

burned. Underlying differences in device accuracy may be compounded in these measures.

Our study is limited by being conducted with young, healthy volunteers in a controlled setting with a convenience sample of a small number of applications and devices. Results should be confirmed in other settings and with other devices.

Increased physical activity facilitated by these devices could lead to clinical benefits not realized by low adoption of pedometers. Our findings may help reinforce individuals' trust in using smartphone applications and wearable devices to track health behaviors, which could have important implications for strategies to improve population health.

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**Author Contributions:** Ms Case had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Study concept and design:* All authors.

*Acquisition, analysis, or interpretation of data:* Case, Patel.

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## COMMENT & RESPONSE

### Treating Chronic Knee Pain With Acupuncture

**To the Editor** In the randomized clinical trial of acupuncture for chronic knee pain,<sup>1</sup> the acupuncture treatment design appeared flawed. Specifically, the acupuncture points were non-standardized and the study lacked the details necessary to ascertain whether the provided interventions were representative of acupuncture sessions appropriate for chronic knee pain.

First, the acupuncture regimen was not consistent in the study, with some patients receiving less than 1 treatment per week, some patients receiving 1 treatment per week, and others receiving 2 treatments per week for 12 weeks. Dr Hinman and colleagues failed to report how many patients received 1 or 2 treatments per week. The commonly used frequency of acupuncture treatments for chronic knee pain due to osteoarthritis is 2 treatments per week for 8 weeks, followed by 2 weeks of 1 treatment per week, then 4 weeks of 1 treatment every other week, and finally 12 weeks of 1 treatment per month.<sup>2</sup>

Furthermore, no details were provided regarding depth of insertion or whether subjective deqi sensation was experienced by the patient. Deqi has been shown to be important to differential neurophysiological analgesic mechanisms in responders vs nonresponders to acupuncture.<sup>3</sup> Hinman and colleagues also did not provide acupuncture with electrical stimulation, which not only has a dose-dependent effect on the degree of analgesia but also induces differential neurotransmitter responses depending on the electrical frequency used.<sup>2,4</sup>

The only conclusion that can be drawn from this study is that unsystematic acupuncture regimens did not result in significant clinical benefit to patients with chronic knee pain.

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**To the Editor** Dr Hinman and colleagues<sup>1</sup> presented a generally well-conducted trial of the effectiveness of acupuncture treatment (stimulation using laser or needles) for pain and function in knee osteoarthritis. However, the authors failed to find any benefit of acupuncture, which is not a surprising outcome—at least for laser acupuncture—given the laser acupuncture treatment parameters used in the trial. These

parameters were well below those that are considered necessary to provide a therapeutic benefit, particularly in terms of the dosage and power outputs used.

Based on a previous systematic review on laser acupuncture,<sup>2</sup> the clinical effectiveness of this form of acupuncture for pain relief depends on application of dosages of at least 0.5 J per point, rather than the 0.2 J per point used in the trial by Hinman et al.<sup>3</sup> Also, the power output of the custom laser device was set at a relatively low 10 mW. The authors did not provide any justification for use of these parameters in their study and did not specify the wavelength used.

Dosage is as important for the effectiveness of therapeutic applications of light-based technologies as it is for pharmacological agents; this is not limited to application of laser in acupuncture treatments and has been demonstrated in reviews of other forms of laser treatment such as laser therapy for tendinopathies.<sup>4</sup>

Knee osteoarthritis is a prevalent condition, with significant associated costs and effects on society, health systems, and individuals; this situation will be exacerbated with the aging of the population and increasing levels of obesity. Identifying novel cost-effective options for management of osteoarthritis, outside the common approach of nonsteroidal anti-inflammatory drugs (NSAIDs) and eventual surgery, is an important priority for research in this area. Acupuncture, including laser acupuncture, may represent one component of a multimodal approach to effective management of osteoarthritis. However, negative findings from studies that use inappropriately low dosages do not serve to elucidate the potential role of this otherwise safe and inexpensive treatment. For laser acupuncture, as for other forms of treatment, effectiveness depends on dosage.

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**To the Editor** Among the findings in the study by Dr Hinman and colleagues<sup>1</sup> was that at 12 weeks, needle and laser acupuncture treatment reduced pain and needle acupuncture improved functional scores compared with control in patients with knee pain persisting for longer than 3 months. One year after needle acupuncture, both outcomes (pain intensity and physical function scores) were still improved by approxi-

mately 25%, but the differences were not statistically significant. The authors concluded that their findings did not support acupuncture in patients older than 50 years with moderate or severe chronic knee pain.

Hinman and colleagues assumed that their results were of a clinically irrelevant magnitude. They cited a single article suggesting minimal clinically important improvements in knee osteoarthritis to be 41% for pain and 26% for physical function.<sup>2</sup> However, patients in the cited trial were treated with NSAIDs, without reporting dosages. Nonsteroidal anti-inflammatory drugs cannot be considered an adequate standard in the treatment of musculoskeletal pain. Despite widespread use, the effectiveness and clinical benefit of NSAIDs have been reported as moderate and variable.<sup>3</sup> Therefore, the thresholds for clinical importance reported in the cited study should not be used as a general reference. Several other trials, as cited by the authors,<sup>4</sup> suggest a pain reduction of 25% to 30% to be clinically relevant.

A recent meta-analysis of acupuncture for chronic pain by Vickers and Linde<sup>5</sup> stated that there is no reason to believe that additional data would change their results demonstrating the effectiveness of acupuncture in chronic pain, with a standard mean difference in osteoarthritis of 0.57 comparing acupuncture with control. Therefore, we do not agree with the conclusions of Hinman et al to not support the further use of acupuncture.

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**To the Editor** We have some concerns about the conclusion and the design of the randomized clinical trial of acupuncture for chronic knee pain reported by Dr Hinman and colleagues.<sup>1</sup> The authors concluded that their findings did not support acupuncture for chronic knee pain because neither needle acupuncture nor laser acupuncture was better than sham laser at 12 weeks and at a 1-year follow-up.

According to their previously published protocol,<sup>2</sup> there were 3 primary hypotheses, mainly testing the effect of laser acupuncture against needle acupuncture, sham laser acupuncture, and no treatment at 12 weeks, as well as needle acupuncture vs no treatment at 12 weeks. It was clear the authors' original primary end point of the trial was at 12 weeks instead of a 1-year follow-up. Their results supported the hypothesis that needle acupuncture was superior to no treatment in improving pain and function scores at 12 weeks. However, Hinman and colleagues then concluded that the findings did not support the use of needle acupuncture for chronic knee pain.

Furthermore, the rationale for a 1-year follow-up after 8 to 12 acupuncture treatments was lacking. It is not surprising that no significant differences were observed across the 4 groups at the 1-year assessment. For patients with chronic knee pain, their condition is likely to deteriorate if no active treatment is offered. A large randomized clinical trial of acupuncture for knee osteoarthritis found that the beneficial effects of an 8-week intensive acupuncture treatment regimen, followed by an 18-week tapering treatment regimen, persisted at 26 weeks.<sup>3</sup> Instead of a 1-year follow-up, more frequent and short-term reassessments during and after acupuncture treatment may have better captured the treatment and maintenance effects of acupuncture.

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**To the Editor** In the trial of acupuncture for knee pain,<sup>1</sup> there were some concerns with regard to the validation of the trial and accuracy of the conclusion.

The comparison of needle acupuncture with sham laser acupuncture was not in the aims or hypotheses of this trial. In the original trial registration in 2009<sup>2</sup> and baseline publication of the protocol in 2012,<sup>3</sup> all the specific aims of the trial focused on testing laser acupuncture. None of the original 9 hypotheses referred to the comparison of needle acupuncture with sham laser acupuncture. Needle acupuncture appeared to be a positive control for laser treatment because it has been proved effective in a previous trial.<sup>4</sup> Therefore, the conclusion that needle acupuncture was not better than sham treatment was based on a post hoc hypothesis.

Sham laser acupuncture is not a valid control for needle acupuncture. Most acupuncturists do not recognize laser treatment as acupuncture. It was not mentioned in a recent review of acupuncture therapy.<sup>5</sup> The placebo effect of this custom laser machine on patients may be different from that of sham needle, and its psychological effect on patients is largely unknown.

Dr Hinman and colleagues<sup>1</sup> explained the reason for the lack of a sham needle control as "the inability to blind acupuncturists." This statement is inconsistent with the fact that needle acupuncture was never proposed as a testing intervention. Without correct controls, a fair evaluation of the effect of needle acupuncture was impossible.

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**In Reply** Our study found no benefit of needle or laser acupuncture compared with sham laser and small clinically irrelevant benefits compared with no acupuncture for chronic knee pain. We took a pragmatic approach, permitting 8 acupuncturists (each with at least 10 years of acupuncture experience) flexibility to choose acupuncture points and treatment frequency (8-12 visits over 12 weeks). Consistent with clinical practice and acupuncture training in Australia, acupuncturists aimed for deqi with needle acupuncture.

Dr He suggests lack of acupuncture standardization, treatment infrequency, and no electrical stimulation may explain our findings. However, when comparing acupuncture with sham treatment, a meta-analysis<sup>1</sup> found no evidence that needle number or placement; use of electrical stimulation; or number, frequency, or duration of treatments influence acupuncture outcomes.

Drs Baxter and Tumilty suggest our laser acupuncture parameters were too low for therapeutic benefit. Our protocol (devised in 2008) used parameters based on recommendations of the Australian Medical Acupuncture College and teaching principles of Australian medical acupuncture training. We used a wavelength of 830 nm. Animal models show that transmittance of infrared light through soft tissues is greatest with wavelengths between 750 and 890 nm.<sup>2</sup> We agree our findings can only be generalized to the regimen we used.

Drs Fleckenstein and Banzer take issue with our definition of a minimal clinically important difference (MCID). We powered our study to detect absolute MCIDs between groups in pain (1.8 units) and function (6 nonnormalized units). Estimated between-group differences did not reach these thresholds, and the active acupuncture groups were not statistically different from sham laser. Based on these findings and our a priori definitions of MCID, our conclusions were appropriate. Although Fleckenstein and Banzer suggest an alternate definition of clinically relevant change based on relative (%) pain improvement, criteria for defining response in osteoarthritis clinical trials suggest a reduction in pain or function of at least 50%, accompanied by an absolute change of 20 units (0-100 scale) in the first instance.<sup>3</sup> It is unlikely our conclusions would be different had we used this definition.

Although needle acupuncture resulted in statistically significant changes in pain and function compared with no acupuncture, as noted by Drs Lao and Yeung, the changes did not reach our threshold for MCID. Lao and Yeung also question the rationale for 1-year follow-up, arguing patients deteriorate without treatment. Our no-treatment control group did not support this assertion because participants tended to improve slightly over 1 year. Had acupuncture resulted in significant clinically meaningful improvements at 12 weeks, it is feasible some benefits may have been maintained at 1 year.

Dr Li suggests that the comparison of needle acupuncture with sham laser was not specified in the protocol. He is correct that we did not explicitly state that we would compare needles with sham laser. We believed it was inherent within the planned analysis that all 3 acupuncture groups would be compared with each other and assumed that statements in the statistical analyses section of our protocol implied that this pairwise comparison would be conducted:

*“Differences in mean change from baseline to each time point will be compared between groups using random effects linear regression modelling...”*

*“Improvement between acupuncture groups (based on the perceived ratings of change) will be compared...”*

We recognize that others may interpret these statements differently and apologize for any confusion this may have caused.

Li also suggests sham laser is not a valid control for needle acupuncture. Research shows sham laser is as credible as needle acupuncture among patients.<sup>4</sup> Although sham needle conditions have been used previously, critics argue these cause cutaneous stimulation and question their validity as a placebo.<sup>5</sup> We chose sham laser acupuncture given these validity concerns and because we could blind acupuncturists, which is not possible with needles.

Fleckenstein and Banzer highlight a large acupuncture meta-analysis<sup>6</sup> reporting an effect size of 0.57 for osteoarthritis pain compared with no acupuncture. However, the effect size relative to sham was much smaller (0.16) and of questionable clinical relevance. We do not expect our study to overturn a meta-analysis of this magnitude. Patients, clinicians, and policy makers will make up their own minds about acupuncture

based on evidence and their own beliefs. Despite the positive meta-analysis findings, the National Institute for Health and Care Excellence (United Kingdom) still advised against acupuncture for osteoarthritis in their 2014 clinical guidelines because of uncertain clinical effectiveness.

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## Contact Precautions for Patients With Multidrug-Resistant Pathogens

**To the Editor** In their recent Viewpoint, Dr Morgan and colleagues<sup>1</sup> suggested that contact precautions for patients colonized or infected with methicillin-resistant *Staphylococcus aureus* (MRSA) or vancomycin-resistant *Enterococcus* (VRE) should be reconsidered until more evidence of their efficacy becomes available, thereby questioning the wisdom of mandatory screening for MRSA. Morgan et al called for “a high-quality quasi-experimental study or cluster-randomized trial comparing the effect of adding contact precautions to the assiduous application of standard precautions on MRSA and VRE infections.”

The Mastering Hospital Antimicrobial Resistance in Intensive Care Units (MOSAR-ICU) study was a European cluster randomized trial evaluating the incremental effects on the acquisition rate of multidrug-resistant pathogens (MRSA, VRE, or highly resistant Enterobacteriaceae) and of contact precau-