#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

## 18. Symptoms and Signs

## Reference

Nishida S, Eguchi E, Ohira T, et al. Effects of a traditional herbal medicine on peripheral blood flow in women experiencing peripheral coldness: a randomized controlled trial. *BMC Complementary Alternative Medicine* 2015; 15: 105.

### 1. Objectives

To evaluate the clinical effects of tokishigyakukagoshuyushokyoto (当帰四逆加呉茱萸生姜湯) for peripheral coldness in women.

## 2. Design

Randomized controlled trial (RCT).

## 3. Setting

One university hospital and 1 hospital.

## 4. Participants

Fifty-eight women with peripheral coldness recruited online, etc. (aged 23-79).

#### 5. Intervention

Arm 1: TSUMURA Tokishigyakukagoshuyushokyoto (当帰四逆加呉茱萸生姜湯) Extract Granules (7.5g/day [2.5g t.i.d.] for 8 weeks) (n=28).

Arm 2: No administration (n=30).

#### 6. Main outcome measures

Blood flow and peripheral skin temperature before cold bathing test, and 1 and 10 minutes after.

#### 7. Main results

One participant could not be followed up and dropped out: 27 participants were analyzed in arm 1. Peripheral coldness was alleviated more in women in the tokishigyakukagoshuyushokyoto group than the control group. Although there was no difference in recovery of peripheral surface temperature between the tokishigyakukagoshuyushokyoto group and the control group, the rate of blood flow recovery was significantly higher in the tokishigyakukagoshuyushokyoto group (P<0.007).

## 8. Conclusion

The study suggests that tokishigyakukagoshuyushokyoto may alleviate coldness by improving peripheral blood flow in women.

## 9. From Kampo medicine perspective

None.

## 10. Safety assessment in the article

None.

# 11. Abstractor's comments

This paper substantiates by cold bathing test the effects of tokishigyakukagoshuyushokyoto, a Kampo medication used for intense coldness since long ago, and whose effects have been enumerated in the texts. It has great significance for evidence building. Preferably, the authors would have scored the subjects' cold sensation, and dealt more fully with the relationship between recovery of peripheral temperature and blood flow, and the decreasing sensation of cold. Although accompanied by some difficulties, a double-blind RCT with placebo using the same evaluation methods is anticipated.

## 12. Abstractor and date

Ushiroyama T, 16 January 2017.