Moxibustion, used for thousands of years in the traditional medicine of Asian countries such as China, Korea, and Japan, can be traced back to the oldest Chinese medical text, the two-thousand-year-old *Yellow Emperor's Canon of Medicine* (*Huangdi Neijing*), which states, “If the needle cannot treat it, moxibustion is appropriate”[1].

Moxibustion, a thermal stimulation, is performed by burning dry *Artemisia vulgaris* at an acupuncture point[2,3]. Generally, there are two methods: (1) direct, in which heat is applied directly over the skin, and (2) indirect, in which the skin is insulated by various materials (*e.g.*, salt, monkshood cake, and sliced ginger or garlic) placed between it and the burning moxa[4].

Of the multiple clinical applications of moxibustion, only a few have been studied in randomized controlled trials (RCTs): breech fetus presentation[5-8], hot flashes[9], constipation[10], chronic fatigue[11], and lumbar disc herniation[12]. Lack of appropriate methodology for conducting high-quality research may be the key stumbling block for moxibustion clinical trial design. Double blinding has been especially difficult in this modality. In pharmaceutical trials, double-blinding is simple. Drug and placebo can be made to be identical in appearance and taste. In trials of moxibustion, acupuncture, and other therapies that involve procedural manipulations, blinding is hard to ensure. However, several sham moxa devices have recently been introduced for use in moxibustion RCTs.

The first sham moxa device was described in 2006 by our team[13]. Seventy-one subjects, 55 to 75 years old, with no prior experience or knowledge of moxibustion, were randomized to verum (*n*=36) or sham (*n*=35) moxibustion groups using a randomized block design. Participants were treated bilaterally at acupoint Zusanli (ST36) three times a week for four weeks with devices consisting of a base
and a moxa pillar. The real device has an opening in the center that allows heat and smoke from the burning pillar to circulate at the surface of the acupoints; the sham device has an insulating plate in the base to prevent the points from receiving heat and smoke stimulation\[^{13}\] (Figure 1). Verum and sham devices are identical in appearance, burning procedure, and burning residue, so the treatment is masked from both patients and practitioners. Results of a blinding effectiveness questionnaire, which was administered to patients and practitioners, showed successful double blinding. Very importantly, even the practitioners were blind to the treatment procedures.

Figure 1 Real and sham moxa devices by Zhao et al\[^{13}\]
The sham device has a thermal-insulating plate.

The sham device posed some potential limitations, as it produced neither the brownish mark that moxa compounds leave on the surface of the skin nor, due to the thermal insulator, a sensation of warmth. To compensate for these limitations, the researchers recruited participants without prior experience of moxibustion and sprayed patients’ skin with gentian violet liquid prior to each treatment.

Since this study, several investigators have used modified sham devices based on the same concept in double-blind clinical trials on various diseases and conditions. These include functional constipation\[^{10}\], knee osteoarthritis\[^{14}\], and chronic fatigue\[^{11}\]. Two investigations evaluated blinding effectiveness\[^{11,15}\] (Table 1). In the first, Kim et al\[^{15}\] tested the effectiveness of a sham device at Hegu (LI4) on healthy volunteers who were randomly divided into verum (n=15) and sham (n=15) groups using computer-generated randomization. The device consisted of a temperature-controlled heat module and a heat-conducting base. The temperature was managed by a control box connected with a direct current power supply and a temperature controller. The verum device had a round inner thermal conductor and an outer thermal-insulating ring; the sham device had a diagonal groove inside the heat conductor. The sham device radiated 39°C of heat to the skin; the verum radiated 44°C, the therapeutic level of clinical moxibustion\[^{15}\]. The research showed that participants in the sham group were unable to guess that they had received sham moxibustion, probably due to the heat produced by the sham device.

Neither the Kim et al investigation\[^{15}\] nor our own\[^{13}\] included an evaluation of treatment effect. However, another RCT by Kim et al\[^{11}\] investigated treating chronic fatigue syndrome (CFS) with indirect moxibustion and evaluated both treatment and blinding effectiveness. Clinical trials on moxibustion for treating CFS are widely reported in the Chinese literature\[^{16,17}\], but well-designed, scientifically rigorous studies are lacking. This study was double-blinded, thus minimizing the risk of bias. Forty-five patients with idiopathic CFS were randomized to verum (n=25) and control (n=20) groups using block randomization. The

### Table 1 Blinding effectiveness of sham devices in moxa RCTs

<table>
<thead>
<tr>
<th>Item</th>
<th>Group</th>
<th>Believed received real moxibustion</th>
<th>Believed received sham moxibustion</th>
<th>Unsure</th>
<th>Design</th>
<th>Acupoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhao et al 2006[^{13}]</td>
<td>TG</td>
<td>30/35 (85.7%)</td>
<td>0/35 (0%)</td>
<td>5/35 (14.3%)</td>
<td>Double-blind RCT</td>
<td>LI4</td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>29/33 (87.9%)</td>
<td>0/33 (0%)</td>
<td>4/33 (12.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kim et al 2011[^{13}]</td>
<td>TG</td>
<td>10/15 (66.7%)</td>
<td>3/15 (20.0%)</td>
<td>2/15 (13.3%)</td>
<td>Single-blind RCT</td>
<td>ST36</td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>12/15 (80.0%)</td>
<td>3/15 (20.0%)</td>
<td>0/15 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kim et al 2013[^{13}]</td>
<td>TG</td>
<td>8/25 (32.0%)</td>
<td>UR</td>
<td>UR</td>
<td>Double-blind RCT</td>
<td>CV4, CV8</td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>1/20 (5.0%)</td>
<td>UR</td>
<td>UR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Park et al 2011[^{10}]</td>
<td>TG</td>
<td>UR</td>
<td>UR</td>
<td>UR</td>
<td>Single-blind RCT</td>
<td>ST23, ST27</td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>UR</td>
<td>UR</td>
<td>UR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ren et al 2012[^{14}]</td>
<td>TG</td>
<td>UR</td>
<td>UR</td>
<td>UR</td>
<td>Double-blind RCT</td>
<td>EX-LE4, ST35, Ashi points</td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>UR</td>
<td>UR</td>
<td>UR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TG: treatment group; SC: sham control; UR: unreported; RCT: randomized controlled trial.
verum device was composed of a moxa cone with a salt flooring intermediary inside bamboo; the sham device included a thermal insulator consisting of a rigid polystyrene plastic and mudpack. The devices were applied at Guanyuan (CV4) and Shenque (CV8) three times a week for four weeks. Fatigue severity was assessed with a self-rating numerical scale and a visual analog scale at 0, 2, and 4 weeks; blood was taken at 0 and 4 weeks to determine patients’ oxidative stress parameters. The researchers found that verum treatment significantly lowered fatigue severity compared to sham moxa control (P<0.05 and P<0.01, respectively; see Table 1). Blood tests also showed that verum moxibustion at CV4 and CV8 had antioxidant properties. The authors did not report their participants’ conjectures about their respective treatment assignments, but there is a brief mention of these in the discussion section of the report. Due to the uncertainty of the effectiveness of the blinding, it is difficult to interpret the results of this trial.\textsuperscript{[11]}

Two additional studies on the efficacy of verum versus sham moxibustion do not report blinding effectiveness. Park \textit{et al}\textsuperscript{[10]} evaluated the effectiveness of moxibustion for the treatment of functional constipation. Twenty-six participants were randomly divided into moxibustion (n=13) and sham (n=13) groups. Participants were treated bilaterally at acupoint Taiyi (ST23) and Daju (ST27) three times a week for four weeks with devices consisting of a base and moxa pillar. The verum and sham devices were identical in appearance, burning procedure, and burning residue, but the sham device included an insulating plate that prevents heat transmission and stimulation. Measurement of defecation frequency and the Bristol Stool Form Scale and the Constipation Assessment Scale showed that moxibustion had no positive effect on constipation compared to sham\textsuperscript{[10]}. Ren \textit{et al}\textsuperscript{[14]} studied the effectiveness of moxibustion on knee osteoarthritis using a new device invented by Professor Zhao; it is similar to the device shown in Figure 2. Fifty-nine participants were randomized to moxibustion (n=31) or sham (n=28) groups. A metal-insulating membrane was added to the sham device to prevent heat and smoke stimulation. The participants were treated at Neixiyan (EX-LE4), Dubi (ST35), and Ashi points three times a week for six weeks. After six weeks of treatment, the moxibustion group showed significant improvement according to the Western Ontario and McMaster Universities’ Osteoarthritis Index (pain, stiffness, and physical function) but no significant improvement in walking speed compared to the sham group\textsuperscript{[14]}.

An intensive “sham” procedure is very likely to produce a therapeutic effect. To compensate for this unintended effect, we recently modified a moxa device to develop a sham apparatus that allows control, through air pores, of the amount of heat that radiates to the skin. As shown in Figure 2, a moxa pillar is fastened to the upper portion of the device, the moxa is lighted, and the upper portion is placed on the base; the pores keep the temperature below the therapeutic norm of 42-44 °C. The device, which blocks therapeutic heat, further improves blinding, and produces a sham treatment identical to verum in appearance, operating procedure, smoke, and smell, needs further evaluation. It is hoped that this modification will improve double-blind, placebo controlled clinical trials of moxibustion.

**Acknowledgements**

The project was partially supported by the National Natural Science Foundation (No. 81320108028 and No. 81373730), and the Key Program of State Administration of Traditional Chinese Medicine of China (No. ZYSNXD-CC-ZDXK-07).

**Conflict of interests**

Professor Bai-xiao Zhao owns one moxibustion device patent (No. ZL200920152348.7) and one sham moxibustion device patent (No. ZL99244856.5); other authors declare that there is no conflict of interests.

**REFERENCES**


Submission Guide

Journal of Integrative Medicine (JIM) is an international, peer-reviewed, PubMed-indexed journal, publishing papers on all aspects of integrative medicine, such as acupuncture and traditional Chinese medicine, Ayurvedic medicine, herbal medicine, homeopathy, nutrition, chiropractic, mind-body medicine, TaiChi, Qigong, meditation, and any other modalities of complementary and alternative medicine (CAM). Article types include reviews, systematic reviews and meta-analyses, randomized controlled and pragmatic trials, translational and patient-centered effectiveness outcome studies, case series and reports, clinical trial protocols, preclinical and basic science studies, papers on methodology and CAM history or education, editorials, global views, commentaries, short communications, book reviews, conference proceedings, and letters to the editor.

- No submission and page charges
- Quick decision and online first publication

For information on manuscript preparation and submission, please visit JIM website. Send your postal address by e-mail to jcim@163.com, we will send you a complimentary print issue upon receipt.