

Evaluating Effectiveness of Fu's Subcutaneous Needling for the Pain Nature and Quality of Life in Patients with Knee Osteoarthritis: A Study Protocol of Randomized Clinical Trial [Response to Letter]

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Dear editor

We appreciate the Editor-in-Chief for giving us the opportunity to respond to comments from Xu et al. We also express our appreciation to Xu et al for the attention on our study entitled "Evaluating Effectiveness of Fu's Subcutaneous Needling (FSN) for the Pain Nature and Quality of Life in Patients with Knee Osteoarthritis: A Study Protocol of Randomized Clinical Trial".¹ Hereby, we provide a point-by-point response to the comments raised by Xu et al from the following aspects.

As Xu's comment, FSN has been used for more 20 years, but does not have a high-quality randomized controlled trial till now, so we design and conduct a rigorously clinical trial to observe and prove the clinical efficacy of FSN. The mechanism of FSN is still insufficient as Xu's comment. We had conducted and published an animal study² to figure out the mechanism of FSN, but there was still a big area of unknown, so simultaneously mechanism studies are very important issues for our research team in the future work.

For the first suggestion of Xu et al, there is actually a meaningful distinction between "efficacy" and "effectiveness" approaches to research, and the understanding of the distinction between "efficacy" and "effectiveness" research is not only crucial when conducting research but also interpreting results from the studies.³ As the definition of Porzolt et al,⁴ "efficacy" can be demonstrated in an explanatory, i.e., a randomized controlled trial completed under ideal study conditions; "effectiveness" can be demonstrated in an observational, i.e., a pragmatic controlled trial completed under real-world conditions. But "effectiveness" studies may also use a randomized trial design while a new treatment being studied is typically compared to treatment using the standard of practice for the patient population being studied.⁵ That is the reason we chosen the term "effectiveness" as the title of our study protocol.

About the second recommendation, we did not indicate visual analog scales (VAS) in the abstract. We will put this key information and presented in the abstract in the future article. As we know, an optimal primary outcome is the one for which there is the most existing or plausible evidence of being associated with the exposure of interest or intervention. According to previous randomized clinical trial studies of degenerative knee osteoarthritis (OA),⁶ acupuncture has been shown to be effective in pain relief,

and suggested for treating various kinds of functional disabilities to knee OA. FSN is originated from Chinese traditional acupuncture, so we choose the VAS as the primary outcome, and the dysfunction-related indicators as the secondary outcomes according to previous research of acupuncture treatment for knee OA.⁶ We will point out the primary and secondary outcomes and make more detail descriptions in our final result article.

In summary, our study provides potential collaborators and institutions, and hot topics, thereby providing a perspective to the developing trend of FSN therapy, which may help researchers explore new directions for future research in this field.

Disclosure

The authors report no conflicts of interest in this communication.

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