

# Letter to the Editor: Acupuncture Based on Regulating Autonomic Nerves for the Prevention of Migraine without Aura: A Prospective, Double-Dummy, Randomized Controlled Clinical Trial [Response to Letter]

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## Dear editor

We sincerely appreciate your interest in our manuscript, and we would like to express our sincere gratitude for your approbation of our study. We will try our best to do this study well.

In the letter, Mr. Xie mentioned a recent cohort analysis in China that showed migraines are common in those aged 10–60 years old,<sup>1</sup> while our inclusion criteria of patients aged 25–50 years old.<sup>2</sup> We thought the main purpose of inclusion criteria in clinical studies is to control confounding factors that may affect the results to make the sample better homogeneity. And it is desirable that the volunteers included in the study have good compliance. In China, most of the people in this age group (25–50 years old) are in the workplace so the social pressures they face are as similar as possible. Before the age of 25, they may still be studying in school, while after the age of 50, they may have retired from the workforce. Moreover, younger patients may have poor adherence to acupuncture therapy. More importantly, studies<sup>3</sup> have shown that a wide age span may lead to a wide range of heart rate variability. The purpose of this study is based on regulating autonomic nerves, so to maintain better homogeneity, we decided to reduce the age span to 25–50 years old.

As for the inclusion criteria that pharmacotherapy and other treatments are not very effective for patients, what we mean is that volunteers recruited in this study have suffered from migraines for many years and have been treated with various methods, including medication (flunarizine is just one kind of drug) or other physical therapy. Migraines may decrease with medication. Unfortunately, they have not been cured and still suffered from frequent attacks. In other words, flunarizine and other pharmacotherapy are effective for migraine attacks, but it is not a cure. Hence, they are looking for more effective treatments. Given that the drug is considered a common treatment for migraine headaches in China, we choose it as the control. And according to our survey, flunarizine is currently approved and recommended for use in many countries, such as the EU,<sup>4</sup> Canada,<sup>5</sup> and China.<sup>6</sup>

The randomization used in our study is simple randomization. The randomization would be performed by individuals who did not participate in this study. Random numbers are generated by Excel, made into distribution cards, and sealed with envelopes. When eligible cases entered the test, the envelopes were opened according to the order of their entry. Then they would be treated according to the group specified by the card inside the envelope. The random number table will be kept strictly until the end of the trial when unblinding is performed.

To avoid what Mr. Xie refers to as psychological factors, we used a double-simulation noninferiority method in this study. Acupuncture and flunarizine are both acceptable methods to Chinese people, which balance the psychological factors. As mentioned by Mr. Xie, different cultural views on acupuncture may affect the outcome of this study. We believe that as the efficacy of acupuncture is more and more proven, it will be more accepted by people all over the world. In addition, to solve the differences caused by different operations of acupuncturists, we chose experienced acupuncturists and combined anatomy knowledge to select points. Since our current study is only a small part, we look forward to similar studies being carried out worldwide.

Finally, we would like to thank Mr. Xie again for your approbation and suggestions. We believe it will help us a lot in improving the quality of our study. And we also look forward to the day when our research can be carried out in different environments and cultures.

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## Disclosure

The authors report no conflicts of interest in this communication.

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