### 18. Symptoms and Signs

#### Reference

Sakaguchi S, Kanai S, Toda S. A randomized controlled trial of the effect of acupuncture and moxibustion on sensitivity to cold\*. *Kansai Iryou Daigaku Kiyou (The Bulletin of Kansai University of Health Sciences)* 2007; 1: 82–5 (in Japanese). Ichushi Web ID: 2008048658

#### 1. Objectives

To evaluate the effect of acupuncture and moxibustion on sensitivity to cold.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Kansai College of Oriental Medicine, Osaka, Japan.

#### 4. Participants

Nineteen volunteers with sensitivity to cold who: 1) responded to recruitment advertisements posted on the bulletin board in Kansai College of Oriental Medicine for approximately 2 weeks from the end of October 2005; and 2) provided written and oral informed consent (mean age, 20.5±3.2 years; range, 18–32 years).

#### 5. Intervention

Arm 1: Acupuncture group. In the supine position, disposable stainless steel needles (0.25×20 mm, Seirin Co., Ltd.) were inserted to a depth of 15 mm at the SP6 (三陰交) and ST36 (足三里) acupuncture points. Pre-cut moxa for heating (Hiei<sup>™</sup>, Senefa Corporation) was attached to the needle handle and burned. At the same time, warming moxibustion was applied around the CV4 (関元) acupuncture point by using 4 moxa rolls (Fukuju-koh<sup>™</sup>, Nippon Wakame Fukyu Kyokai) inserted in a guide tube for warm moxibustion (蓮台). Then, in the prone position, the moxibustion was applied around the BL32 (次髎) acupuncture point in the same manner as described above for CV4 (関元) while irradiating the lumbar area with infrared light (n=10).

Arm 2: Control group. No treatment during the intervention period (n=9).

One subject in Arm 1 with incomplete data was excluded from the analysis.

Treatment was administered taking into consideration each subject's menstrual cycle; once or twice per week, a total of 5 times, between the end of the menstrual period and the beginning of the next one.

#### 6. Main outcome measures

Degree of suffering from coldness assessed on a 6-point numerical rating scale (0-5; self-administered): 0=no cold feeling, 5=maximal coldness.

Score for static blood (瘀血, *oketsu*) measured by a masked evaluator before and after the intervention. Peripheral blood hematocrit, remnant-like particles-cholesterol (RLP-C) level, and viscosity.

#### 7. Main results

Degree of suffering from coldness showed no interaction with treatment arms and no significant between-arm difference. Similarly, score for static blood showed no interaction with treatment arms and no significant between-arm difference. The three hematologic variables also showed no interaction and no significant between-arm difference.

#### 8. Conclusions

Acupuncture and moxibustion has no additional effect over that of control treatment on sensitivity to cold.

- 9. From acupuncture and moxibustion medicine perspective
- The authors linked the development of sensitivity to cold with static blood.

# **10.** Safety assessment in the article

Not mentioned.

### **11.** Abstractor's comments

This valuable RCT evaluated the efficacy of acupuncture and moxibustion for reducing sensitivity to cold as compared with no treatment. Although the validity was not evaluated, the study is appreciated for seeking high-quality RCT by masking the evaluator of the static blood score. As a result, no effect of acupuncture and moxibustion was found, but it may become possible to detect a therapeutic effect on sensitivity to cold if sample size were predefined and outcome measures changed. The selection of treatment acupuncture points seems to have taken the link between sensitivity to cold and static blood into account, but the quantity and quality of the intervention should be discussed more extensively. Since sensitivity to cold is thought to occur over a wide age range, comparative trials including a wider range of age groups is desired.

# 12. Abstractor and date

Takahashi N, 6 December 2011.