENTRAL and Science and Technology Proceedings up to November 2007 for randomised (RCT) and quasi-randomised (CCT) controlled trials and prospective controlled cohorts of acupuncture as treatment for a medical or psychological condition in adults. An update citation search was conducted in April 2010. We included studies that mentioned soliciting response expectancies.
Results: We found 58 RCTs that fulfilled our inclusion criteria. Around half referenced one of five published instruments, most of which were designed to measure sham credibility and included one question on response expectancy. A wide range of question phrasing and response scales was used. There was some evidence that response scales may influence the measurement of expectations. Eight trials analysed the association between pre-randomisation expectations for assigned treatment and outcomes, and six the effect of pre-randomisation expectations across all patients independent of treatment allocation. Some showed associations but others did not.
Conclusions: There is some evidence that response expectancies interact with outcomes in acupuncture trials however the variety of question phrasing and analysis methods precludes drawing a firm conclusion about for whom and under which circumstance. To further our understanding of expectations, more methodological work is needed to standardise the questions and response scales that are used.

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Introduction

Acupuncture is a treatment area that has attracted substantial research interest. Although acupuncture trial reporting quality has improved, it remains low[1,2] and credibility and clinical applicability of the research is not improved by a lack of consensus around intervention design.[3] These trials, therefore, attract methodological interest around phenomena that might compromise validity. One such phenomenon is response expectancies. Defined as an individual's nonviolitional, self-confirming 'gut' reaction to a situation or behaviour,[4,5] how an individual expects to respond to a treatment is likely to be mediated by previously held beliefs or perceptions and information received, for example during informed consent.[6]

Strong expectancies can be aroused from relatively novel treatments such as acupuncture[7,8] and research in other areas indicate they have the potential to bias outcomes in open-label randomised trials if one treatment garners higher pre-randomisation expectations.[9,10] In such situations, internal validity could be compromised if, for example, participants with low expectations for their allocated treatment tend to respond less well to the intervention, and there are systematic differences in such expectations between groups. The problem is not solved by randomisation, indeed it is caused by it; however, effects could be mitigated by stratifying randomisation by the strength of response expectancy, accounting for expectation interactions with treatment analytically by adding pre-randomisation expectation as a covariate, or including expectation as a factor predicting outcome in two way analysis. In clinical practice, patients' choice of treatment will be to some extent influenced by their expectation about its effectiveness. As such choices are unfettered by allocation, there may be concern over generalisability of treatment effect sizes from open-label trials with pre-randomisation expectation imbalances that interact with treatment.

Expectations are also relevant in sham-controlled trials of acupuncture, particularly as trials involving sham medical devices may have large placebo effects.[11] Here particularly strong response expectancies might make the detection of between-group differences more difficult, and expectancy x treatment effects could result in spurious findings where unaccounted blinding failures occur unequally between arms.[12–14] In addition, around 20% of sham-trial acupuncture trials do not tell participants that the test is between verum (real) and sham but two competing treatments of acupuncture.[15] Outcomes of such trials could potentially be influenced by differing expectancies for the two competing treatments; such effects might compromise generalisability to consented sham controlled trials.

Regardless of the mechanism by which expectations might potentially interfere with trial validity, accuracy of measurement is essential, indeed demonstration of effect might be hampered by inadequate measures.[9]

We aimed to conduct a systematic review and report: (1) the measurement of response expectancies in acupuncture trials, and (2) the effect of pre-randomisation response expectancies on outcomes.

Methods

The search strategy was developed to identify abstracts and papers of randomised controlled trials (RCTs), quasi-randomised trials (CCTs) and prospective controlled cohort studies (some participants received acupuncture, some did