KIDS MOOD+

All-Natural Mood Support*

amare®

TECHNICAL DATA

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KIDS
MOOD+

Multiple scientific studies have shown the key ingredients in Kids Mood+ provide significant benefits for mood support, including stress resilience, cognitive performance, calmness, focus, and positivity. All in a delicious, easy-to-digest powder — perfect for kids and teens.*

In a recently-conducted pilot clinical trial, Kids Mood+ was shown to improve standardized measures of mood, focus and resilience in 10 out of 10 children 6–16 years of age. Using an objective survey developed by the American Academy of Pediatrics, results showed a dramatic improvement in "Attributes" such as focus, attention, mood, listening, tension, irritation, as well as "Performance" measures associated with schoolwork, math, reading, writing, and social relationships (see graphs below). This data will be presented at the upcoming International Society for Nutritional Psychiatry Research Conference in London.

KEY INGREDIENTS

affron® Saffron:

Lepticrosalides are the main bioactive components of saffron that improve mental wellness-related behaviors

- Normalizes neurotransmitter activity (serotonin, dopamine, norepinephrine/noradrenaline, GABA)
- Reduces oxidative stress and damage to cells and cellular components (e.g., DNA, tissues)
- Neuroprotective and reduces stress hormones (cortisol) and inflammation

Rosemary:

- Helps with muscle discomfort
- Improves memory
- Improves immune and circulatory system
- Rosemary is a perennial plant (it lives more than two years), and health benefits include improved concentration, digestion and brain aging

Clove:

- Helps with inflammation, weight, gas and bloating
- Cloves are high in antioxidants, including eugenol and vitamin C, both of which can help reduce oxidative stress

Oregano:

- Rich in antioxidants and reduces inflammation
- Natural antibacterial properties
- Oregano is high in antioxidants and may help fight off bacteria and viruses, potentially reduce the growth of cancer cells and helps alleviate inflammation

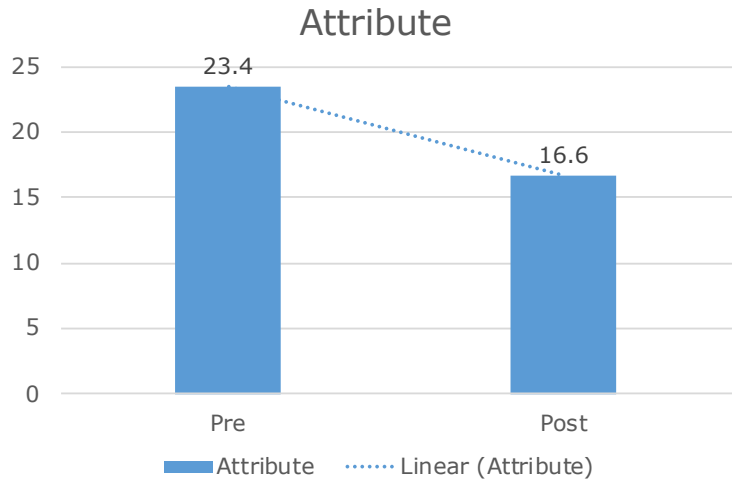
Holy Basil:

- Helps with inflammation and joint pain, stress and anxiety

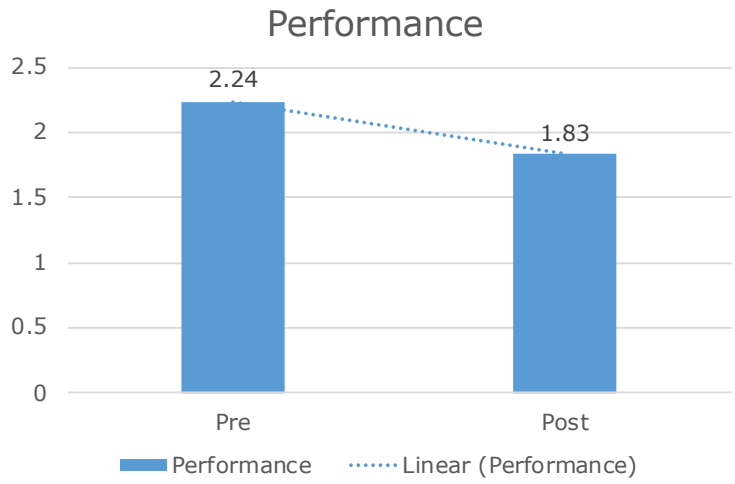
- Adaptogen that provides your brain and body with ease

Kids Mood+ Pilot Clinical Trial (10 children)

Focus, Attention, Mood, Listening, Tension, Irritation



School Work, Math, Reading, Writing, Social Relationships



CLINICAL STUDIES

affron®, a standardised extract from saffron (Crocus sativus L.) for the treatment of youth anxiety and depressive symptoms: A randomised, double-blind, placebo-controlled study.

J Affect Disord. 2018 May;232:349-357.

Lopresti AL(1), Drummond PD(2), Inarejos-García AM(3), Prodanov M(4).

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BACKGROUND:

Saffron has antidepressant and anxiolytic effects in adults with mild-to-moderate depression. However, this is the first study examining its mood-related effects in teenagers.

METHODS:

In this 8-week, randomised, double-blind, placebo-controlled study, youth aged 12-16 years, with mild-to-moderate anxiety or depressive symptoms were given tablets containing placebo or a saffron extract (affron®, 14 mg b.i.d). The youth and parent versions of the Revised Child Anxiety and Depression Scale (RCADS) were used as outcome measures.

RESULTS:

80 participants were enrolled and 68 completed the study. Based on youth self-reports, affron® was associated with greater improvements in overall internalising symptoms ($p = 0.049$), separation anxiety ($p = 0.003$), social phobia ($p = 0.023$), and depression ($p = 0.016$). Total internalising scores decreased by an average of 33% compared to 17% in the placebo group ($p = 0.029$). However, parental reports of improvements were inconsistent as mean improvements in RCADS scores were greater in the saffron group (40% vs 26%) ($p = 0.026$), although no other significant differences were identified. affron® was well-tolerated and there was a trend of reduced headaches in participants on the active treatment.

LIMITATIONS:

The use of a self-report instrument, limited study duration, single treatment dose, and non-clinical sample used in this study limit the generalisability of study findings.

CONCLUSION:

The administration of a standardised saffron extract (affron®) for 8 weeks improved anxiety and depressive symptoms in youth with mild-to-moderate symptoms, at least from the perspective of the adolescent. However, these beneficial effects were inconsistently corroborated by parents.

affron® a novel saffron extract (Crocus sativus L.) improves mood in healthy adults over 4 weeks in a double-blind, parallel, randomized, placebo-controlled clinical trial.

Kell G1, Rao A2, Beccaria G1, Clayton P3, Inarejos-García AM4, Prodanov M5.

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ABSTRACT

BACKGROUND:

In recent years phytotherapy has been explored as a source for alternative treatments for mood disorders. One potential candidate is saffron (Crocus sativus L.), whose main bioactive components are crocins and safranal.

OBJECTIVES:

The aim of this study was to investigate the efficacy of affron®, a standardised stigmas extract from Crocus sativus L. for improving mood, stress, anxiety and sleep quality in healthy adults.

METHODS:

In this 3 arm study, 128 participants self-reporting low mood but not diagnosed with depression, were given affron® at 28 mg/day, 22mg/day, or a placebo treatment in a randomized, double-blind, placebo-controlled trial for 4 weeks. Mood was measured at baseline and at the end of the study, using the POMS (primary outcome measure) and PANAS questionnaires, and the DASS-21 scale. Sleep was monitored using Sleep Quality Index (PSQI).

RESULTS:

Analysis indicated a significant decrease in negative mood and symptoms related to stress and anxiety at a 28 mg/day dose (with a significant difference between 28 mg/day and placebo on the POMS Total Mood Disturbance scale, $p<0.001$, $d=-1.10$), but no treatment effect at the 22 mg/day dose.

LIMITATIONS:

The main weaknesses of this investigation were found in the self-reporting nature of both the screening and the testing.

CONCLUSIONS:

affron® increased mood, reduced anxiety and managed stress without side effects, offering a natural alternative to standard treatments.

affron®, a standardised extract from saffron (Crocus sativus L.) for the treatment of youth Crocus sativus L. Versus Methylphenidate in Treatment of Children with Attention-Deficit/ Hyperactivity Disorder: A Randomized, Double-Blind Pilot Study

ABSTRACT

OBJECTIVE:

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common neuropsychiatric disorders of childhood and adolescence. About 30% of patients do not respond to stimulants or cannot tolerate their side effects. Thus, alternative medication, like herbal medicine, should be considered. The aim of this trial is to compare the safety and efficacy of Crocus sativus (saffron) versus methylphenidate in improving symptoms of children with ADHD.

METHODS:

In a 6-week randomized double-blind study, 54 patients (children 6–17 years old) with a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of ADHD were randomly assigned to receive either 20–30 mg/d (20 mg/d for <30 kg and 30 mg/d for >30 kg) methylphenidate (MPH) or 20–30 mg/d saffron capsules depending on weight (20 mg/d for <30 kg and 30 mg/d for >30 kg). Symptoms were assessed using the Teacher and Parent Attention-Deficit/Hyperactivity Disorder Rating Scale-IV (ADHD-RS-IV) at baseline and weeks 3 and 6.

RESULTS:

Fifty patients completed the trial. General linear model repeated measures showed no significant difference between the two groups on Parent and Teacher Rating Scale scores ($F = 0.749$, $df = 1.317$, $p = 0.425$, and $F = 0.249$, $df = 1.410$, $p = 0.701$, respectively). Changes in Teacher and Parent ADHD Rating Scale scores from baseline to the study end were not significantly different between the saffron group and the MPH group ($p = 0.731$ and $p = 0.883$, respectively). The frequency of adverse effects was similar between saffron and MPH groups.

CONCLUSION:

Short-term therapy with saffron capsule showed the same efficacy compared with methylphenidate. Nevertheless, larger controlled studies with longer treatment periods are necessary for future studies.

Herbal medicines in the treatment of psychiatric disorders: 10-year updated review.

Phytother Res. 2018 Jul;32(7):1147-1162. doi: 10.1002/ptr.6055. Epub 2018 Mar 25.

Sarris J.

NICM Health Research Institute, School of Science and Health, Western Sydney University, Westmead, NSW, Australia.

Department of Psychiatry, The Melbourne Clinic, Professorial Unit, ARCADIA Research Group, The University of Melbourne, Melbourne, VIC, Australia.

This paper provides a 10-year update of the 2007 systematic review of herbal medicines studied in a broad range of psychiatric disorders, including depression, anxiety, obsessive-compulsive, seasonal affective, bipolar, psychotic, phobic, somatoform, and attention-deficit hyperactivity disorders. Ovid Medline, PubMed, and the Cochrane Library were searched for herbal medicines with both pharmacological and clinical evidence of psychotropic activity. This updated review now covers clinical trial evidence for 24 herbal medicines in 11 psychiatric disorders. High-quality evidence was found to exist for the use of Piper methysticum (Kava),

Passiflora spp. (passionflower) and Galphimia glauca (galphimia) for anxiety disorders; and Hypericum perforatum (St John's wort) and Crocus sativus (saffron) for major depressive disorder. Other encouraging herbal medicines with preliminary evidence include Curcuma longa (turmeric) in depression, Withania somnifera (ashwagandha) in affective disorders, and Ginkgo biloba (ginkgo) as an adjunctive treatment in Schizophrenia. Although depression and anxiety are commonly researched, many other mental disorders still require further prospective investigation. Although the previous review suggested increasing the adjunctive study of select herbal medicines with pharmaceuticals, this was still only found to sparingly occur in research designs. Aside from this, future focus should involve the incorporation of more biomarker analysis, in particular pharmacogenomics, to determine genetic factors moderating response to herbal medicines.

Saffron in the treatment of depression, anxiety and other mental disorders: Current evidence and potential mechanisms of action.

J Affect Disord. 2018 Feb;227:330-337. Shafiee M(1), Arekhi S(2), Omranzadeh A(2), Sahebkar A(3).

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ABSTRACT

BACKGROUND:

Depression and anxiety are two common mental health problems with high economic and social costs. Currently, a number of treatments are available for patients with depression and anxiety disorders such as psychotherapy, electroconvulsive therapy and antidepressant drugs. Due to safety concerns, adverse effects, limited efficacy and low tolerability associated with many antidepressant and anti-anxiety medications, identification of novel agents with less toxicity and more favorable outcome is warranted.

METHODS:

The current article provides a non-systematic review of the available in vitro, in vivo and clinical evidence on the efficacy, safety and mechanisms of action of saffron and its active ingredients in the treatment of anxiety, depression and other mental disorders.

RESULTS:

Several interesting data have been reported about the antidepressant and anti-anxiety properties of saffron, the dried stigmas of Crocus sativus L., in several preclinical and clinical studies. In particular, a number of clinical trials demonstrated that saffron and its active constituents possess antidepressant properties similar to those of current antidepressant medications such as fluoxetine, imipramine and citalopram, but with fewer reported side effects.

CONCLUSION:

Saffron may exert antidepressant effects and represents an efficacious and safe treatment.

The effects of crocin on the symptoms of depression in subjects with metabolic syndrome.

Adv Clin Exp Med. 2017 Sep;26(6):925-930. Jam IN(1), Sahebkar AH(2), Eslami S(3), Mokhber N(4), Nosrati M(1), Khademi M(3), Foroutan-Tanha M(3), Ghayour-Mobarhan M(1), Hadizadeh F(2), Ferns G(5), Abbasi M(6).

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(3)Pharmaceutical Research Center, School of Pharmacy, Mashhad University of Medical Sciences, Iran.
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(6)Qaem Hospital Cardiology Department, School of Medicine, Mashhad University of Medical Sciences, Iran.

ABSTRACT:

BACKGROUND:

Studies have suggested that metabolic syndrome (MetS) is associated with increased depressive symptoms, and reducing depression in subjects with MetS is important. Crocin, an active component of saffron, has useful properties for subjects with MetS, including antidepressant properties.

OBJECTIVES:

The aim of the study was to assess the effect of a preparation of crocin on the symptoms of depression in subjects with MetS, and the relationship between changes in those symptoms and the serum pro-oxidant/anti-oxidant balance (PAB).

MATERIALS & METHODS:

This sub-study was carried out on 34 subjects with MetS from the authors' previous randomized double-blind controlled clinical trial (RCT), all of whom met the inclusion criteria for this study. The subjects were randomly assigned to treatment and placebo groups (n = 17 in each group) and received each 30 mg of crocin (2 tablets of 15 mg) or placebo for 8 weeks. Depressive symptoms were assessed using the Beck Depression Inventory (BDI). The BDI questionnaire was completed for each subject at the baseline and at the end of the 8th week of treatment. Blood samples were taken from the subjects before and after the intervention period. Statistical analyses were performed using the SPSS for Windows, v. 16 (SPSS Inc., Chicago, USA).

RESULTS:

Out of the 34 participants enrolled, 33 completed the trial. The degree of depression decreased significantly in the crocin group ($p = 0.005$), but not in the placebo group ($p > 0.05$), and the difference between the 2 groups was statistically significant ($p = 0.013$). No significant relationship was observed between changes in depression symptoms and changes in the serum PAB ($p > 0.05$).

CONCLUSION:

This study demonstrates that at a dose of 30 mg per day for 8 weeks, crocin reduced the symptoms of depression in subjects with MetS compared to the control group, and this effect was independent of its effect on the serum PAB.

Efficacy of curcumin, and a saffron/curcumin combination for the treatment of major depression: A randomised, double-blind, placebo-controlled study.

J Affect Disord. 2017 Jan 1;207:188-196. Lopresti AL(1), Drummond PD(2).

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(1)School of Psychology and Exercise Science, Murdoch University, Perth, Western Australia 6150, Australia. Electronic address: a.lopresti@murdoch.edu.au.

(2)School of Psychology and Exercise Science, Murdoch University, Perth, Western Australia 6150, Australia.

ABSTRACT:

BACKGROUND:

Several studies have supported the antidepressant effects of curcumin (from the spice turmeric) and saffron for people with major depressive disorder. However, these studies have been hampered by poor designs, small sample sizes, short treatment duration, and similar intervention dosages. Furthermore, the antidepressant effects of combined curcumin and saffron administration are unknown.

METHODS:

In a randomised, double-blind, placebo-controlled study, 123 individuals with major depressive disorder were allocated to one of four treatment conditions, comprising placebo, low-dose curcumin extract (250mg b.i.d.), high-dose curcumin extract (500mg b.i.d.), or combined low-dose curcumin extract plus saffron (15mg b.i.d.) for 12 weeks. The outcome measures were the Inventory of Depressive Symptomatology self-rated version (IDS-SR30) and Spielberger State-Trait Anxiety Inventory (STAI).

RESULTS:

The active drug treatments (combined) were associated with significantly greater improvements in depressive symptoms compared to placebo (p=.031), and superior improvements in STAI-state (p<.001) and STAI-trait scores (p=.001). Active drug treatments also had greater efficacy in people with atypical depression compared to the remainder of patients (response rates of 65% versus 35% respectively, p=.012). No differences were found between the differing doses of curcumin or the curcumin/saffron combination.

LIMITATIONS:

Investigations with larger sample sizes are required to examine the efficacy of differing doses of curcumin and saffron/curcumin combination. Its effects in people with atypical depression also require examination in larger scale studies.

CONCLUSION:

Active drug treatments comprising differing doses of curcumin and combined curcumin/saffron were effective in reducing depressive and anxiolytic symptoms in people with major depressive disorder.

Natural products of relevance in the prevention and supportive treatment of depression.

Psychiatr Pol. 2015 May-Jun;49(3):435-53. Muszyńska B(1), Łojewski M(1), Rojowski J(2), Opoka W(2), Sułkowska-Ziaja K(1).

Author information:

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(2)Chair of Inorganic and Analytical Chemistry, Faculty of Pharmacy, Jagiellonian University Medical College.

The use of herbs or their parts: leaves, roots, rhizomes, flowers, seeds, natural strains, as well as extracts or isolated metabolites is becoming more and more popular. Natural remedies not only act prophylactically, but also help to alleviate symptoms of many diseases and enhance the overall functioning of the internal organs. Many raw materials of natural origin plays a role in treatment of health problems, and also in case of serious diseases such as depression. Depression (affective disorder) now affects about 10% of the population, but in next few years due to the development of civilization and increasing pace of
life, the probable number of people suffering from this disease can grow rapidly. Natural raw materials such as Bacopa monnieri, Crocus sativus, Eleutherococcus senticosus, Griffonia simplicifolia, Hypericum perforatum, Sceletium tortuosum, Piper methysticum, Rhodiola rosea, Aspalathus linearis, Camellia sinensis, Ficus carica, Lycium chinense, Cuminum cyminum, Panax Ginseng can effectively assist the prevention and treatment of depression. Daily diet may also have positive effect in prevention of this disease. It was found that 5-hydroxy-L-tryptophan, L-tryptophan (which are precursors of serotonin in the CNS), omega-3 fatty acids and anthranilic acid (vitamin L1) are able to improve mood. L-Tryptophan, 5-hydroxy-L-tryptophan are present in the largest quantities in the fruiting bodies of edible mushrooms. Omega-3 fatty acids are found in the flesh of fish, walnuts, soybeans, beans and chicken egg protein, while the anthranilic acid is commonly found in plants.

Efficacy and Safety of Saffron Supplementation: Current Clinical Findings.

Sci Nutr. 2016 Dec 9;56(16):2767-76. Broadhead GK(1), Chang A(1), Grigg J(1), McCluskey P(1).

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Saffron (Crocus savitus) is a Middle-Eastern herb with strong antioxidant properties. Its major constituents, safranal, crocin, and crocetin, are also antioxidants and bear structural similarities to other well-known natural antixodant substances, such as zeaxanthin. Given the role of oxidative stress in many diseases, considerable interest has been shown into the potential role of saffron supplementation as a treatment for a range of diseases. In vitro and animal studies have provided evidence that saffron and its constituents may be potent therapies for a range of pathologies, including Alzheimer's disease, age-related macular degeneration (AMD) and cardiac ischemia. Whether these findings translate into clinical efficacy, however, has as of yet been incompletely assessed. This makes assessing the role of saffron supplementation in these diseases difficult. Here, we review the current human clinical evidence supporting saffron supplementation as a treatment for a range of pathologies and the underlying science supporting its use.

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

J Affect Disord. 2015 Mar 15;174:51-6. Talaei A (1), Hassanpour Moghadam M(2), Sajadi Tabassi SA(3), Mohajeri SA(4).

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ABSTRACT:

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).

METHODS:

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.

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.

J Affect Disord. 2014 Feb;155:216-22. Shahmansouri N(1), Farokhnia M(2), Abbasi SH(3), Kassaian SE(1), Noorbala Tafti AA(2), Gougol A(2), Yekehtaz H(2), Forghani S(4), Mahmoodian M(1), Saroukhani S(1), Arjmandi-Beglar A(1), Akhondzadeh S(5).

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(4)Razi Vaccine and Serum Research Institute, Karaj, Iran.
(5)Psychiatric Research Center, Roozbeh Hospital, Tehran University of Medical Sciences, Tehran, Iran. Electronic address: s.akhond@neda.net.

ABSTRACT:

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.

Herbal medicine for depression, anxiety and insomnia: a review of psychopharmacology and clinical evidence.

Eur Neuropsychopharmacol. 2011 Dec;21(12):841-60. Sarris J(1), Panossian A, Schweitzer I, Stough C, Scholey A.

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Research in the area of herbal psychopharmacology has increased markedly over the past decades. To date however, a comprehensive review of herbal antidepressant, anxiolytic and hypnotic psychopharmacology and applications in depression, anxiety and insomnia has been absent. A search of MEDLINE (PubMed), CINAHL, PsycINFO, and the Cochrane Library databases was conducted (up to February 21st 2011) on commonly used psychotropic herbal medicines. A review of the literature was conducted to ascertain mechanisms of action of these botanicals, in addition to a systematic review of controlled clinical trials for treatment of mood, anxiety and sleep disorders, which are common comorbid psychiatric disorders. Specific emphasis was given to emerging phytomedicines. Analysis of evidence levels was conducted, as were effect sizes (Cohen's d) where data were available. Results provided evidence of a range of neurochemical, endocrinological, and epigenetic effects for 21 individual phytomedicines, which are detailed in this paper. Sixty six controlled studies were located involving eleven phytomedicines. Several of these provide a high level of evidence, such as Hypericum perforatum for major depression, and Piper methysticum for anxiety disorders. Several human clinical trials provide preliminary positive evidence of antidepressant effects
(Echium amoenum, Crocus sativus, and Rhodiola rosea) and anxiolytic activity (Matricaria recutita, Ginkgo biloba, Passiflora incanata, E. amoenum, and Scutellaria lateriflora). Caution should however be taken when interpreting the results as many studies have not been replicated. Several herbal medicines with in vitro and in vivo evidence are currently unexplored in human studies, and along with use of emerging genetic technologies "herbomics", are areas of potential future research.

Saffron in phytotherapy: pharmacology and clinical uses.

Wien Med Wochenschr. 2007;157(13-14):315-9. Schmidt M(1), Betti G, Hensel A.

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Saffron (stigmata of Crocus sativus L.) has been used for medicinal purposes for millennia. 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.

The Effects of a Saffron Extract (affron®) on Menopausal Symptoms in Women during Perimenopause: A Randomised, Double-Blind, Placebo-Controlled Study

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Objectives:

There is preliminary evidence suggesting saffron may effectively treat menopausal symptoms. The aim of this study was to examine the tolerability and efficacy of a standardised saffron extract (affron®) on menopausal complaints in perimenopausal women.

Methods:

In this 12-week, parallel-group, double-blind, randomised controlled trial, 86 perimenopausal women experiencing menopausal complaints received either a placebo or 14 mg of a saffron extract (affron®), twice daily. Outcome measures included the Greene Climacteric Scale (GCS), Positive and Negative Affect Schedule (PANAS), and Short Form-36 Health Survey (SF-36).

Results:

Based on data collected from 82 participants, saffron was associated with greater improvements in mood and psychological symptoms compared to the placebo. Results from the GCS revealed a significantly greater reduction in the GCS psychological score (P = 0.032), characterised by a 33% reduction in anxiety and a 32% reduction in depression scores from baseline to week 12. There was also a significantly greater reduction in the PANAS negative affect score (P = 0.043) compared to the placebo. However, compared to the placebo, saffron was not associated with greater improvements in vasomotor symptoms, somatic symptoms, or other quality of life measures. Saffron intake was well tolerated with no reported major adverse events.

Conclusions:

The saffron extract, affron® , administered for 12 weeks at a dose of 14 mg twice daily was associated with greater improvements in psychological symptoms. Further studies in perimenopausal women presenting with varying severity of menopausal symptoms, using different doses of saffron will be useful to examine in future clinical trials.

Effects of saffron on sleep quality in healthy adults with self-reported poor sleep: a randomized, double-blind, placebo-controlled trial

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Abstract:

Study objectives: Herbal medicines are frequently used by adults with sleep difficulties. However, evidence of their efficacy is limited. Therefore, the goal of this study was to examine the sleep-enhancing effects of a standardized saffron extract (affron).

Methods:

This was a 28-day, parallel-group, double-blind, randomized controlled trial. Sixty-three healthy adults aged 18-70 with self-reported sleep problems were recruited and randomized to receive either saffron extract (affron; 14 mg twice daily) or a placebo. Outcome measures included the Insomnia Severity Index (ISI; primary outcome measure) collected at baseline and days 7, 14, 21, and 28 and the Restorative Sleep Questionnaire (RSQ) and the Pittsburgh Sleep Diary (PSD) collected on days -1, 0, 3, 7, 14, 27, and 28.

Results:

Based on data collected from 55 participants, saffron was associated with greater improvements in ISI total score (P = .017), RSQ total score (P = .029), and PSD sleep quality ratings (P = .014) than the placebo. Saffron

intake was well tolerated with no reported adverse effects.

Conclusions:

Saffron intake was associated with improvements in sleep quality in adults with self-reported sleep complaints. Further studies using larger samples sizes, treatment periods, objective outcome measures, and volunteers with varying demographic and psychographic characteristics are required to replicate and extend these findings.

affron® a novel saffron extract (Crocus sativus L.) improves mood in healthy adults over 4 weeks in a double-blind, parallel, randomized, placebo-controlled clinical trial

Author links open overlay panel

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Background:

In recent years phytotherapy has been explored as a source for alternative treatments for mood disorders. One potential candidate is saffron (Crocus sativus L.), whose main bioactive components are crocins and safranal.

Objectives:

The aim of this study was to investigate the efficacy of affron®, a standardised stigmas extract from Crocus sativus L. for improving mood, stress, anxiety and sleep quality in healthy adults.

Methods:

In this 3 arm study, 128 participants self-reporting low mood but not diagnosed with depression, were given affron® at 28 mg/day, 22 mg/day, or a placebo treatment in a randomized, double-blind, placebo-controlled trial for 4 weeks. Mood was measured at baseline and at the end of the study, using the POMS (primary outcome measure) and PANAS questionnaires, and the DASS-21 scale. Sleep was monitored using Sleep Quality Index (PSQI).

Results:

Analysis indicated a significant decrease in negative mood and symptoms related to stress and anxiety at a 28 mg/day dose (with a significant difference between 28 mg/day and placebo on the POMS Total Mood Disturbance scale, $p < 0.001$, $d = -1.10$), but no treatment effect at the 22 mg/day dose.

Limitations:

The main weaknesses of this investigation were found in the self-reporting nature of both the screening and the testing.

Conclusions:

affron® increased mood, reduced anxiety and managed stress without side effects, offering a natural alternative to standard treatments.