In Reply On behalf of our coauthors, we thank Dr Stein for his interest in our study, “Effect of Stellate Ganglion Block Treatment on Posttraumatic Stress Disorder Symptoms: A Randomized Clinical Trial.” We are pleased to have the opportunity to address his questions.

Regarding the question about why the study enrolled fewer patients than were indicated in our ClinicalTrials.gov registration; enrollment failed to meet estimates used for the study design in the trial’s first months. An interim sample size reestimation pooling all participants and conducted when the first 82 participants had 8-week data was conducted by analysts blinded to treatment regimen. The observed SD in the Clinician-Administered PTSD Scale for the DSM-5 (CAPS-5) score at 8 weeks was lower (12.4) than that used in the initial sample size estimate (25). Using this revised SD, we estimated that a smaller sample size of 100 to 120 participants (the range that appeared likely with a fixed additional recruitment period of 9 months) would provide reasonable power (80%-95%) to detect a difference of 10 to 15 points in CAPS-5 total symptom severity scores (TSSSs) between the 2 treatment groups. The study sample size was adjusted accordingly.

We also appreciate the opportunity to clarify the trial’s primary outcome. The trial was designed to detect a mean change difference in CAPS-5 TSSSs from baseline to 8 weeks between the 2 groups, with the hypothesis that the mean change would be greater in the active than sham treatment group. Specifically, the study had 80% to 95% power to demonstrate a difference in mean change between the SGB and sham arms with a smaller SD suggested adequate statistical power to detect a difference in mean change between the SGB and sham arms with a smaller sample size, and the study indeed detected a statistically significant between-group change difference. The revised protocol (March 3, 2018), in which the primary outcome was changed from a 15-point to a 10-point reduction, was submitted for institutional review board approval in early March 2018, prior to the end of the study and before data analysis was begun.

We hope these responses address the concerns identified by Dr Stein. We appreciate the opportunity to have made corrections to the original article to clarify these points.

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Bradford B. Walters, MD, PhD
Dennis Wallace, PhD

CORRECTION
Clarifications to Measures, Analyses, and Findings in Trial of Stellate Ganglion Block Treatment for Posttraumatic Stress Disorder Symptoms: In the Original Investigation, “Effect of Stellate Ganglion Block Treatment on Posttraumatic Stress Disorder Symptoms: A Randomized Clinical Trial,” published online on November 6, 2019, and in the February 2020 issue, clarifications were needed for the measures, statistical analyses, and findings. Corrections have been made to the Abstract, Methods, Results, and Discussion sections of the text and Table 2. A new Table 3 has also been added. A letter explains the clarifications in detail. An earlier correction was made to this article. On both occasions, the article was corrected online.
