

## OS08.02

**A traditional herbal formula, Yukmijihwang-tang, ameliorate oral moisture in the elderly complaining with xerostomia**

Gajin Han, Seok-Jae Ko, Juyeon Kim, Jae-Woo Park, Jinsung Kim

Kyung Hee University

**Purpose:** Xerostomia is common symptoms in the elderly and this has been impaired quality of life continuously. Many conventional treatments for xerostomia have limitations for their side effects. Hence, interest in treatment using the traditional Korean medicine (TKM) has been rising. In TKM theory, the main pathology of xerostomia in the elderly is considered as Yin-Deficiency (YD) and Yukmijihwang-tang (YJT) has been used for treatment of YD. This study aimed to investigate the efficacy and safety of YJT for xerostomia in the elderly and evaluate the correlation the xerostomia and YD.

**Methods:** The current study was randomized, placebo-controlled, double-blinded, two center trial conducted in Kyung Hee University Korean Medicine Hospital and Kyung Hee University Hospital at Gangdong. Ninety-six subjects aged 60-80 years with xerostomia for over 3 months were randomly allocated to YJT and placebo group. These subjects also presented with score >40 on VAS for xerostomia and unstimulated salivary flow rate under 0.3 mL/min. The subjects and all researchers were blinded to the group assignment. YJT or placebo was administered to each group for 8 weeks. The primary outcome was change in the scores of the VAS for xerostomia from 0 to 8 weeks.

**Results:** Both YJT and placebo group had xerostomia-relieving effect after 8 week administration by decreasing VAS for xerostomia and other xerostomia-related variables. In addition, 8 week-administration of YJT increased the level of oral moisture. The participants with BMI lower than 29.37 kg/m<sup>2</sup> showed improvement of VAS after 8 week treatment in YJT group only. There were not any significant adverse events related to YJT including SAE. In addition, xerostomia-related variables had causal relationship with YDQ and Ig A.

**Conclusion:** YJT could increase oral moisture status and improve subjective symptom of dry mouth in the elderly with lower BMI and more YD tendency. Besides, the correlation between xerostomia and YD was reconfirmed.

**Contact:** Gajin Han, [kmdhgj@naver.com](mailto:kmdhgj@naver.com)

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## OS08.03

**Chinese herbal medicine for oligomenorrhoea and amenorrhoea in polycystic ovary syndrome: A randomised feasibility study in the United Kingdom**

Lily Lai<sup>1</sup>, Andrew Flower<sup>1</sup>, Philip Prescott<sup>2</sup>, Michael Moore<sup>1</sup>, George Lewith<sup>1</sup>

<sup>1</sup>Primary Care and Population Sciences, University of Southampton

<sup>2</sup>Mathematical Sciences, University of Southampton

**Purpose:** Polycystic ovary syndrome (PCOS) affects 6-18% of women of reproductive-age and oligomenorrhoea and amenorrhoea are cardinal symptoms. Conventional management is associated with side-effects and anecdotal evidence suggests Chinese herbal medicine (CHM) can help. Individualised CHM is regarded as more effective than standardised, but requires investigation in randomised controlled trials (RCTs). This study explores the feasibility of conducting an RCT comparing standardised and individualised CHM for regulating menses in PCOS.

**Methods:** This pragmatic, practitioner-blinded feasibility study randomised 40 PCOS participants with oligo- or amenorrhoea into 2 parallel groups - standardised or individualised CHM - prescribed at 16 g granules/day as a tea for 6 months. Our primary aim was to evaluate feasibility of offering standardised and individualised CHM within an RCT and collect menstrual data for sample size calculation. Secondary data included body mass index, weight, hirsutism and safety data on liver/kidney function and adverse events.

**Results:** 40 women were recruited within our planned 7-month recruitment-period. 29 participants (72.5%) completed the study, 3 were lost-to-follow-up (7.5%) and 8 withdrew (20%). Analysis of covariance (ANCOVA) of menstrual rate per month showed statistically significant improvements in standardised CHM (MD 0.18±SE0.06, 95%CI 0.06 to 0.29) and in individualised CHM (MD 0.27±SE0.07, 95%CI 0.15 to 0.39). This did not reach between-group statistical significance (MD 0.10±SE0.08, 95%CI -0.07 to 0.26, p=0.26). ANCOVA of secondary measures suggest no important changes in body mass index or weight. Liver/kidney function at Week 4 was normal (n=35), abnormal ALT (n=1); at final visit was normal (n=30), abnormal (n=0). The case of abnormal ALT was later confirmed an acute response to alcohol.

**Conclusion:** We have demonstrated that a CHM RCT for PCOS is feasible and preliminary data suggests promising menstrual response in both groups. This data will be used to inform sample-size calculation and design of a main study that will incorporate an active or placebo-control.

**Contact:** Lily Lai, [l.y.w.lai@southampton.ac.uk](mailto:l.y.w.lai@southampton.ac.uk)

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