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.

10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Kato S, Tamano M, Okamura A, et al. Clinical Research The preventive effects of Kampo medications for common cold syndrome in the elderly^{*}.*Kampo Igaku (Science of Kampo Medicine)* 2015; 39: 183-6.

1. Objectives

To verify the effectiveness of Kampo medications for the prevention of common cold syndrome in the elderly.

2. Design

Randomized controlled trial (RCT).

3. Setting

Health facility for the elderly (number of centers not mentioned), Japan.

4. Participants

Sixty elderly people staying at a health facility for the elderly, aged at least 75-years, who can orally take a Kampo medication unaided, and who do not have underlying pulmonary diseases (39 females and 21 males).

5. Intervention

Arm 1: A Kampo medication selected on the basis of Kampo medical diagnosis, taken for 6 months (n=30) (TSUMURA Rikkunshito [六君子湯] Extract Granules [n=6], TSUMURA Hochuekkito [補中益 気湯] Extract Granules [n=4], TSUMURA Juzentaihoto [十全大補湯] Extract Granules [n=7], TSUMURA Ninjinyoeito [人参養栄湯] Extract Granules [n=3], TSUMURA Rokumigan [六味丸] Extract Granules [n=3], TSUMURA Hachimijiogan [八味地黄丸] Extract Granules [n=2]), and TSUMURA Goshajinkigan [牛車腎気丸] Extract Granules [n=5]).

6. Main outcome measures

NK-cell activity (⁵¹Cr) before trial start and in month 3; frequency of common cold syndrome occurring from months 3 to 6.

7. Main results

The results for 60 participants were analyzed. NK-cell activity increased by a statistically significant amount in month 3 in arm 1, but it did not increase in arm 2 (P<0.01). Frequency of common cold syndrome was lower by a statistically significant amount in arms 1 and 2 (P<0.01).

8. Conclusion

Taking a deficiency-pattern treating Kampo formula activates NK-cells, improves appetite, stimulates metabolism, and prevents common cold syndrome.

9. From Kampo medicine perspective

Kampo medical diagnoses were made when selecting the specific Kampo medication in arm 1.

10. Safety assessment in the article Not mentioned.

11. Abstractor's comments

This is an important paper evaluating the preventive effects of Kampo medications on common cold syndrome. Although it is described as a randomized controlled trial, some doubt is raised about whether it was truly randomized by the fact that the group of 30 participants in the Kampo administration group were further divided by Kampo medical diagnosis into 3 groups (10 participants per group) and then administered 7 Kampo formulae: it is advisable to describe allocation methods in detail. The authors mention that ANOVA analysis was carried out, however, the graphs show repeated testing comparing 2 items, trial start and trial end data, in one group, so it is difficult to determine that ANOVA analysis testing between 3 or more groups was carried out. The authors also do not describe the criteria for diagnosing a cold. This paper is an important underpinning for further elucidation of the effectiveness of Kampo medications in preventing common cold syndrome, and hopefully the authors will continue with a paper that explicitly states the allocation method and diagnosis criteria.

12. Abstractor and date

Koike H, 23 April 2018