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Paterson *et al*[1] conclude from their randomised controlled trial (CACTUS study) that an addition of 12 sessions of five-element acupuncture to usual care resulted in improved health status and wellbeing. We were immediately attracted to their article by the clinical relevance of investigating treatment in patients with medically unexplained physical symptoms (MUPS). MUPS are an interesting and relevant problem in primary health care, because these patients are often 'frequent attenders' and this leads to high medical costs, frustrated doctors, and patients who feel misunderstood. The authors recommend in their study the use of five-element acupuncture for patients with MUPS as a safe and potentially effective intervention. However, we have some questions and comments about the outcome measures applied and the selection of patients in their study.

The conclusion of the study is only based on the outcomes of two questionnaires, that is to say, the Measure Yourself Medical Outcome Profile (MYMOP) and the Wellbeing Questionnaire (W-BQ12). At 26 weeks' follow-up, when adjusted for missing values and baseline scores, a significant difference in the between-group analysis is only seen on the W-BQ12. Moreover, the medical and clinical relevance of the outcome measures of these, for clinicians, relatively-unknown questionnaires are not described. Although acupuncture in people with MUPS may lead to improved wellbeing, there was no evidence that the GP consultation rate or medication use was decreased. The Patient Enablement Instrument was omitted because it did not perform well as a repeated measure. The authors state that many control group patients checked 'not applicable' because they thought the questions related only to the acupuncture treatment. What is this statement based on and how bad did it perform as a repeated measure?

Because patients were selected by their own GPs, selection bias is likely. Besides, inclusion criteria are not clear enough. Four inclusion criteria are stated in Box 1, however, the authors also report 'other inclusion criteria (from electronic record search).' What is meant with this? Is this an additional criterion or a new criterion for inclusion? One of the inclusion criteria of this study was the existence of the symptom for at least 3 months, but the table of participant characteristics shows two patients with a duration of the complaint of 4 to 12 weeks. Why were these patients included in the study?

With these comments, it is hard for us to estimate the clinical relevance of this study.

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Editor's response

The *BJGP* Editorial Board considered this correspondence recently. The Board endorsed the Journal's peer review process and did not consider that there was a case for retraction of the paper or for releasing the peer reviews. The Board did, however, think that the results of the study were highlighted by the Journal in an overly-positive manner. However, many of the criticisms published above are addressed by the authors themselves in the full paper.

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Authors' response

Much of the response to our papers about acupuncture as a treatment for medically unexplained symptoms, some as letters to the Journal and some in other online fora, relates to the headline messages. In the papers we acknowledged the limitations of our work and explained our choice of methods. The trial and accompanying process evaluation was always intended to be a pragmatic real world trial, with all its attendant potential biases, and we have attempted to report its results fully, warts and all. The pragmatic interpretation that Lawson asks for is as we reported: within the limits of the trial, five-element acupuncture is a safe and potentially effective intervention for patients with medically unexplained symptoms that may help some of them to take an active role in their treatment and make cognitive or behavioural lifestyle changes.

The design of the study was a standard waiting list controlled pragmatic trial, that was the best design to answer a pragmatic question. It was also best as a precursor to a cost effectiveness study, that would further inform NHS provision. The effect size was demonstrated on the basis of the preselected primary outcome measure, using standard statistical methods. It was conducted according to its registered protocol with the exception of the sample size that was revised downward because, in common with many trials, recruitment was slower than anticipated. This deviation from protocol was fully reported in the paper. We noted that the results were sensitive to missing data and that the study may have been underpowered.

Devroey and Van De Vijver complain that the sample was a heterogenous group with different diagnoses, but has missed the point that patients in this group all lacked diagnoses. As we explain in the paper, sham acupuncture controls are used to investigate the efficacy of a particular needling protocol, usually for a narrowly defined diagnosis, but are not appropriate for answering the pragmatic question of whether a referral for a series of acupuncture treatments is likely to be beneficial. The reason for doing the trial in the first place is that this group of patients are challenging for their doctors and occupy a considerable amount of their time.

We acknowledge in the paper that the 'study design precludes assigning the benefits of this complex intervention to any one component of the acupuncture consultations, such as the needling or the amount of time spent with a healthcare professional', but the suggestion that simply spending more time with physicians would achieve the same effect fails to address the issue, either for doctor or patients. The Measure Yourself Medical Outcome Profile instrument has been validated in settings other than complementary medicine.[1,2] In terms of determining clinical significance, we can draw on work done with other seven-point scales, that concludes 'the smallest