

## **Effect of acupuncture and moxibustion on common cold symptoms: multi-center randomized controlled trials and future directions**

*Norihito Takahashi*

Department of Geriatric Acupuncture and Moxibustion, Meiji University of Oriental Medicine

We report the results of multi-center randomized controlled trials (RCTs) on the effects of acupuncture and moxibustion therapy on the common cold, and comment on future clinical trial design. In 2000, a pilot trial was carried out using a small sample number of subjects. Positive results from the pilot study warranted a large-scale RCT covering 5 centers and 329 subjects. No significant differences were found between the intervention and control groups. However, converted effects and sex differences were found. Next, we performed an RCT with 6 centers (367 patients) using moxibustion therapy. In this study, we found a tendency toward effectiveness in the intervention group, but this result was not statistically significant. Moreover, in spite of uniform procedures, the results varied between centers, suggesting that differences in the environment of each center affected the results. Following this study, a multi-center RCT was carried out that unified the appraisal method, but used the original intervention method for common cold symptoms at each center. No clear curative or preventive effects were found.

The results of the multi-center studies suggested that problems in running large-scale RCTs included differences in management between the centers, as well as difficulty in obtaining a large number of subjects at the same time. To solve these problems we applied an n-of-1 clinical trial design, then integrated and generalized the results using the Bayesian method. We carried out a pilot n-of-1 trial on the effects of moxibustion on the common cold. The results were negative, but we confirmed that each trial could be easily carried out. Future studies will continue to accumulate n-of-1 trial results and will integrate these results in an overall general analysis.

Keywords: multi-center RCT, n-of-1 trial, Bayesian method