

Letters

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Acupuncture for 'frequent attenders' with medically unexplained symptoms

The June issue of the *BJGP* has a paper, 'Acupuncture for "frequent attenders" with medically unexplained symptoms: a randomised controlled trial [CACTUS study]'.¹ It has lots of numbers, but the result is very easy to see. Just look at Figure 2 (omitted from the print version, online only).¹

There is no need to wade through all the statistics; it's perfectly obvious at a glance that acupuncture has, at best, a tiny and erratic effect on any of the outcomes that were measured. The effects, even if some are real, are obviously too small to be of any clinical significance. The paper is fascinating because it is the clearest demonstration I have ever seen that acupuncture is ineffective, and that it does not even have a worthwhile placebo effect. One may certainly criticise the lack of a sham acupuncture control group but, in a sense, that is what makes the paper fascinating. Despite the inability of the experimental design to distinguish between non-specific effects and genuine effects of acupuncture, next to no benefit was seen. The result may have been fascinating, but its significance was lost altogether on the authors. The conclusion of the paper said:

'The addition of 12 sessions of five-element acupuncture to usual care resulted in improved health status and wellbeing that was sustained for 12 months.'

The meaning of the paper was also lost on the Editor, who issued a press release:

'Although there are countless reports of the benefits of acupuncture for a range of medical problems, there have been very few well-conducted, randomised controlled trials. Charlotte Paterson's work considerably strengthens the evidence base for using acupuncture to help patients who are troubled by

symptoms that we find difficult both to diagnose and to treat.'

Both of these statements directly contradict what is actually apparent from the figure.

One wonders what went wrong. Presumably the referees, like the authors, were partisan when it comes to needling. We don't know because the Editor has declined to release the reports. It is harder to explain the press release. All one can conclude is that the paper had not been read very carefully before the press release was written. Mistakes of this sort do great harm to journals. The paper in question has already been analysed carefully in four blogs (two of them by GPs)²⁻⁵ and has been the subject of a devastating spoof in *The Daily Mash*.⁶ Had the Editor admitted the mistaken interpretation, one could have forgotten the matter. We all make mistakes sometime. By refusing to admit that the paper and the press release were very misleading, the Journal has been brought into disrepute.

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The headline in June's *BJGP* says that five-element acupuncture 'has a significant and sustained benefit' [print version only].¹ The associated editorial says that the review offers 'more evidence for the effectiveness of acupuncture'.² The heading on the front cover says 'Acupuncture: effective ...'.

I feel that these are misleading. Many GPs, and the media, rely on the headlines and editorials to be accurate, as we don't have time to read every article. What this rather small study actually shows is that the whole acupuncture consultation made a significant difference in just one of the three wellbeing scores used, but did not make a significant difference in two of the three scores, nor in consultation rates.¹ The authors acknowledge that their study does not show that needling itself was responsible for any changes seen, and also explain that they didn't choose a sham-acupuncture control because it may 'interfere with the participative patient-therapist interaction'.¹

I am not going to debate here all the other evidence regarding acupuncture, but I feel strongly that the *BJGP* needs to be more responsible in how it headlines articles and in printing editorials that make claims regarding efficacy that is not supported by the evidence.

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The lively presentational style of the revamped Journal is welcome, and the new concise and accessible approach to research will certainly help time-pressed clinicians. However, there is an uncomfortable tension between the need to present data to busy practitioners in an easily digestible format and gross-oversimplification that risks the misinterpretation of data. The Editor seems to have fallen into this trap with Paterson et al's study on acupuncture with medically unexplained symptoms.¹

The study is riddled with bias in a number of key areas including participant selection and the unblinded intervention. The construction of the study lends itself to a positive result and there is little value in conducting acupuncture studies without adjusting for this bias by using some kind of sham treatment. The authors do discuss the 'black-box' effect of the intervention and this does raise the unfortunate, but in this case appropriate, image of a terrible crash that needs careful post-disaster investigation. Even given the obvious bias, the effect was small and the graphs presented in the full-length article,¹ sadly missing in the print version, made this abundantly clear.

The *BJGP* has done a disservice to the communication of science, and the uncritical message, propagated through the RCGP, of the effectiveness of acupuncture in this study simply doesn't stand up to any reasonable scrutiny. Thanks to the *BJGP* press release, the national print media picked up on the story and ran it uncritically in the true spirit of modern 'churnalism'.² Pragmatic studies need pragmatic interpretation and shouldn't develop into publicity campaigns that can be boiled down to 140 characters. Ironically, it is subsequently through Twitter and the blogosphere that the damage to the reputation of the *BJGP* has been done.³ I recognise the need to make research palatable but the headline front-cover conclusion printed by the *BJGP* is ill-judged and owes more to a tabloid approach to journalism than any sober consideration of the true nature of the findings in this study.

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We have some serious concerns about the methodology and the conclusions of the studies by Paterson, Rugg and colleagues.^{1,2}

First of all, the results of these studies would have been more acceptable if five-element acupuncture would have been compared to placebo, that was not the case. Acupuncturists often argue that placebo control is not feasible with acupuncture. But in several studies investigators were able to compare acupuncture to placebo by using non-invasive acupuncture or superficial needling at non-acupuncture points.^{3,4}

It has been proven that simulated acupuncture procedures are a reasonable control treatment for acupuncture-naïve individuals in randomised controlled trials (subjects receiving acupuncture with real needles versus pokes with a toothpick in a guide-tube).³ In a placebo controlled study with patients suffering from chronic low back pain there were no significant differences between real acupuncture and minimal acupuncture at non-acupuncture points.⁴

Second, the studies by Paterson, Rugg and colleagues do not clearly describe how patients with medically unexplained physical symptoms (MUPS) were defined. Inclusion and exclusion criteria remain unclear. Being an inhomogeneous group, patients with MUPS undoubtedly present with different diagnoses, each needing a specific treatment. As the study groups consisted of frequent attenders with MUPS, we are concerned about a selection bias favouring 'medical shoppers'. These patients may feel better after any medical 'consultation' as such, enhancing the role of a placebo effect. In this study the patients knew whether they were in the treatment group or control

group. The cross-over design of the study does not surmount this issue, especially because all outcome measures are subjective evaluations of health status and wellbeing.

Third, improvement on the Measure Yourself Medical Outcome Profile score was only borderline significant ($P = 0.05$), while, except for wellbeing, there was no significant improvement for any of the other parameters. This confirms the fact that medical 'attention' may play a more important role than the treatment, for example, acupuncture itself.

Finally, the non-significant decrease in consultations with the GP should have been adjusted with the 12 sessions of acupuncture. In our opinion, the gain in number of consultations will be small, but there will be a shift in consultations from the GP to the acupuncturist.

In conclusion, we are not convinced of the benefit of acupuncture for patients with MUPS. There certainly is a further need for higher quality trials in this domain before treatment guidelines can recommend acupuncture for MUPS.

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The report of the CACTUS study¹ and the accompanying editorial² 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 'frustrerebo reaction'.⁵ The measured placebo effect

will be the sum of the negative placebo or 'frustrerebo 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.

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Paterson and colleagues do not provide any evidence for their claim that

acupuncture is effective for patients with multiple unexplained symptoms¹ 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.

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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'.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.

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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'.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.

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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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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 heterogeneous 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

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

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

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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.

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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 heterogeneous 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

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

difference that patients consider important is often approximately 0.5.³ Consequently, our finding of a 0.6 mean difference between the groups is likely to be clinically significant – especially as substantial numbers of patients in the trial will have perceived more benefit than this.

Adjustment of consultation rates for the extra acupuncture consultations would not change the inference on the within – and between-group inference on consultation rates. All the 41 control patients were offered acupuncture after a period of 6 months, and 35 took up the offer. Patients from both the intervention and the control groups were interviewed.

The rationale for offering acupuncture to this group of patients is that medicine seems to have little to offer them; this mixed methods study suggests an acceptable and potentially valuable way out of what is often an impasse for doctors and patients.

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Domestic violence, PTSD, and diagnostic enquiry

It was refreshing to read a paper¹ and editorial² that sought to identify causes of patients' anxiety in their life events, as patients complain that doctors often fail to ask why they are anxious or depressed.³ The reported research identified domestic violence and abuse (DVA) as a cause of anxiety using the HARK questions (four short questions relating to Humiliation, being Afraid, Raped, and Kicked).⁴

The paper also notes that the Generalised Anxiety Disorder Scale (GAD-7) can be used as a 'case-finder' for panic-disorder, social anxiety disorder, and post-traumatic stress disorder (PTSD), as well as generalised anxiety disorder (GAD). The questions of the GAD-7 overlap with the questions required to make the diagnoses above, that is why GAD-7 can act as a 'case-finder'.¹ However, I think it is a mistake to conclude from the paper that domestic violence causes GAD, as the editorial seems to. Sherina et al do not claim this. They did not pursue further analysis of the type of anxiety disorder patients were suffering from in their research. Diagnostic rigour helps the doctor and patient understand the consequences of DVA and thus find appropriate solutions. Sherina et al discuss the association of PTSD and DVA.

A meta-analysis⁵ on the prevalence of mental health problems among those who

had experienced DVA found mean prevalences of 63.8% in 11 studies of PTSD, 47.6% in 18 studies of depression, 17.9% in 13 studies of suicidality, 18.5% in 10 studies of alcohol abuse, and 8.9% in four studies of drug abuse. Dose-response relationships of violence to depression and PTSD were observed.

The best explanatory model linking domestic violence and anxiety disorders is PTSD. It makes sense that terrifying and humiliating experiences of DVA result in nightmares, flashbacks (intrusive thoughts), avoidance behaviours, and hyper-arousal. However, a positive GAD-7 score may usefully act as a tool of communication, and a prompt to the GP for further questioning about PTSD symptoms and DVA using HARK questions.

The linked editorial² correctly identifies the lack of evidence for the use of 'routine enquiry' for DVA in general practice, as opposed to its evidence-based use in antenatal clinics.⁶ This is reiterated by the Department of Health.³ I am writing the RCGP e-learning course on DVA. I encourage GPs to work from patients' symptoms, using 'diagnostic enquiry' rather than 'routine enquiry'.⁷ The course will, I hope, provide safe, pragmatic guidance that is congruent with how we GPs work.

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