



A brief overview of the challenges of acupuncture trials in obesity



Previous studies suggest that the effect of acupuncture combined with lifestyle modification on obesity is high, and there might be no difference between true or sham acupuncture combined with lifestyle modification Kim et al ¹. However, the number of studies comparing true acupuncture alone with sham acupuncture alone, or no treatment or standard treatment alone, is small. In fact, to confirm the clinical effectiveness of pure acupuncture, more studies are required on the net effect of acupuncture on obesity Kim et al ¹. One of the challenges in designing and implementing such studies is the ethics committees' opposition to this type of study design. They do not support pure acupuncture trials, arguing that depriving the patient of standard treatment is immoral. To address this challenge, acupuncture trials should first look for the potential superiority of the effect of combination of real acupuncture and lifestyle modification over the combination of sham acupuncture and lifestyle modification, with creative study designs. This goal should be pursued by designing clinical trials with large sample sizes and low risk of bias, with sufficient intervention time at least 8–12 weeks, appropriate sham acupuncture design, and appropriate study groups. The design of sham acupuncture is very important in such studies. Superficial needle insertion or puncturing outside the true acupoints does not seem to be appropriate. The use of placebo needles such as “Streitberger” is advisable in such interventions, although the high cost of these needles is a serious challenge, because a relatively high number of needles are needed in the treatment of obesity. The study design is suggested to include at least three groups of combined true acupuncture and lifestyle modification, combined sham acupuncture and lifestyle modification, and lifestyle modification alone in order to determine the effect size of sham acupuncture compared with lifestyle modification besides the effect size of true acupuncture compared with lifestyle modification. By that, a great step will be taken to eliminate the uncertainty of the effect of true acupuncture against sham acupuncture within the limited ethical considerations. In the meantime, attention to the proper and sufficient acupuncture

stimulation would be a determining factor in the results. Factors such as the type of acupuncture, the selected acupoints, and the duration and frequency of needle stimulation can all contribute to the adequacy of acupuncture stimulation.

Another important issue to enrich the scientific support of the acupuncture effect in obesity is to follow the path of new drug interventions, which is the design of more accurate animal studies and the translation and transfer of animal studies to human clinical trials. In this regard, the simulation of traditional acupuncture points used in human clinical practice on animals, and clarification of the mechanisms of acupuncture in obesity through animal studies, are major research gaps Wang et al ².

If the superiority of the effects of combination of true acupuncture and lifestyle modification on combination of sham acupuncture and lifestyle modification, also over the lifestyle modification alone are demonstrated in such studies; and further animal studies support the effects of different acupuncture points and mechanisms, ethics committees can be persuaded to approve the design of pure acupuncture trials.

References

1. Kim SY, Shin IS, Park YJ. Effect of acupuncture and intervention types on weight loss: A systematic review and meta-analysis. *Obes Rev.* 2018;19(11):1585–1596.
2. Wang LH, Huang W, Wei D, et al. Mechanisms of acupuncture therapy for simple obesity: An evidence-based review of clinical and animal studies on simple obesity. *Evid Based Complement Alternat Med.* 2019;2019(Feb 3):5796381.

Hoda Azizi

Department of Chinese and Complementary Medicine, School of Persian and Complementary Medicine, Mashhad University of Medical Sciences, Mashhad, Iran