

**The effects of alcoholic extract of saffron (*Crocus sativus* L.) on mild to moderate comorbid depression-anxiety, sleep quality, and life satisfaction in type 2 diabetes mellitus:
A double-blind, randomized and placebo-controlled clinical trial.**

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Abstract

OBJECTIVE:

Depression and anxiety are major health problems throughout the world. Metabolic changes in type 2 diabetes mellitus induces and aggravates mental disorders, such as depression and anxiety. Saffron as a therapeutic herb may attenuate Comorbid Depression- Anxiety (CDA). So, this trial is designed to investigate the effect of saffron alcoholic extract on symptoms of CDA in type 2 diabetic patients.

METHODS:

Fifty-four outpatients suffered from mild to moderate CDA diagnosed by using Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV), were assessed by Hamilton Depression and anxiety measurements, the Pittsburgh Sleep Quality Index (PSQI), and the Satisfaction with Life Scale (SWLS). The participants of this double-blind, placebo-controlled, single center and randomized trial were randomly assigned to intake 30 mg/day saffron or placebo capsules for 8 weeks.

RESULTS:

After the intervention, mild to moderate CDA, anxiety and sleep disturbance, but not depression alone, were relieved significantly in the saffron group ($P < 0.05$), whereas, the changes were not significant in the placebo group. Anthropometric measures and blood pressure parameters of the patients in either groups did not change significantly ($P > 0.05$) during the intervention. Moreover, dietary intake and physical activity did not differ during the study in the two groups. Changes in the life satisfaction were not significant.

CONCLUSION:

The results indicate the beneficial effect of saffron on the mild to moderate CDA in type 2 diabetic patients.

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KEYWORDS:

Comorbid depression-anxiety; *Crocus sativus* L.; Life satisfaction; Saffron; Sleep quality; Type 2 diabetes mellitus