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**Q&A and Clinical Research Summary**

[Saffrosun For Children](https://www.thenakedpharmacy.com/products/saffrosun-for-children)**®**

1. **What is Saffrosun For Children®?**

Saffrosun For Children® is a supreme quality, all natural, high potency nutritional supplement made exclusively by The Naked Pharmacy, a company committed to the ‘food as medicine’ approach to health, using food-based ingredients at the optimal strength and correct dosage.

Saffrosun is so-called because its active ingredients are sourced from high quality saffron, an ingredient used in cooking for hundreds of years which is derived from the stigma of the crocus flower. At the correct strength and dosage, saffron’s active components have been clinically proven in randomized controlled trials (the ‘gold standard’ of testing) to reduce symptoms of emotional imbalance, tiredness and fatigue.

1. **Who can benefit?**

Saffron For Children® has been carefully formulated to support in children aged 6 to 14 who may be suffering from poor emotional balance, and/or poor quality sleep. Saffrosun For children® is unique in containing high quality, Spanish saffron extract, which has been shown in clinical studies to help emotional balance. Adults can also benefit from the adult formulation of this product, Saffrosun®

1. **What are the active ingredients contained in Saffrosun For Children**®**?**

Saffrosun For Children® contains the world’s strongest, premium-grade **Saffron** stigma extract, sourced from La Mancha in Catalonia, Northern Spain, where the world’s most potent saffron is grown. It uniquely contains a standardised strength of **3.5% bioactives** compared to Saffron grown in other areas, which provides only a 0.3% strength of one of these bioactives. As such, it is the world’s highest strength saffron extract.

The saffron itself contains 3 active ingredients: Crocin, Saffranal and Picrocrocin, which belong to a subclass of carotenoids known as **Lepticrosalides.** Saffrosun For Children® also contains 100% of the recommended daily amount of vitamin B12 for children, as this vitamin has also been shown in clinical research studies to reduce tiredness and fatigue. It also contains vitamin D3 which can be lacking in the diets of young people, yet is important for healthy functioning and for growth.

1. **How does Saffrosun For Children**® **work?**

Saffron contains lepticrosalides - a subclass of carotenoids - which have been clinically proven to improve psychological balance, tiredness, and help individuals feel rested and refreshed on waking. These compounds are thought to work by boosting the body’s levels of serotonin - a hormone found in the brain, gut and blood platelets. Serotonin regulates mood and sleep. It also induces the ‘full’, contented feeling after eating a meal. Low serotonin levels are linked with depression, anxiety, poor sleep and other conditions.

1. **Is there scientific evidence that Saffrosun For Children**® **works?**

There is a growing body of evidence proving the active ingredients in are effective in both adults and children. Lepticrosalides have been *clinically proven* to improve psychological balance, tiredness, and help people feel rested and refreshed on waking. Indeed, the results of a new, randomized, double blind clinical [trial](http://www.sciencedirect.com/science/article/pii/S0965229917300821)1 conducted in Queensland, involving 128 participants reporting low self-mood, were published in the journal, *Complimentary Therapies in Medicine* published by Elsevier.The results show good statistical differences in depression, anxiety and stress levels when trial subjects received saffron extract. A new study2 researching the benefits of saffron in children suffering from ADHD is due for publication in 2017/18.

1. **Why is Saffrosun For Children**® **unique?**

This supplement uniquely contains saffron with a standardised strength of **3.5% bioactives,** compared to Saffron grown in other areas, which provides only a 0.3% strength of one of these bioactives. As such, this supplement contains the world’s highest strength saffron extract.

1. **How is Saffrosun For Children**® **taken?**

For children aged 6 – 10, one capsule is taken each morning with food.

For children aged 10 – 14, two capsules are taken daily, with food.

Capsules can be twisted open and the contents mixed with food if preferred. (Yogurt works best.)

1. **Is it safe to take by children on medication/s?**

Yes, this supplement is an effective option to use alongside conventional medicines.

1. **Are there any side effects?**

Saffrosun For Children® is well tolerated in clinical testing, there have been no recorded side effects.

1. **What inspired the formulation of Saffrosun For Children**®**?**

Saffrosun For Children® was formulated following the personal experience of The Naked Pharmacy’s founder, Kevin Leivers, whose son, Aragon, now aged 6, was an overactive child who seemed not to need to sleep: It has been formulated for children aged 6 to 14 as a nutritional support for those who suffer from being nervous, having low mood, poor emotional balance, frequent tiredness and/or poor quality sleep.

1. **Is it suitable for vegans and vegetarians?**

Yes, it is suitable for vegans and vegetarians, and has not been irradiated for shelf life purposes. All of its ingredients are traceable, and production is from a single supplier that controls all steps, from cultivation to final extract.

1. **Has it been tested on animals?**

No, the supplement has not been tested on animals. It has been tested on humans in clinical trials, and found to be safe and effective.

1. **Where is it available? What does it cost?**

Saffrosun For Children® is available online at [www.TheNakedPharmacy.com](http://www.TheNakedPharmacy.com) as well as at selected pharmacies and health stores. It costs £18.95 for a one to two month supply.

[Saffrosun](https://www.thenakedpharmacy.com/collections/nervous-system/products/saffrosun) for adults is available as either a one month supply (60 capsules) priced £39.95 - or as a starter pack (30 capsules) priced £18.95

**ABOUT THE NAKED PHARMACY**

The Naked Pharmacy is the first natural pharmacy dedicated to evidence-based natural medicines and high-strength food-based supplements. We believe that great Health is a gift that is available to everyone. Everyone has the right to make their own choices based on clear, honest and transparent information about the conventional and natural treatments available. By using a range of high quality natural ingredients at effective strengths, The Naked Pharmacy has developed a unique, natural and effective range of medicines and supplements.

To learn more, please visit [www.TheNakedPharmacy.com](http://www.TheNakedPharmacy.com) | [Facebook](https://www.facebook.com/The-Naked-Pharmacy-920272091345335/) | [Instagram](https://www.facebook.com/The-Naked-Pharmacy-920272091345335/) | [Twitter](https://twitter.com/nakedpharmacy?lang=en-gb)

**REFERENCES**

1 [Complementary Therapies in Medicine](http://www.sciencedirect.com/science/journal/09652299) [Volume 33](http://www.sciencedirect.com/science/journal/09652299/33/supp/C),  August 2017, Pages 58-64

 <http://www.sciencedirect.com/science/article/pii/S0965229917300821>

2 ADHD Trial Submission: <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=372113>

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**Clinical Research Summary**

**A double-blind, randomized and placebo-controlled trial of Saffron (Crocus sativus L.) in the treatment of anxiety and depression.**

[Mazidi M, Shemshian M, Mousavi SH, Norouzy A, Kermani T, Moghiman T, Sadeghi A, Mokhber](http://www.ncbi.nlm.nih.gov/pubmed/?term=Mokhber%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27101556) [N,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Mokhber%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27101556) [Ghayour-Mobarhan M](http://www.ncbi.nlm.nih.gov/pubmed/?term=Ghayour-Mobarhan%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=27101556)[,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Mokhber%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27101556) [Ferns GA](http://www.ncbi.nlm.nih.gov/pubmed/?term=Ferns%2520GA%255BAuthor%255D&cauthor=true&cauthor_uid=27101556)[.](http://www.ncbi.nlm.nih.gov/pubmed/?term=Mokhber%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27101556)

**Published June 1st 2016 in J Complement Integr Med.**

**BACKGROUND:**

Depression and anxiety are prevalent serious psychiatric disorders. Several drugs are used to treat these conditions but these are often associated with serious side effects. For this reason alternative therapies, including herbal medication such as saffron, have been proposed. We aimed to assess the effects of saffron extract for the treatment of anxiety and depression using a 12-week double-blind, placebo-controlled trial design.

**METHODS:**

Sixty adult patients with anxiety and depression were randomized to receive a 50 mg saffron capsule (Crocus sativus L. stigma) or a placebo capsule twice daily for 12 weeks. Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI) questionnaires were used at baseline, 6 and 12 weeks after initiating medication. 54 subjects completed the trial.

**RESULTS:**

Saffron supplements had a significant effect on the BDI and BAI scores of subjects in comparison to placebo at the 12 week time-point (p<0.001).

**CONCLUSIONS:**

Saffron appears to have a significant impact in the treatment of anxiety and depression disorder. Side effects were rare.

**Crocus sativus L. versus Citalopram in the Treatment of Major Depressive Disorder with Anxious Distress: A Double-Blind, Controlled Clinical Trial.**

[Ghajar A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ghajar%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)1, [Neishabouri SM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Neishabouri%2520SM%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)2, [Velayati N](https://www.ncbi.nlm.nih.gov/pubmed/?term=Velayati%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)1, [Jahangard L](https://www.ncbi.nlm.nih.gov/pubmed/?term=Jahangard%2520L%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)2, [Matinnia N](https://www.ncbi.nlm.nih.gov/pubmed/?term=Matinnia%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)3, [Haghighi M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Haghighi%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)2, [Ghaleiha A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ghaleiha%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)2, [Afarideh M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Afarideh%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)1, [Salimi S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Salimi%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)4, [Meysamie A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Meysamie%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)5, [Akhondzadeh S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Akhondzadeh%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=27701683)1.

**Published Oct 4th 2016 in Pharmacopsychiatry**

**Abstract**

**Introduction:** Saffron (Crocus sativus L.) has demonstrated antidepressant effects in clinical studies and extensive anxiolytic effects in experimental animal models.

**Methods:** 66 patients with major depressive disorder accompanied by anxious distress were randomly assigned to receive either saffron (30 mg/day) or citalopram (40 mg/day) for 6 weeks. Hamilton Rating Scale for Depression (HAM-D) and Hamilton Rating Scale for Anxiety (HAM-A) were used to assess treatment effect during the trial.

**Results:** 60 participants finished the study. Patients who received either saffron or citalopram showed significant improvement in scores of the Hamilton Rating Scale for Depression (P-value<0.001 in both groups) and Hamilton Rating Scale for Anxiety (P-value<0.001 in both groups). Comparison of score changes between the 2 trial arms showed no significant difference (P-value=0.984). Frequency of side effects was not significantly different between the 2 groups.

**Discussion:** The present study indicates saffron as a potential efficacious and tolerable treatment for major depressive disorder with anxious distress.

**Crocin, the main active saffron constituent, as an adjunctive treatment in major depressive disorder: a randomized, double-blind, placebo-controlled, pilot clinical trial.**

[Talaei A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Talaei%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=25484177)1, [Hassanpour Moghadam M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hassanpour%2520Moghadam%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=25484177)2, [Sajadi Tabassi SA](https://www.ncbi.nlm.nih.gov/pubmed/?term=Sajadi%2520Tabassi%2520SA%255BAuthor%255D&cauthor=true&cauthor_uid=25484177)3, [Mohajeri SA](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mohajeri%2520SA%255BAuthor%255D&cauthor=true&cauthor_uid=25484177)4.

**Published 15th March 2015 in J Affect Disord.**

**OBJECTIVE:**

Herbal remedies play an important role in treatment of psychiatric disorders. The aim of this study was to assess the efficacy of crocin, the main active constituent of saffron, as an adjunctive treatment in major depressive disorder (MDD).

**METHOD:**

This study was a randomized, double-blind, placebo-controlled, pilot clinical trial. It was carried out during 4 weeks in two groups (placebo and treatment) on 40 MDD patients between 24 and 50 years old in Ibn-e-Sina psychiatric hospital, Mashhad, Iran, from March 2013 to December 2013. The crocin group (n=20) was given one selective serotonin reuptake inhibitor (SSRI) drug (fluoxetine 20mg/day or sertraline 50mg/day or citalopram 20mg/day) plus crocin tablets (30mg/day; 15mg BID) and placebo group (n=20) was administered one SSRI (fluoxetine 20mg/day or sertraline 50mg/day or citalopram 20mg/day) plus placebo (two placebo tablets per day) for 4 weeks. Both groups filled beck depression inventory (BDI), beck anxiety inventory (BAI), general health questionnaire (GHQ), the mood disorder questionnaire (MDQ), side effect evaluation questionnaire, and demographic questionnaire before and after one month intervention.

**RESULTS:**

The crocin group showed significantly improved scores on BDI, BAI and GHQ compared to placebo group (Pvalue<0.0001). The averages of decrease in BDI, BAI and GHQ scores in placebo group were 6.15, 2.6 and 10.3 respectively, whereas the values in crocin group were 17.6, 12.7 and 17.2 after 4 weeks trial.

**LIMITATIONS:**

Poor patient compliance with medications and short trial period, small sample size and self-report assessments were the major limitations of this study.

**CONCLUSION:**

These results demonstrated the effect of crocin in depression and could be administered in treatment of MDD patients

**Crocus sativus L. in the treatment of mild to moderate depression: a double-blind, randomized and placebo-controlled trial.**

[Akhondzadeh S1, Tahmacebi-Pour N, Noorbala AA, Amini H, Fallah-Pour H, Jamshidi AH, Khani](http://www.ncbi.nlm.nih.gov/pubmed/?term=Khani%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=15852492)

[M.](http://www.ncbi.nlm.nih.gov/pubmed/?term=Khani%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=15852492)

**Published Feb 2005 in Phytother Res**

**Abstract**

Depression is a serious disorder in today's society, with estimates of lifetime prevalence as high as 21% of the general population in some developed countries. As a therapeutic plant, saffron is considered excellent for stomach ailments and as an antispasmodic, to help digestion and to increase appetite. It is also used for depression in Persian traditional medicine. Our objective was to assess the efficacy of the stigmas of Crocus sativus (saffron) in the treatment of mild to moderate depression in a 6-week double-blind, placebo-controlled and randomized trial. Forty adult outpatients who met the Diagnostic and Statistical Manual of Mental Disorders, 4th edition for major depression based on the structured clinical interview for DSM IV participated in the trial. Patients had a baseline Hamilton rating scale for depression score of at least 18. In this double-blind, placebo-controlled, single-centre and randomized trial, patients were randomly assigned to receive a capsule of saffron 30 mg[sol ]day (BD) (Group 1) or a capsule of placebo (BD) (Group 2) for a 6-week study. At 6 weeks, Crocus sativus produced a significantly better outcome on the Hamilton depression rating scale than the placebo (d.f. = 1, F = 18.89, p < 0.001). There were no significant differences in the two groups in terms of the observed side effects. The results of this study indicate the efficacy of Crocus sativus in the treatment of mild to moderate depression. A large-scale trial is justified.

**Hydro-alcoholic extract of Crocus sativus L. versus fluoxetine in the treatment of mild to moderate depression: a double-blind, randomized pilot trial.**

[Noorbala AA](http://www.ncbi.nlm.nih.gov/pubmed/?term=Noorbala%2520AA%255BAuthor%255D&cauthor=true&cauthor_uid=15707766)1, [Akhondzadeh S](http://www.ncbi.nlm.nih.gov/pubmed/?term=Akhondzadeh%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=15707766), [Tahmacebi-Pour N](http://www.ncbi.nlm.nih.gov/pubmed/?term=Tahmacebi-Pour%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=15707766), [Jamshidi AH](http://www.ncbi.nlm.nih.gov/pubmed/?term=Jamshidi%2520AH%255BAuthor%255D&cauthor=true&cauthor_uid=15707766).

**Published 28th Feb 2005 in J Ethnopharmacol.**

**Abstract**

Depressive disorders are very common in clinical practice, with approximately 11.3 of all adults afflicted during any a year. Saffron is the world's most expensive spice and apart from its traditional value as a food additive, recent studies indicate several therapeutic effects for saffron. It is used for depression in Persian traditional medicine. Our objective was to compare the efficacy of hydro-alcoholic extract of Crocus sativus (stigma) with fluoxetine in the treatment of mild to moderate depression in a 6-week double-blind, randomized trial. Forty adult outpatients who met the Diagnostic and Statistical Manual of Mental Disorders, fourth edition for major depression based on the structured clinical interview for DSM-IV and with mild to moderate depression participated in the trial. In this double-blind, single-center trial and randomized trial, patients were randomly assigned to receive capsules of saffron 30 mg/day (BD) (Group 1) and capsule of fluoxetine 20 mg/ day (BD) (Group 2) for a 6-week study. Saffron at this dose was found to be effective similar to fluoxetine in the treatment of mild to moderate depression (F = 0.13, d.f. = 1, P = 0.71). There were no significant differences in the two groups in terms of observed side effects. The results of this study indicate the efficacy of Crocus sativus in the treatment of mild to moderate depression. A large-scale trial is justified.

**Comparison of petal of Crocus sativus L. and fluoxetine in the treatment of depressed outpatients: a pilot double-blind randomized trial.**

[Akhondzadeh Basti A](http://www.ncbi.nlm.nih.gov/pubmed/?term=Akhondzadeh%2520Basti%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=17174460)1, [Moshiri E,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Moshiri%2520E%255BAuthor%255D&cauthor=true&cauthor_uid=17174460) [Noorbala AA,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Noorbala%2520AA%255BAuthor%255D&cauthor=true&cauthor_uid=17174460) [Jamshidi AH,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Jamshidi%2520AH%255BAuthor%255D&cauthor=true&cauthor_uid=17174460) [Abbasi SH,](http://www.ncbi.nlm.nih.gov/pubmed/?term=Abbasi%2520SH%255BAuthor%255D&cauthor=true&cauthor_uid=17174460) [Akhondzadeh S.](http://www.ncbi.nlm.nih.gov/pubmed/?term=Akhondzadeh%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=17174460)

**Published 30th March 2007 in Prog Neuropsychopharmacol Biol Psychiatry**

**Abstract**

Depression is one of the most common neuropsychiatric conditions, with a lifetime prevalence approaching 17%. Although a variety of pharmaceutical agents is available for the treatment of depression, psychiatrists find that many patients cannot tolerate the side effects, do not respond adequately, or finally lose their response. On the other hand, many herbs with psychotropic effects have far fewer side effects. They can provide an alternative treatment or be used to enhance the effect of conventional antidepressants. A number of recent preclinical and clinical studies indicate that stigma and petal of Crocus sativus have antidepressant effect. Our objective was to compare the efficacy of petal of C. sativus with fluoxetine in the treatment of depressed outpatients in an 8-week pilot double-blind randomized trial. Forty adult outpatients who met the DSM- IV criteria for major depression based on the structured clinical interview for DSM- IV participated in the trial. Patients have a baseline Hamilton Rating Scale for Depression score of at least 18. In this double-blind and randomized trial, patients were randomly assigned to receive capsule of petal of C. sativus 15 mg bid (morning and evening) (Group 1) and fluoxetine 10 mg bid (morning and evening) (Group 2) for a 8-week study. At the end of trial, petal of C. sativus was found to be effective similar to fluoxetine in the treatment of mild to moderate depression (F=0.03, d.f.=1, P=0.84). In addition, in the both treatments, the remission rate was 25%. There were no significant differences in the two groups in terms of observed side effects.

**A randomized, double-blind, clinical trial comparing the efficacy and safety of Crocus sativus L. with fluoxetine for improving mild to moderate depression in post percutaneous coronary intervention patients.**

[Shahmansouri N](http://www.ncbi.nlm.nih.gov/pubmed/?term=Shahmansouri%2520N%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)1, [Farokhnia M](http://www.ncbi.nlm.nih.gov/pubmed/?term=Farokhnia%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)2, [Abbasi SH](http://www.ncbi.nlm.nih.gov/pubmed/?term=Abbasi%2520SH%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)3, [Kassaian SE](http://www.ncbi.nlm.nih.gov/pubmed/?term=Kassaian%2520SE%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)1, [Noorbala Tafti AA](http://www.ncbi.nlm.nih.gov/pubmed/?term=Noorbala%2520Tafti%2520AA%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)2, [Gougol A](http://www.ncbi.nlm.nih.gov/pubmed/?term=Gougol%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)2, [Yekehtaz H](http://www.ncbi.nlm.nih.gov/pubmed/?term=Yekehtaz%2520H%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)2, [Forghani S](http://www.ncbi.nlm.nih.gov/pubmed/?term=Forghani%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)4, [Mahmoodian M](http://www.ncbi.nlm.nih.gov/pubmed/?term=Mahmoodian%2520M%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)1, [Saroukhani S](http://www.ncbi.nlm.nih.gov/pubmed/?term=Saroukhani%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)1, [Arjmandi-Beglar A](http://www.ncbi.nlm.nih.gov/pubmed/?term=Arjmandi-Beglar%2520A%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)1, [Akhondzadeh S](http://www.ncbi.nlm.nih.gov/pubmed/?term=Akhondzadeh%2520S%255BAuthor%255D&cauthor=true&cauthor_uid=24289892)5.

**Published Feb 2014 in J Affect Disord.**

**OBJECTIVE:**

A significant correlation exists between coronary artery diseases and depression. The aim of this trial was to compare the efficacy and safety of saffron versus fluoxetine in improving depressive symptoms of patients who were suffering from depression after performing percutaneous coronary intervention (PCI).

**METHODS:**

In this randomized double-blind parallel-group study, 40 patients with a diagnosis of mild to moderate depression who had undergone PCI in the last six months were randomized to receive either fluoexetine (40mg/day) or saffron (30mg/day) capsule for six weeks. Participants were evaluated by Hamilton depression rating scale (HDRS) at weeks 3 and 6 and the adverse events were systemically recorded.

**RESULTS:**

By the study endpoint, no significant difference was detected between two groups in reduction of HDRS scores (P=0.62). Remission and response rates were not significantly different as well (P=1.00 and P=0.67; respectively). There was no significant difference between two groups in the frequency of adverse events during this trial.

**LIMITATIONS:**

Relatively small sample size and short observational period were the major limitations of this study.

**CONCLUSION:**

Short-term therapy with saffron capsules showed the same antidepressant efficacy compared with fluoxetine in patients with a prior history of PCI who were suffering from depression.

**Randomized clinical trial to determine the efficacy of Saffron on moderating mood, social behaviour, memory and alleviating mild anxiety in healthy adults over 4 weeks**

**Trial conducted by University of Queensland**

128 participants enrolled
Average age 40 years (range 18-70) Men and Women

**The study aims**

* Assess the effectiveness on mood, stress and anxiety Evaluate safety and tolerability
* Assess the effect of on cognition and memory
* Provide information that will be required by International regulatory bodies to support product tolerability and therapeutic claims

**Outcome measures**

Profile of Mood States (POMS) questionnaire

Total Mood Disturbance (TMD)

PANAS (Positive Affect Negative Affect Schedule)

DASS (Depression, Anxiety and Stress Scale)

Cognitive and psychomotor performance: simple reaction test + short term Memory test

Sleep quality – Pittsburg Sleep index

General safety and tolerability

**Saffrosun has shown significant results after 4 weeks in:**

Increasing positive mood, Reducing negative feelings

Reducing Stress and Anxiety

**ABOUT THE NAKED PHARMACY**

To learn more, visit [www.TheNakedPharmacy.com](http://www.TheNakedPharmacy.com) | [Facebook](https://www.facebook.com/The-Naked-Pharmacy-920272091345335/) | [Instagram](https://www.facebook.com/The-Naked-Pharmacy-920272091345335/) | [Twitter](https://twitter.com/nakedpharmacy?lang=en-gb)

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