intensity, and health-related quality of life outcomes, but these domains are consistent with the core outcome set for clinical trials of nonspecific LBP.3 Licciardone also raised concerns about our inclusion of patients with subacute LBP, given that they may spontaneously improve. First, patients with subacute LBP are at higher risk of chronic LBP than patients with acute LBP. International guidelines consistently highlight differences between management of persistent and acute LBP.4 Second, even though our recruitment was open to patients with subacute LBP, only patients with chronic LBP (minimum LBP duration of 0.5 years) actually participated.1 Quesnay and colleagues question the choice of standard OMT as our experimental intervention.1 They suggest it would have been better to address the question of osteopathic care. We agree this question should be considered in future research because models for osteopathic care have progressively shifted from biomechanical to biopsychosocial models. However, the intended purpose of our study was to compare standard OMT with sham OMT. Our design choices, including the choice of interventions, were made in accordance with this purpose. Contextual factors, which are important in clinical practice, were purposefully controlled in both arms to specifically assess the effects of the manipulative component of osteopathic care. Standard OMT was personalized based on the results of osteopathic assessment. Only sham OMT (ie, light touch) was standardized. Even though light touch has limitations, we found no important imbalance in credibility or treatment expectations between standard and sham OMT groups. Finally, Quesnay and colleagues questioned our study design choice of a randomized clinical trial. They suggested that realist evaluations may be superior to randomized clinical trials when assessing the effect of a complex intervention. We disagree. The choice of study design depends on the purpose of the trial, not only on the type of interventions. If a conventional parallel group randomized clinical trial is not possible, the Medical Research Council recommends considering alternative designs.5 However, the randomized clinical design remains the gold standard to compare effectiveness. Considering the specificities and context of our interventions, the randomized clinical design was best suited to address our specific research question.6

Christelle Nguyen, MD, PhD
Rafael Zegarra-Parodi
Isabelle Boultron, MD, PhD

Author Affiliations: UFR de Médecine, Faculté de Santé, Université de Paris, Paris, France (Nguyen, Boultron); AP-HP, Centre-Université de Paris, Hôpital Cochin, Service de Rééducation et de Réadaptation de l’Appareil Locomoteur et des Pathologies du Rachis, Paris, France (Nguyen); INSERM UMRS-1124, Toxicité Environnementale, Cibles Thérapeutiques, Signalisation Cellulaire et Biomarqueurs (TJS), Campus Saint-Germain-des-Prés, Paris, France (Nguyen); A.T. Still Research Institute, A.T. Still University, Kirkville, Missouri (Zegarra-Parodi); COME Collaboration, Pescara, Italy (Zegarra-Parodi); School of Health Sciences, HES-SO University of Applied Sciences and Arts Western Switzerland, Fribourg, Switzerland (Zegarra-Parodi); AP-HP, Centre-Université de Paris, Hôpital Hôtel-Dieu, Centre d’Épidémiologie Clinique, Paris, France (Boultron); INSERM UMR-S 1153, Centre de Recherche Épidémiologie et Statistique, ECaMO Team, Paris, France (Boultron).

Corresponding Author: Christelle Nguyen, MD, PhD, AP-HP, Centre-Université de Paris, Hôpital Cochin, Service de Rééducation et de Réadaptation de

1144 JAMA Internal Medicine August 2021 Volume 181, Number 8 jamainternalmedicine.com © 2021 American Medical Association. All rights reserved.