5. Psychiatric/Behavioral Disorders

Reference

Numata T, Gunfan S, Takayama S, et al. Treatment of posttraumatic stress disorder using the traditional Japanese herbal medicine saikokeishikankyoto: A randomized observer-blinded controlled trial in survivors of the great East Japan earthquake and tsunami. *Evidence-Based Complementary and Alternative Medicine* 2014: 1-6. doi:10.1155/2014/683293 CENTRAL ID: CN-00988474, Pubmed ID: 24790634

1. Objectives

To evaluate the efficacy and safety of saikokeishikankyoto (柴胡桂枝乾姜湯) for posttraumatic stress disorder (PTSD).

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Forty-three patients aged 20 years or older who survived the Great East Japan Earthquake and tsunami and had a diagnosis of PTSD according to the Diagnostic and Statistical Manual of Mental Disorders fourth edition (text revision) (DSM-IV TR), with an Impact of Event Scale-Revised Questionnaire (IES-R) score of ≥25. The patients meeting any of the following four criteria were excluded from the study: 1) major medical illness such as neoplastic disease, acute inflammation, and any other disease precluding successful completion of the study; 2) psychosis due to other disorders such as schizophrenia, depression, and dementia; 3) delirium due to drugs, alcohol; and 4) use of neuroleptics, antianxiety drugs, antiepileptic drugs, antidepressants, or herbal remedies during the past 2 months.

5. Intervention

Arm 1: TSUMURA Saikokeishikankyoto (柴胡桂枝乾姜湯) Extract Granules 2.5 g t.i.d. for 2 weeks orally (n=21).

Arm 2: No administration (n=22).

6. Main outcome measures

The primary outcome measure was severity of PTSD as measured on the total IES-R scale. The secondary outcome measures were scores on three IES-R subscales: the intrusion subscale of 8 items, Questions 1, 2, 3, 6, 9, 14, 16, and 20; the avoidance subscale of 8 items, Questions 5, 7, 8, 11, 12, 13, 17, and 22; and the hyperarousal subscale of 6 items, Questions 4, 10, 15, 18, 19, and 21.

7. Main results

Twenty-one subjects in Arm 1 and 22 subjects in Arm 2 were included in the analysis. One subject in Arm 1 dropped out of the study due to cough on Day 3. Changes in total IES-R scores were significantly different between the two arms ($P<0.001$). Total IES-R scores were significantly improved from baseline to the completion of the study in Arm 1 ($P<0.001$) but not in Arm 2. The between-arm differences in all three subscales were significant ($P=0.025$ for avoidance subscale; $P=0.005$ for hyperarousal subscale; $P<0.001$ for intrusion subscale). From baseline to the completion of the study, there was a significant improvement in three subscale scores in Arm 1 ($P=0.003$ for avoidance sub-scale; $P<0.001$ for hyperarousal subscale; $P<0.001$ for intrusion sub-scale) and a significant improvement in one subscale score in Arm 2 ($P=0.032$ for avoidance subscale). There were significant inter-arm differences in the scores on Questions 1, 3, 6, 14, 19, 20, and 21 ($P<0.001$ for Question 1; $P=0.005$ for Question 3; $P<0.001$ for Question 6; $P=0.003$ for Question 14; $P=0.001$ for Question 19; $P=0.002$ for Question 20; $P=0.001$ for Question 21).

8. Conclusions

Saikokeishikankyoto is effective for alleviation of PTSD.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One subject in the saikokeishikankyoto arm was withdrawn from the study on Day 3 due to mild cough.

11. Abstractor's comments

This was an innovative clinical study evaluating the efficacy of a Kampo product for treatment of post-disaster PTSD, and a valuable study given the rarity of this type of disaster. However, as mentioned by the authors, the small number of subjects, the influence of placebo effect, and the absence of control drugs for comparison seems to preclude adequate evaluation of the efficacy. Although there are many limitations to the conduct of this type of study, based on this study's findings, further development of clinical studies with longer follow-up and inclusion of positive and negative controls for comparison is anticipated.

12. Abstractor and date

Goto H, 31 March 2017.