

Project Summary

A Randomised placebo controlled study of the effect of a herbal product on mood swings and anxiety in younger women.

This study is a single centre, double blind, randomised, placebo-controlled trial (RCT). It will take place over 12 weeks (a 4 week monitoring cycle followed by 8 weeks of the RCT).

This Herbal Supplement contains Tyrosine, Cimicifuga racemosa extract, Pyridoxine HCl, Folic acid, Cyanocobalamin, Chromium picolinate, Calcium hydrogen phosphate. A recent large randomised controlled trial has shown that black cohosh (Cimicifuga racemosa) extract is an effective treatment for menopause symptoms, including psychological symptoms. Tyrosine appears to prevent the substantial decline in various aspects of cognitive performance and mood associated with many kinds of acute stress. Chromium supplements have been variably shown to improve glucose metabolism and might help reduce sugar cravings.

The measurement instruments

Psychological symptoms will be measured using the 42 question DASS (42-DASS). Physical symptoms will be measured using the Physical Symptom Score (PSS). The 42-DASS (Depression, Anxiety, Stress Score) is a well validated, psychological research tool, which has been designed to measure the negative emotional states of depression, anxiety and stress.

We wish to study the effect of the Herbal Supplement in reducing the psychological and physical symptoms in younger women by examining whether there is a significant difference in the 42-DASS score between subjects taking 2 tablets daily of Herbal Supplement compared to subjects taking 2 placebo tablets daily. The secondary aims are to examine the impact of this treatment on DASS sub-scores and some common physical premenstrual symptoms.

The clinical trial will include 110 women who suffer from mild to moderate psychological symptoms confirmed during one monitoring cycles, aged between 18 and 45. Recruitment will be facilitated through mail-outs, newspaper advertising, and television.

The potential subject will be invited to participate in a questionnaire on the internet twice during a 4-week screening cycle. As many women have significant variation in mood throughout their menstrual cycle, participants will be asked to complete the 42-DASS at specific points in their cycle (Day 1 or 2). On each of these data entry points, the subject will be asked to recall what happened over the preceding seven days. If they have at least one behavioural symptom and DASS scores that meet the entrance criteria, the subject will be randomized. After randomization to active or placebo treatment, all subjects will be monitored for three menstrual cycles.

Key Survey Tool will be applied via Web site: www.keysurvey.com. 42-DASS and physical symptom scores questionnaire will be created in the website. The web link will be emailed to eligible subjects 5 days before this entry points, and following up will be conducted via email reminder or telephone. The summary of data entry will be checked on the daily basis at the site to minimise missing data.