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LETTER

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 [Letter]

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Dear editor

We are very happy to read Chiu et al's paper published in the *Journal of Pain Research*, entitled "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."[1] That is one small paper for the journal, one giant leap for Fu's Subcutaneous Needling (FSN).

FSN has been used in China for more than 20 years. However, the related studies cannot keep up with FSN. As far as we know, FSN does not have a high-quality randomized controlled trial. Previously published studies were basically Chinese local articles. Articles published in the international community are mostly based on observational studies, such as case reports or retrospective studies, and there are few randomized controlled trials. Most of them are poorly designed and lack evidence-based power. The paper, 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, is the first rigorously designed clinical trial, which will promote the development of FSN.

On the other hand, the research on the mechanism of FSN is still insufficient. At present, there is few research focusing on the mechanism of FSN, neither the Chinese academic community nor the international community. If the research on FSN can be carried out simultaneously from the perspectives of clinical efficacy and mechanism of action, this technology that has been used in clinical practice for many years can coruscate more powerful vitality.

At the same time, this article can be modified to be more perfect via some precise descriptions. First of all, the title used "effectiveness" to describe the curative effect. In fact, "effectiveness" is used to describe a larger sample, multi-center, and more extrapolative conclusion.[2] There are 90 subjects in the trial, then "efficacy" or "effect" will be more suitable. Secondly, the outcome, visual analog scales, had been not indicated in the abstract. Key information in the main body should be presented in the abstract totally. In addition, authors should point out the primary outcome and secondary outcomes in the protocol, which will determine the final result. If primary outcome is positive while secondary outcomes are negative,

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the study is still positive because primary outcome deals with primary research question successfully. Moreover, primary outcome also determines the sample size calculation method. Hence, the authors should indicate primary outcome in the paper, especially in a study protocol.

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Disclosure

The authors declare no conflicts of interest in this communication.

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