Abstract Book

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S-13. The effects of soy protein and isoflavones on body composition - a six-month double-blind randomized placebo-controlled trial among Chinese postmenopausal women

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Objective: In vitro and animal studies suggested soy protein and isoflavones promote weight and body fat loss but data from clinical trials are limited. This study aimed to investigate whether soy protein with isoflavones is effective or isoflavones benefit body composition on body composition among postmenopausal women. Design: A 6-month double-blind, randomized, placebo-controlled trial was conducted among 180 Chinese postmenopausal women aged 48 - 70 y with untreated mild hyperglycemia. After 2-week adaptation, participants were randomized into the 3 treatment arms with daily supplementing of soy protein for 100mg isoflavones (Soy group), or 15g milk protein + 100mg isoflavones (Iso group), or 1.5g Soya Peptide. Height, weight, waist and hip circumferences were measured according to standard protocols. Results: Both Soy and Iso groups, but not the placebo group, showed a significant reduction in body fat mass and fat-free mass. The percentage change in body fat mass was -3.74% (-5.88% to -0.69% P=0.017) between the Soy and Iso group, and -0.69% (-5.69 to -1.2%) P=0.08 between the Soy and Placebo group. The results were consistent after adjusting for the potential confounders or confined to those (90%) with good compliance (supplement > 80% compliance). The effects were more pronounced in women aged 48 - 56 years postmenopausal. Conclusion: Six-month supplementation of soy protein containing isoflavones had a modest favorable effect on body composition in Chinese postmenopausal women.

S-14. Safety and Efficacy of Black Cohosh and Red Clover for the Management of Vasomotor Symptoms: A Randomized Controlled Trial

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Objective: Since the results of the Women's Health Initiative, there has been a reduction in the use of hormone therapy (HT) for the relief of vasomotor symptoms and an increased interest in and use of botanical dietary supplements. Despite high consumer demand for botanicals for the management of vasomotor symptoms, there have been few rigorous clinical investigations. This study aimed to evaluate the safety and efficacy of these botanicals.

Background: Clitoridium racemosum (L. Nutt.) and red clover (Trifolium pratense L.) are used for relief of vasomotor symptoms. Design: This was a randomized, four-arm, double-blind clinical trial of standardized black cohosh, red clover, placebo and CEE/MPA one year period. The HT arm, the conventional and recognized approach for the relief of vasomotor symptoms in menopausal women, was included as a positive control. The primary outcome measures were reduction in signs and symptoms and laboratory analyses (hot flashes and night sweats) of black cohosh and red clover compared to placebo; secondary outcomes included safety evaluation, reduction of other menopausal complaints and overall improvement in quality of life. In total, 89 women were randomized to the study. Eighty women completed 12 months, eight women terminated early but were included in the intent to treat (ITT) analysis and one woman was lost to follow up. The intention to treat analysis rate was 98.8% (n=89) to follow-up rate of 1%. The overall adherence rate across groups was 88.6% with no significant differences in completion between groups. The average age was 53 years with a last menstrual period averaging 4.3 years earlier. Almost 55% of women in this study were from under-represented minorities (50% African American and 4.5% Hispanic). At baseline, study participants experienced, on average, 52 (placebo) to 71 (CEE/MPA) vasomotor symptoms per month. Results: The