The report of the CACTUS study[1] and the accompanying editorial[2] are flawed by several biases and errors. The Editor's review gave the study an unjustified commendation by stating, 'A series of five-element acupuncture treatments has significant and sustained benefit in patients who frequently attend with medically unexplained symptoms'.[3] In fact, the flaws and biases are so many that we can expose only the most important ones: failure to consider clinical relevance and measurement precision, and failure to consider the risk of bias in unblinded pragmatic trials such as CACTUS.

The differences in outcome measures are small and imprecise and therefore unlikely to be relevant to patients. For example, the primary outcome measure in CACTUS was the Measure Yourself Medical Outcome Profile score at 26 weeks. For this outcome the difference was only –0.6 on a 7 point scale with a wide 95% confidence interval (–1.1 to 0.0). Had the graphs in Figure 2 shown the confidence intervals rather than the point estimates alone, it would have been inescapably obvious that, although some results are statistically significant, no results are clinically important.

When differences are statistically significant, the results cannot easily be explained by chance. However, this does not mean that they cannot easily be explained by bias, and the onus is on authors to justify assumptions that the risk of bias is small. Like many other advocates of acupuncture and integrative medicine, the authors and editorialists fail to understand two important limitations of unblinded pragmatic trials that rely on subjective outcome measures: first, that their results have a high potential for bias, and second, that the size of the bias effect is likely to be larger than effects specific to acupuncture.[4]

The purpose of having a control group to control for biases is undermined if there is no blinding and the control is not a true control, that is to say, similar in all aspects to the treatment group except for the treatment. In the CACTUS study, control group participants were not similar for, as the authors acknowledge, they were likely to have been unhappy about not receiving acupuncture. They were likely, therefore, to experience a negative placebo reaction, or as we have termed it, a 'frustrebo reaction'.[5] The measured placebo effect will be the sum of the negative placebo or 'frustrebo effect' in the control group plus the positive placebo effect in the treatment group. To the unwary, the harm to the control group will appear as a benefit to the treatment group and the overall benefit of treatment (if any) will be exaggerated. We have explained this in greater detail elsewhere.[5] The statement that the statistician was blinded is irrelevant and serves no purpose other than to suggest some degree of objectivity.

It is a pity that the opportunity provided by the qualitative study to investigate likely causes of a negative placebo effect was lost. By restricting the qualitative study to those who had completed acupuncture, the chance was missed to capture the experience of those who had been denied it. A comparison between the test and control groups' feelings at 26 weeks would have been very informative.

It is convenient for advocates of complementary and alternative medicine that clinical relevance and the role of bias have been overlooked once again.

Michael Power,

Clinical Guideline Developer and Medical Informatician, Stable House, High Warden Hexham, NE46 4SR.
E-mail: HMichaelPower@gmail.com

Kevork Hopayian,

GP, Leiston Surgery and School of Medicine, Health Policy, and Practice, University of East Anglia, Norwich.

REFERENCES

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. Shan WSY, Ho CVC. Acupuncture: filling the effectiveness gaps in Western medicine? *Br J Gen Pract* 2011; **61(587):** 374–375.
3. Jones R. Editor's briefing. *Br J Gen Pract* 2011; **61(587):** 372.
4. O'Connell NE, Wand BM, Goldacre B. Interpretive bias in acupuncture research?: a case study. *Eval Health Prof* 2009; **32(4):** 393–409.
5. Power M, Hopayian K. Exposing the evidence gap for complementary and alternative medicine to be integrated into science-based medicine. *J R Soc Med* 2011; **104(4):** 155–161.

DOI: 10.3399/bjgp11X588303

Paterson and colleagues do not provide any evidence for their claim that acupuncture is effective for patients with multiple unexplained symptoms[1] for two main reasons. First, their study did not test acupuncture at all, and second, there were so many methodological flaws that no conclusions of any kind could reliably be drawn. Had no needling taken place, and patients in the intervention group simply been given the same amount of time talking to their physicians, could the authors state with any conviction, that the results would have been different? This question could be readily answered with a properly designed trial, that Paterson *et al* rejected in favour of their 'pragmatic' design.

But it gets worse. The study was stopped early (probably because of the slow recruitment that is reported in the paper), and at an interesting point. The figure showing the Measure Yourself Medical Outcome Profile scores for both treatment groups reveals that (a) effect sizes were very small, and (b) that the score for the intervention group oscillated above and below the line for the control group. Conveniently, the study stopped when the intervention score was higher than the control score.

The rationale for the study, as explained in the introduction, was that these patients consume substantial health care resources. Yet there was no effect of the intervention on these resources. For example, consultation rates were unchanged. Paterson *et al* try to justify their choice of study design as being more representative of clinical practice. But as there was no benefit to clinical practice, why do the study at all? Or at least, they should draw a conclusion that makes sense with regard to the data.

It is interesting to see that patients received explanations of 'five-element acupuncture'. Why were they thus misled as to how the body works, with misinformation that has no basis in science? Surely the days of paternalistic medicine are over? One has to wonder about a peer review system that allows such a flawed paper to be published. It does a disservice to science, and the damage is that it will be cited by opponents of evidence-based medicine, and even more patients will be misled.

Les Rose,

Clinical Science Consultant, Pharmavision Consulting Ltd, 11 Montague Road, West Harnham, Salisbury, SP2 8NJ.
E-mail: lesrose@ntlworld.com

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.

Martin Wallace,

24 Stonebridge Estate, Wallace Road, R D 9, Hamilton 3289, New Zealand.
E-mail: mart-jan@xtra.co.nz

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/bjgp11X588321

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'.[1] 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'.[2] 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.

Margaret McCartney,

1 Sackville Avenue, Glasgow, G13 1NG.
E-mail: margaret@margaretmccartney.com

REFERENCES

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).

DOI: 10.3399/bjgp11X588330

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'.[1] 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'.[2] 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.

Stuart Farrimond,

Doctor, 13 Polebarn Road, Trowbridge, Wiltshire, BA14 7EG.
E-mail: Stuart.Farrimond@wiltshire.ac.uk

REFERENCES

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.