

The Impact of Fu's Subcutaneous Needling on Lower Limb Muscle Stiffness in Knee Osteoarthritis Patients: Study Protocol for a Pilot Randomized Controlled Trial [Response to Letter]

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Dear editor

We appreciate the Editor-in-Chief for allowing us to respond to comments from Dayong Zhong.¹ We also thank Dayong Zhong for his interest in our study, "The Impact of Fu's Subcutaneous Needling on Lower Limb Muscle Stiffness in Knee Osteoarthritis Patients: Study Protocol for a Pilot Randomized Controlled Trial".² His insightful comments offer an excellent opportunity to clarify and expand upon the points they raised.

We recognize the necessity of distinguishing our current research from previous studies, including the earlier work;³ this study differs in several aspects. First, we have utilized shear wave elastography (SWE) as an objective measurement tool. Unlike our previous work, which emphasized subjective outcomes like pain relief and functional improvement, the current study uses SWE as the primary outcome measure to quantify lower limb muscle stiffness changes objectively. This novel approach allows for a more in-depth investigation into the physiological mechanisms of Fu's Subcutaneous Needling (FSN). We created a standardized SWE protocol to reduce measurement errors and improve result reproducibility, enhancing the reliability of our findings in this protocol. Second, we extended the follow-up period and increased the sample size to boost the study's statistical power and assess the long-term durability of treatment effects. In addition, this study incorporates a broader range of outcome measures, including quality of life assessments (SF-12) and more frequent evaluations of pain and function. This comprehensive approach will provide a more nuanced understanding of the effects of the treatment.

Regarding the frequency of evaluations using the Numeric Rating Scale (NRS) and WOMAC, we conducted more frequent assessments to capture dynamic changes in pain and function throughout the treatment period for several reasons in our protocol. Several studies have demonstrated that FSN exhibits significant short-term efficacy in rapidly alleviating pain and improving knee joint function in knee osteoarthritis (KOA) patients.^{3,4} However, another study⁵ suggests its benefits may plateau after several sessions, showing no significant difference from control groups over more extended periods. By investigating this plateau, we aim to determine the optimal treatment duration that maximizes patient outcomes while minimizing unnecessary interventions. Frequent assessments enable us to precisely monitor the point at which additional treatments yield diminishing benefits, thereby optimizing the treatment protocol. Although this approach differs from previous acupuncture studies on KOA, the benefits of obtaining detailed temporal data justify the

increased assessment frequency. Participants are fully informed of the assessment schedule, and measures are taken to minimize inconvenience, maintaining high levels of compliance.

Finally, we have adjusted the control intervention in the current protocol. Previously, we compared FSN to transcutaneous electrical nerve stimulation (TENS), but we used electroacupuncture (EA) as the control intervention in this protocol for the following reasons. First, EA is more widely used to treat knee OA in China and has a more robust literature evidence base than TENS. Second, EA provides a more comparable sham control to FSN, as both involve needle insertion, potentially improving blinding. Third, using EA allows us to compare two active interventions, providing more clinically relevant information. These changes enable a more direct comparison between the two acupuncture-derived techniques.

In summary, we appreciate the opportunity to address these crucial points, enhancing our work's clarity and impact. Our study is designed to advance understanding of FSN's role in treating KOA by investigating its mechanisms, optimal treatment dosage, and comparative efficacy. We look forward to sharing the results with the scientific community and contributing to improved therapeutic strategies for KOA.

Disclosure

The authors declare no conflicts of interest in this communication.

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