



Clinical Trials and Research of Saffron

Effects of Saffron Extract on Sexual dysfunction

Sexual Clinical Trials					
No	Date	Flouxetine + Saffron Compared with	Duration	Selected	Tested
1	2012	Fluoxetine + Placebo (Female)	4 Week	50	38
2	2012	Fluoxetine + Placebo (Male)	4 Week	54	36

Contents

1. Saffron in Phytotherapy: Pharmacology and clinical uses

Wiener Medizinische Wochenschrift (WMW) 2007; 157: 315-319

2. A randomized, double - blind, placebo - controlled study of safety of the adjunctive Saffron on sexual dysfunction induced by a Selective Serotonin Reuptake Inhibitor Journal of Medicinal Plants volume 10, No 37, winter 2011

3. Saffron treatment of Fluoxetine-induced sexual dysfunction in women: randomized double-blind placebo-controlled study Wiley Online Library. Human Psychopharmacology 2013; 28: 54-60

4. Effect of Saffron on Fluoxetine-induced sexual impairment in men: randomized double-blind placebo-controlled trial. Original Investigation Psychopharmacology DOI 10.1007/s00213-012-2729-6

5. Springer Low-Cost Approaches to Promote Physical and Mental Health.

1. Saffron in Phytotherapy: Pharmacology and clinical uses

Wiener Medizinische Wochenschrift (WMW) 2007; 157: 315-319

Mathias Schmidt, Georges Betti & Andreas Hensel

[Themenschwerpunkt](#)

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Wien Med Wochenschr 157, 315 (2007). <https://doi.org/10.1007/s10354-007-0428-4>

Summary:

Saffron (stigmates of *Crocus sativus* L.) has been used for medicinal purposes for millenaries. Throughout history, uses against cancer and depressive mood can regularly be identified. These applications have also been in the focus of modern research. Promising and selective anti-cancer effects have been observed in vitro and in vivo, but not yet in clinical trials. Antidepressant effects were found in vivo and in clinical pilot studies. Saffron extracts thus have the potential to make a major contribution to rational phytotherapy.

2. A randomized, double - blind, placebo - controlled study of safety of the adjunctive Saffron on sexual dysfunction induced by a Selective Serotonin Reuptake Inhibitor

Journal of Medicinal Plants volume 10, No 37, winter 2011

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 - **Acceptance: 9 Mar. 2011**
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Abstract :

Background:

Recent studies have indicated potential of saffron for applying in a wide variety of diseases such as psychiatric and neurologic disorders. The concurrent use of saffron with SSRIs can lead to reducing the dose of SSRIs. Saffron at a dose of 200 mg may change some hematological and biochemical parameters.

Objective:

The goal of this trial was to assess the safety of concomitant administration of saffron and SSRI in patients with major depressive disorder (MDD).

Methods:

Twenty adult outpatients between 18 to 55 years-old with the diagnosis of MDD who were receiving an SSRI for at least 1 month prior to the initiation of the study entered this double-blind trial. They were randomly assigned to receive capsule of saffron (15 mg twice daily) or placebo. Some laboratory parameters were measured at baseline and week 4 of the study. Other side effects checked on a prepared list of side effects, were systematically recorded

throughout the study at baseline and on a weekly basis.

Results:

Saffron as an add-on medication to SSRIs for 4 weeks did not cause any statistically significant changes in laboratory parameters including AST, ALT, ALP, BUN, Cr., FBS, TG, TC, WBC, RBC, Hgb, Ht, PT, INR, and PI count.

Conclusion: This preliminary study provides safety evidences of concurrent intake of saffron and SSRI.

3. Saffron treatment of Fluoxetine-induced sexual dysfunction in women: randomized double-blind placebo-controlled

Study Wiley Online Library. Human Psychopharmacology 2013; 28: 54-60

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human psychopharmacology

Hum. Psychopharmacol Clin Exp 2013; 28: 54–60.

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Objective:

Saffron (*Crocus sativus* L.) has shown beneficial aphrodisiac effects in some animal and human studies. The aim of the present

study was to assess the safety and efficacy of saffron on selective serotonin reuptake inhibitor-induced sexual dysfunction in women.

Methods:

This was a randomized double-blind placebo-controlled study. Thirty-eight women with major depression who were stabilized on

fluoxetine 40 mg/day for a minimum of 6 weeks and had experienced subjective feeling of sexual dysfunction entered the study. The patients

were randomly assigned to saffron (30 mg/daily) or placebo for 4 weeks. Measurement was performed at baseline, week 2, and week 4 using

the Female Sexual Function Index (FSFI). Side effects were systematically recorded.

Results :

Thirty-four women had at least one post-baseline measurement and completed the study. Two-factor repeated measure analysis of

variance showed significant effect of time treatment interaction [Greenhouse–Geisser’s corrected: $F(1.580, 50.567) = 5.366, p = 0.012$] and

treatment for FSFI total score [$F(1, 32) = 4.243, p = 0.048$]. At the end of the fourth week,

patients in the saffron group had experienced significantly more improvement in total FSFI ($p <$

0.001), arousal ($p = 0.028$), lubrication ($p = 0.035$), and pain ($p = 0.016$) domains of FSFI but not in

desire ($p = 0.196$), satisfaction ($p = 0.206$), and orgasm ($p = 0.354$) domains. Frequency of side effects was similar between the two groups.

Conclusions It seems saffron may safely and effectively improve some of the fluoxetine-induced sexual problems including arousal,

lubrication, and pain. Copyright © 2012 John Wiley & Sons, Ltd.

4. Effect of Saffron on Fluoxetine-induced sexual impairment in men: randomized double-blind placebo-controlled trial.

Original Investigation Psychopharmacology DOI 10.1007/s00213-012-2729-6

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Psychopharmacology volume 223, pages381–388 (2012)

- [Published: 03 May 2012](#)

Abstract

Rationale:

Saffron (*Crocus sativus* L.) has shown aphrodisiac effects in some animal and human studies.

Objectives:

To assess the efficacy and tolerability of saffron in fluoxetine-related sexual dysfunction.

Methods:

This was a 4-week randomized double-blind placebo-controlled study. Thirty-six married male patients with major depressive disorder whose depressive symptoms had been stabilized on fluoxetine and had subjective complaints of sexual impairment entered the study. The patients were randomly assigned to saffron (15 mg twice per day) or placebo for 4 weeks. International Index of Erectile Function scale was used to assess sexual function at baseline and weeks 2 and 4.

Results:

Thirty patients finished the study. Baseline characteristics as well as baseline and final depressive symptoms scores were similar between the two groups. Effect of time \times treatment interaction on the total score was significant [Greenhouse–Geisser-corrected, $F(1.444, 40.434) = 6.154$, $P = 0.009$]. By week 4, saffron resulted in significantly greater improvement in erectile function ($P < 0.001$) and intercourse satisfaction domains ($P = 0.001$), and total scores ($P < 0.001$) than the placebo group. Effect of saffron did not differ significantly from that of placebo in orgasmic function ($P = 0.095$), overall satisfaction ($P = 0.334$), and sexual desire ($P = 0.517$) domains scores. Nine patients (60%) in the saffron group and one patient (7%) in the placebo group achieved normal erectile function (score > 25 on erectile function domain) at the end of the study (P value of Fisher's exact test = 0.005). Frequency of side effects were similar between the two groups.

Conclusions:

Saffron is a tolerable and efficacious treatment for fluoxetine-related erectile dysfunction.

5. Springer Low-Cost Approaches to Promote Physical and Mental Health.**Shahin Akhondzadeh , PhD ,2 Javad Maleki, MD**

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Iran J Psychiatry 2006; 1: 1-11

Objective:

This review will indicate the quality of the evidence supporting the clinical effects of a number of commonly used types of herbal medicines for psychiatric and neurological disorders.

Method: We conducted a review of literature to understand the biochemical and evidential bases for the use of herbs in psychiatric and neurological disorders as follow:

1) Alzheimer's disease, 2) Depression, 3) Anxiety, 4) Insomnia, 5)

Substance use disorders, 6) Attention deficit/hyperactivity disorder

(ADHD), 7) Migraine.

Results:

: Evidences support use of Ginkgo biloba, Huperzine A, Galantamine, Melissa officinalis, and Salvia officinalis for Alzheimer's disease; St. John's wort, Lavender, and Saffron for depression; Passionflower, and Kava, for anxiety disorders; Valerian, and English Lavender for sleep disorders; Hypericum for substance related disorders; Ginkgo biloba, and Passionflower for ADHD; and feverfew, and Butterbur root for migraine. The highest level of confidence derives from well-designed, randomized, double blind controlled studies.

Conclusion: Herbs may have beneficial effects in variety of psychiatric and neurological disorder; however we must consider their potential side effects and drug-drug interactions

