

## REFERENCE

1. Paterson C, Taylor RS, Griffiths P, *et al*. Acupuncture for 'frequent attenders' with medically unexplained symptoms: a randomised controlled trial (CACTUS study). *Br J Gen Pract* 2011; DOI: 10.3399/bjgp11X572689.

DOI: 10.3399/bjgp11X588312

I read with alarm the article by Paterson *et al* published in your journal last month.

This is the paper that, in its conclusions, claims an effect for acupuncture even though the data in the paper show no effect at all.

I cannot understand how this has happened. All the published data in the medical literature to date show no or insignificant effects for acupuncture. Given that, it seems all the more important to examine claims to the contrary with scientific rigour.

Indeed, the College expects that of any scientific paper. In my opinion you should withdraw the paper and admit an error was made. *The Lancet* did just that over the immunisation paper.

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I was dismayed to see the headline on the front of the *BJGP* claiming that 'Acupuncture: effective in a randomised trial for patients with unexplained symptoms'.<sup>1</sup> Alas, this is the kind of handling I would expect from the tabloid press.

The study did not take account of recent systematic reviews that sham acupuncture is as good as 'real' acupuncture, and that the effect in any case was 'to lack clinical relevance and cannot be clearly distinguished from bias'.<sup>2</sup> To know this, and not to account for it, is a major design flaw and one that infers that this research paper wasted resources. Second, the paper showed marginal effects from a ratings scale not established out with 'complementary' medicines, and an

increased attendance rate at general practices in the intervention group compared with the control group. Yet the authors concluded that acupuncture is effective and GPs should offer it. If a pharmaceutical company presented the same findings in support of a drug we would rightly ignore it.

This kind of research is damaging. It promotes false ideas, fails to take account of previous findings, and places expectations with patients who then have to be let down by GPs who wish to practice evidence-based and compassionate health care.

I would ask that the paper is withdrawn and the headline retracted. To learn and move on, the peer reviews made of the paper should be published. In future, if the *BJGP* makes an error in press releasing and headlining a research project, then the entire article should be made immediately free to view to all online, so that we can make our own judgments even before letters of dissent in the journal are eventually published.

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1. Paterson C, Taylor RS, Griffiths P, *et al*. Acupuncture for 'frequent attenders' with medically unexplained symptoms: a randomised controlled trial (CACTUS study). *Br J Gen Pract* 2011; DOI: 10.3399/bjgp11X572689.
2. Vested Madsen M, Gøtzsche PC, Hróbjartsson A. Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. *BMJ* 2009; **338**: a3115.  
<http://www.bmj.com/content/338/bmj.a3115.full> [accessed 11 Jul 2011].

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The June issue of the *BJGP* was noteworthy for several reasons. Most strikingly was the beautiful redesign and compelling headline, 'Acupuncture: effective in a randomised trial for patients with unexplained symptoms'.<sup>1</sup> Fantastic, I thought — groundbreaking research! So, it was with much anticipation that I removed the last shreds of cellophane to delve into your esteemed tome.

Sadly, it was wholly disappointing and somewhat incensing to read the actual acupuncture research. Heralded by you as 'positive results' from a 'randomised controlled trial' revealing 'significant and sustained benefit (for patients) who

frequently attend (GP clinics) with medically unexplained symptoms'.<sup>2</sup> I fear these comments were more than liberal with the truth.

As a medically trained doctor who now works in education, part of my remit is to teach the scientific method to 16 and 17 year olds. I dare say that the methodological flaws present in the acupuncture trials would have been obvious even to them. The research used a very poorly defined patient group (medically unexplained symptoms), had numerous patient selection biases and had failed to use a true placebo. This only scratches the surface; an internet search for 'acupuncture; *BJGP*' will present you numerous articles that report the articles' failings in great depth.

In an age where peer-reviewed journals are coming under increasing scrutiny, I do not envy your position. In part, I can sympathise with the pressures of being a periodical editor having recently undertaken the role of editing a popular science magazine myself. However, your periodical has a very unique audience: time-harassed GPs seeking the best evidence-based practice, many of whom will barely have the time to read past the editorial and abstracts. The high quality reader-friendly redesign is definitely a step forward, but it is imperative that content is to the same standard.

So it was with much surprise on receiving this month's (July) edition of *BJGP* to find no mention of the controversial acupuncture trials in either the letters section or the editorial. In all humility, I strongly urge you to reconsider your unequivocal praise for this research. At the very least, please engage in discussion with your readers about the merits/failings of this research. June's edition of the *BJGP* has been ridiculed as 'tabloid medical journalism'; for the sake of the profession's reputation and, most importantly, patient welfare, take action now and set the record straight.

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1. Paterson C, Taylor RS, Griffiths P, *et al*. Acupuncture for 'frequent attenders' with medically unexplained symptoms: a randomised controlled trial (CACTUS study). *Br J Gen Pract* 2011; DOI: 10.3399/bjgp11X572689.

2. Jones R. Editor's briefing. *Br J Gen Pract* 2011; **61(587)**: 372.

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Paterson *et al*<sup>1</sup> 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.<sup>1,2</sup> In terms of determining clinical significance, we can draw on work done with other seven-point scales, that concludes 'the smallest