Letter to the Editor

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Response to a letter to editor from Hohenschurz-Schmidt et al

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To the Editor,

We are grateful to Hohenschurz-Schmidt and colleagues [1] for their interest in our brief report on the potential effects of osteopathic manipulative therapy (OMTh) in patients with patellofemoral pain syndrome (PFPS) [2] and for their valuable effort to enhance the rigor of research in osteopathic medicine.

In what we perceived as an absence of shared guidelines for performing placebo-controlled trials in manual therapy, we took particular care in designing the methods for this brief report (pilot study) and specifically trained practitioners in the application of the “sham” therapy we selected for therapy-naïve participants. Hohenschurz-Schmidt et al. [1] acknowledged the effort made in controlling for “non-specific effects of touch and the therapeutic encounter,” but suggested further improvements to the manual-placebo intervention. Since the use of a placebo arm is crucial to disentangle the bottom-up and top-down effects of a specific touch, we particularly appreciated the clinical suggestion. While the idea to “provide simple touch to the symptomatic area or some form of tissue movement” to enhance “the potential of the placebo intervention to be considered as a true treatment” is interesting, we believe it is still insubstantial, as the effect of OMTh also was observed in the pilot trial after treatment was delivered to areas remote from the pain site. Thus, treatment that was indirect to the symptomatic area was a factor shared by the active and the sham intervention groups and would have theoretically

undermined the credibility of both. In our previous work [3, 4], we designed another manual-placebo intervention and introduced a “deblinding” questionnaire. This survey, delivered posttreatment after patients were “deblinded,” demonstrated that a fair percentage of participants who received the placebo intervention found it effective, thus suggesting that the “sham” (the very same adopted in the present brief report) was actually credible.

Interestingly, Hohenschurz-Schmidt et al. [1] attributed the lack of change seen in our control group over time to a “frustration effect.” The fact that five patients who dropped out of our pilot study were from the placebo group might suggest that the passive nature of the sham intervention may have determined such attrition. However, from a clinical point of view, the lack of change in the control group cannot be strictly considered a null effect, as PFPS is characterized in 70–90% of individuals by recurrent or chronic pain [5]. Therefore, the fact that self-reported pain did not change in the placebo group during the assessment period would suggest a positive effect of sham on recurrence of symptoms, at least.

Aside from the academic discussion on the best way to design a placebo-control intervention, we believe results from a pilot study like ours can be discussed in terms of efficacy or clinical effectiveness. As Hohenschurz-Schmidt correctly pointed out, a pilot is “a future study conducted on a smaller scale,” and including some consideration of the clinical importance of these preliminary findings will, in fact, justify the development and assessment of more complex intervention programs [1]. Regarding their concern that readers unfamiliar with the “required methodological standards of clinical trials” [1] might assume that the described osteopathic intervention resulted in a high level of evidence or a recommendation for the treatment of the patellofemoral syndrome, we are confident enough that limitations we acknowledged in the appropriate section of our article and our fairly cautious conclusions [2] will guide readers’ understanding. Our report might, at most, complement recent evidence [6] demonstrating a positive effect of osteopathic treatment (when compared with exercise protocol) for reducing knee pain in runners with PFPS [6].

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Moreover, as the the Cochrane tool for assessing risk of bias (RoB) in randomized trials (RoB2) [7] is intended “to evaluate the risk of bias in each study included in a systematic review” to document “potential flaws in the evidence summarized,” [1] we are puzzled by the RoB assessment offered by the authors of the letter – which should, at least, include the same evaluation conducted on evidence similar to the one presented in our brief report [7], while the “high” concerns in domains two, three, and five are not particularized in the letter.

We would also like to underline that we submitted the manuscript as a brief report. Although the study design is not flawless (which is why you perform a pilot), our paper aimed at sharing our preliminary clinical experience on this new osteopathic topic. We hope that we have provided helpful feedback and clarification.

Editor’s Note: *Journal of Osteopathic Medicine* now only accepts for publication prospective human subject studies that have been submitted to a clinical trial registry, in accordance with the Declaration of Helsinki.

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the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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