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• Review

Can moxibustion, an ancient treatment modality, be evaluated in a double-blind randomized controlled trial? — A narrative review

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ABSTRACT: For thousands of years, moxibustion has been used for various diseases in China and other Asian countries. Despite the recent surge in Chinese herbal studies, few randomized controlled trials have been conducted on this modality, possibly due to the lacking of suitable double blinding methodology. This is a review of extant sham moxa devices and an introduction to a recently developed device that needs further validation.
KEYWORDS: moxibustion; direct moxibustion; indirect moxibustion; randomized controlled trial; reviews

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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 allow 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.

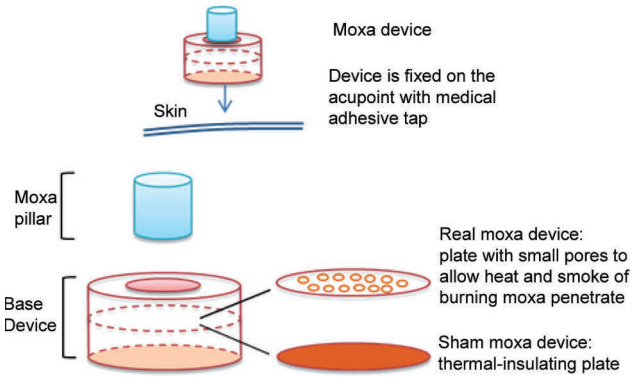

Figure 1 Real and sham moxa devices by Zhao *et al*[13]
The sham device has a thermal-insulating plate.

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 ℃ of heat to the skin; the verum radiated 44 ℃, 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

Item	Group	Subjects' understanding			Design	Acupoints
		Believed received real moxibustion	Believed received sham moxibustion	Unsure		
Zhao *et al* 2006[13]	TG	30/35 (85.7%)	0/35 (0%)	5/35 (14.3%)	Double-blind RCT	LI4
	SC	29/33 (87.9%)	0/33 (0%)	4/33 (12.1%)		
Kim *et al* 2011[15]	TG	10/15 (66.7%)	3/15 (20.0%)	2/15 (13.3%)	Single-blind RCT	ST36
	SC	12/15 (80.0%)	3/15 (20.0%)	0/15 (0%)		
Kim *et al* 2013[11]	TG	8/25 (32.0%)	UR	UR	Double-blind RCT	CV4, CV8
	SC	1/20 (5.0%)	UR	UR		
Park *et al* 2011[10]	TG	UR	UR	UR	Single-blind RCT	ST23, ST27
	SC	UR	UR	UR		
Ren *et al* 2012[14]	TG	UR	UR	UR	Double-blind RCT	EX-LE4, ST35, Ashi points
	SC	UR	UR	UR		

TG: treatment group; SC: sham control; UR: unreported; RCT: randomized controlled trial.