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Safety and efficacy of StressCare capsules in enhancement of well-being in subjects with emotional discouragement: A double blind, placebo-controlled study

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Abstract

Emotional discouragement is one of the manifestations of stress related conditions among different age groups, if not properly identified and managed results in emotional suffering, loss of productivity in work place and other emotional psychological complications. The aim of this study was to evaluate the clinical efficacy and safety of StressCare Capsules in well-being of subjects with emotional discouragement. This study was a prospective, randomized, double blind, placebo-controlled clinical trial performed at the Department of Psychiatry, NHL Medical College and VS Hospital, Ahmedabad on sixty consecutive subjects (38 males and 22 females) who were presenting with symptoms of emotional discouragement. All the subjects were clinically evaluated at regular intervals, statistical analysis were performed between the groups. StressCare group showed statistically significant enhancement of well-being as compared to placebo. These results indicate that daily supplementation with StressCare Capsules may improve emotional well-being in the subjects with emotional discouragement suggesting that herbal approaches could be beneficial in alleviateing stressful conditions.

Key words: StressCare capsules, Emotional discouragement, placebo.

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1.0 Introduction:

Emotional discouragement is a common and widespread emotional state with a prevalence of 16% to 20% and is an important cause of healthcare burden across the globe. Even though various modalities of management are available, emotional discouragement remains inadequately managed [1-3]. Adequate and timely diagnosis of emotional discouragement bears great potential for improvements in general health and well-being. An equally promising approach is to enable diagnostic evaluation and management on evidence-based recommendations and interdisciplinary holistic health care [4,5]. Emotional discouragement is often due to various causes like biological, social and psychological factors and all these factors contribute to the development, severity and length of the episode. Emotional discouragement can develop at any age, from childhood through late adulthood. During a period of emotional discouragement, people typically complain of a wide range of behavioral changes[6]. The causes of emotional disturbances are unknown, but risk factors include: genetic factors, stress, bereavement, co-morbid medical and psychiatric illnesses, certain medications, substance abuse, intoxication or withdrawal, cognitive impairment or brain injury, and a history of childhood trauma [7]. Emotional discouragement should be considered in subjects who repeatedly present with number of vague complaints. As many as half of all primary care visits are for emotional conditions that present as medical complaints such as pain without significant organic cause like fatigue, unsteadiness and sleep disorders [7]. There are reports that there is considerable overlap between symptoms of mild occasional anxiousness and emotional discouragement, and that the same environmental triggers can provoke symptoms in either condition, may help to explain this high rate of co-morbidity [8].An episode of emotional discouragement frequently lasts six months or longer. Although spontaneous recurrence may be full or partial, many remain intermittently symptomatic for several years, and a small subset of subjects remain chronically symptomatic. Subjects without proper management of emotional discouragement are more likely to suffer complications of co-morbid medical conditions since they are less likely to be compliant with recommended interventions or engage in appropriate self-care activities.[7]

A great number of studies suggest that exercise training may reduce emotional symptoms in non-clinical and clinical populations [9-11] and in subjects with emotional discouragement [12,13]. Individuals report deterioration in their physical and intellectual ability, emotional state, personal relationships and career development. Both cognitive behavioral therapies and interventions have been proven to be effective.Behavioral therapy, in particular, has been beneficial. However, better-tolerated formulations are often needed, and there is a trend towards herbal management as these formulations are devoid of adverse effects in longer duration.There are also many traditional herbal remedies for emotional well-being that have been used for centuries in many parts of the world. Some of the better-known herbs including Kava, Magnolia bark, Phellodendron bark, St. John's Wort, and Passion flower have been found to improve emotional well-being. This clinical study was planned to evaluate the safety and efficacy of one such formulation, StressCare Capsules, a polyherbal formulation which is used in Ayurvedic system of medicine to enhance the well-being in subjects with emotional discouragement.

2.0 Materials and methods

This study was a prospective, randomized, double blind, placebo-controlled clinical trial performed on sixty consecutive subjects (38 males and 22 females) who were presenting with symptoms of emotional discouragement (like occasional

sleep disturbances, occasional excess sleep, loss of interest, occasional mild fatigue, easy irritability, feeling of worthlessness, diminished ability to concentrate, and recurrent sad mood). This study was conducted at the Department of Psychiatry, NHL Medical College and V.S Hospital, Ahmadabad, India.The interested subjects were informed of the voluntary nature of the trial and written consent was obtained**.**

Study procedure

Sixty consecutive subjects (38 males and 22 females) in the age group of 50-60 years with emotional discouragement, were selected for this study as per the subject selection criteria. On admission into the study, informed consent was obtained from the eligible subjects after explaining to them the nature of the study. The subjects were free to opt out from this study, if they so desired. The subjects were randomly designated in two groups, A and B. Subjects in Group A received StressCare in the dosage of 2 capsules, twice a day, while the subjects in Group B received identical placebo in the same dosage, for 6 weeks. No other medication was administered to these subjects. Detailed medical history was obtained from all enrolled subjects. Demographic data of subjects on entry is given in Table-1.All the subjects were evaluated at regular intervals of 2 weeks for a period of 6 weeks using HRSD [14].The Hamilton Rating Scale for Depression (HRSD) is a standardized and authentic multiple item questionnaire used to provide an indication of depression, and as a guide to evaluate recovery. It comprises the assessment of 17 items including depressed mood, feeling of guilt, insomnia, work and activities, easy irritability, anxiety, general somatic symptoms and others. The clinical parameters for emotional discouragement were assessed for their presence or absence at entry and at 6 weeks. All the enrolled subjects were monitored for 6 weeks, for any reported or observed adverse effects. At each follow-up visit, the investigator recorded information about intercurrent illness, therapeutic interventions and concomitant medication/s. Medications considered necessary for the subject's welfare, and which will not interfere with the study medication (e.g. NSAIDs) were allowed. Adverse effects reported, or observed by the subjects were recorded with information about severity, date of onset, duration and action taken. Relation of adverse events to study interventions was predefined as *Unrelated, Possible*, *Probable* and *Certain.* Subjects were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific intervention. For subjects withdrawing from the study, efforts were made to ascertain the reason for dropout. Non-compliance (defined as failure to take less than 80% of the intervention) was not regarded as intervention failure and reasons for non-compliance were noted.

Features	**Group A: StressCare (n=30)**	**Group B: Placebo (n=30)**
Mean age (years) (Mean ± SD)	52.63 ± 9.46	50.11 ± 10.29
Sex (M/F)	21/9	17/13
Mean weight (kg) (Mean ± SD)	51.80 ±10.01	53.32 ± 11.20
Mean duration of illness (months) (Mean ± SD)	4.8 ± 2.5	4.4 ± 3.5
HRSD score (Mean ± SD)	33.00 ± 8.00	31.00 ± 8.32

Table-1: Demographic data of subjects on entry (Mean ± SD)

Follow-up and assessment

Subjects were evaluated at regular intervals on the clinical parameters of emotional discouragement and HRSD for 6 weeks.

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Primary endpoints

The primary endpoint was defined as clinical recovery from symptoms of emotional discouragement (occasional sleep disturbances, occasional excess sleep, loss of interest, occasional mild fatigue, easy irritability, feeling of worthlessness, diminished ability to concentrate, and recurrent sad mood) and reduction in mean HRSD scores.

Sl.No	Parameter	Duration	No. of subjects showing incidence of symptoms		Significance
			StressCare	Placebo	
1	Occasional sleep disturbances	On entry	17	14	NS
		Week 6	3	11	p<0.0021
2	Occasional excess sleep	On entry	13	16	NS
		Week 6	2	13	p<0.0021
3	Loss of interest	On entry	13	11	NS
		Week 6	5	9	NS
4	Occasional mild fatigue	On entry	19	21	NS
		Week 6	7	20	p<0.0016
5	Easy irritability	On entry	29	25	NS
		Week 6	8	23	p<0.0002
6	Occasional reduced ability to concentrate	On entry	25	28	NS
		Week 6	10	26	p<0.0001
7	Occasional mild worthlessness	On entry	24	26	NS
		Week 6	10	24	p<0.0006
8	Recurrent sad feelings	On entry	14	11	NS
		Week 6	3	10	p<0.05

Table-2: Effect of StressCare on symptoms of emotional discouragement
Statistical analysis: Fisher's exact test. Analysis was performed between the groups for "on entry" and "week 6" values.
NS: Not significant

Secondary endpoints

Inclusion criteria:

Adult subjects of both gender with symptoms of emotional discouragementi.e., occasional sleep disturbances, occasional excess sleep, loss of interest, occasional mild fatigue, easy irritability, feeling of worthlessness, diminished ability to concentrate, and recurrent sad feelings.

Exclusion criteria:

Subjects with aggression, seizure disorders or any psychiatric condition that would require inpatient or partial psychiatric hospitalization, current abusers of alcohol or other substances were excluded from the study.In addition, subjects clinically judged by the investigator to be at risk for suicide or suffering from systemic illness likeliver, kidney, and heart conditions as well as pregnant or lactating women. Subjects have a history of allergy to any medications were excluded from the study.

Stastical analysis

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Results were analyzed statistically by repeated measures of ANOVA using Friedman test followed by Dunnett's Multiple Comparison test or Fishers Exact test.Between group analysis were performedusing Graphpad Prism software Version 4.03, San Diego, California, USA.

Follow up visits	HRSD scores (Mean ± SD)		Significance
	StressCare	Placebo	
On entry	33.00 ± 8.00	31.00 ± 8.32	NS
Week 2	27.00 ± 9.94	29.00 ± 8.20	NS
Week 4	16.00 ± 8.42*	26.00 ± 8.64	p<0.0001
Week 6	10.00 ± 4.94*	27.00 ± 9.01	p<0.0001

Statistical analysis: Unpaired t-test, analysis was performed between the groups on entry, week-2, week-4 and on week-6 values.
NS: Not significant.
Table-3: Effect of StressCare on HRSD scores

3.0 Results and discussion

Results of between group analysis of the symptoms are given in Table-2. Occasional sleep disturbances which were presented by seventeen subjects on entry in StressCare group reduced to only three subjects presenting with the symptoms at week 6. In the placebo group, occasional sleep disturbances which were present in fourteen subjects on entry and eleven subjects still persisted to have the symptom at the end of 6 weeks. Statistically significant (p<0.0021) reduction of occasional sleep disturbances in the StressCare group as compared to placebo at 6 weeks was also observed. Occasional excess sleep was observed in thirteen subjects on entry which reduced to two subjects with StressCare capsules at 6 weeks. In the placebo group, occasional excess sleep which were presented by sixteen subjects at entry, reduced to thirteen subjects with placebo. Between group analysis at 6 weeks, showed a statistical significant (p<0.0021) reduction of occasional excess sleep in StressCare group as compared to placebo group. Loss of interest was present in thirteen subjects in StressCare group on entry, which reduced to five subjects at 6 weeks. In the placebo group loss of interest werepresented by eleven subjects on entry and at the end of 6 weeks, nine subjects still persisted to have loss of interest. Occasional mild fatigue was observed in nineteen subjects on entry, which reduced to seven subjects at 6 weeks with StressCare capsules. In the placebo group, occasional mild fatigue which were presentedbytwenty one subjects on entry, twenty subjects still persisted to have occasional mild fatigue at the end of 6 weeks. Statistically significant (p<0.0016) reduction was found at 6 weeks with StressCare capsules as compared to placebo. Easy irritability was observed in twenty nine subjects in StressCare group on entry which reduced to only eight subjects presenting easy irritability with StressCare capsules at 6 weeks. In the placebo group easy irritability was present in twenty five subjects on entry and twenty three subjects persisted to have easy irritability at the end of 6 weeks. Statistically significant (p<0.0002) reduction of easy irritability was seen at 6 weeks in the StressCare group as compared to placebo. Occasional reduced ability to concentrate was evident in twenty five subjects on entry which reduced to ten at week 6 with StressCare capsule. Between group analysis showed a significant (p<0.0001) improvement in ability to concentrate at week 6 in the StressCare group as compared to placebo. Feeling of worthlessness was seen in twenty four subjects on entry in StressCare group which reduced to ten at week 6. In the placebo group, feeling of worthlessness were observed in twenty six subjects on entry and twenty four subjects persisted to have

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symptoms at the end of 6 weeks. Statistically analysis conducted between the groups has shown that, the level of significance was found to be $p<0.0006$ in the StressCare group as compared to Placebo. Recurrent sad feelings were seen in fourteen subjects on entry in StressCare group which reduced to 3 subjects at week 6.In the placebo group, recurrent sad feelings which were presented by eleven subjects on entry 10 subjects persisted to present symptom with placebo. Between group statistical analysis showed that at 6 weeks, there is a statistically significant ($p<0.05$) reduction in recurrent sad feelings in the StressCare group as compared to the placebo group. Effect of interventions on HRSD scores are presented in Table-3. The HRSD score on entry in StressCare group were 33.00 ± 8.00 which reduced to 27.00 ± 9.94 at week 2, 16.00 ± 8.42 at week 4 and 10.00 ± 4.94 at week 6. In the placebo group, the level of HRSD score which were 31.00 ± 8.32 at entry reduced to 27.00 ± 9.01 at the end of week 6. Statistically significant reduction ($p<0.0001$) was observed in the StressCare group as compared to placebo at week 4 and 6. There were no significant changes in the HRSD score in placebo group. There were no adverse effects reported or observed in the study and compliance to the study was good.

While everyone occasionally feels sad, these feelings tend to pass rather quickly. By contrast, in some individuals, sadness or despair lasts for longer. These individuals tend to feel helpless and hopeless and blame themselves for having these feelings. It may interfere with activities of daily living such as working or concentrating on tasks, or even eating and sleeping. Other possible symptoms include chronic pain, headaches or stomach aches. Some people may feel angry or restless for long periods. People may feel exhausted or fatigued and stop participating in certain everyday activities, altogether and may withdraw from family and friends.Stress and its effects on health generally run a long course. They may present with varied or vague symptoms. The study indicates that StressCare is beneficial in maintaining emotional well-being. StressCare could prove useful as an adjuvant to other forms of therapy in the management of various conditions involving emotional disturbances.The beneficial effects of StressCare Capsules could be due to the sum total effects of its ingredients.

Chyavanaprasha

It is a classical preparation and holds an important therapeutic application in Indian Medicine. It has potent restorative & tonic activity [15].Various trials have shown rejuvenating and adaptogenic properties as well as in maintaining general well-being [16,17].

Capparis spinosa

Capparis spinosa has rejuvenating properties, which correct and prevent the free radical-induced oxidative damage to various organs and systems[18].It is known to protect liver, spleen, and kidney and thus help maintain general well-being [19].

Cichoriuminty bus

Cichoriuminty bus contain escutetin and glycosides. The bio-active principles exhibit protective action on liver and kidney[20]. Trials also suggest that extract of *Cichoriuminty bus* has free radical scavenging activity thus helps maintain general well-being [21].

Solanum nigrum

Solanum berries contain solasonine and sapogenins. They help improve the circulation in small vessels and also improve muscle function. Phenolic compounds present in *Solanum nigrum* extract are also helpful in maintenance of overall health [22].

Cassia occidentalis

Anthroquinone derived from *Cassia occidentalis* has action on the colon movements, and helps regular healthy bowel movements [23].*Cassia occidentalis* is also used as a general tonic in weakness. It protects liver from various damaging agents [24].

Terminalia arjuna

Bark of *Terminalia arjuna* helps reduce high blood pressure and also helps lipid Metabolism[25]. It also possess nitric oxide suppressant,cardioprotective, antioxidant, membrane stabilizing activities; all these helps to maintain general health [26].

Achilleamille folium

It has beneficial effects on gastrointestinal system and circulatory system. It is known to be beneficial in mild, spasmodic discomforts of gastrointestinal tract. It is also used in cough, cold, healing wounds and other skin conditions[28]. Selenium present in *Achilleamille folium* has antioxidant activity and helps in proper functioning of heart [29].

Tamarix gallica

Tamarix gallica contain the bio-actives like polyphenols, gallic acids, ellagic acid, which has health promoting activities [29]. The extract also has protective action on liver which may be due to its antioxidant activity [30].

Crocus sativus

Safranal, isolated from Crocus sativus has shown activity in preventing oxidative damage in brain tissue. It is used as antioxidant in various health related conditions [31-32].

Curculigo orchioides

It contains actives like glycosides, curculigoside and alkaloid lycorine. It has beneficial effects on vigor, liver health and functions as a general tonic [33].It also promotes overall immunity [34].

Caesalpinia digyna

The extract of plantroot has exhibited its protective action against free radicals in liver and kidneys due to its antioxidant activities [35].

Asparagus racemosus

Asparagus racemosus contains important minerals which plays a role in the enhancement of its medicinal properties including rejuvenating, adaptogenic and strength promoting activities. Trials show that *Asparagus racemosus* root administration could also help in lipid metabolism [36].

Withania somnifera

Alkaloids in the root are known to prevent cellular damage due to daily stress and delay the premature aging. It is known to normalize RBC levels and hemoglobin, and thus used as a health supplement [37].

Glycyrrhiza glabra

Glycyrrhiza glabra helps to maintain lipid metabolism [38].It provides thick protective mucous for the linings of the stomach and protects from inflammation and ulcerations [39].

Centella asiatica

*Centella asiatica*is a known nervine tonic and also helps in improving blood pressure and memory disturbances. It also helps correct sleep disturbances [40].

Shilajeet (Purified)

Shilajeet helps to control the carbohydrate metabolism. It increases appetite, and useful in gastric discomfort[41]. Shilajeet also regulates excess lipids, and maintains well-being [42]. It is alsofound to provide positive influence on hormones and brain functions [43].

Terminalia chebula

Terminalia chebula promotes health due to its antioxidant activities [44].The extract is also known for its benefits in bowel cleansing[45].

Mucuna pruriens

The antioxidant activity of *Mucuna pruriens* was demonstrated by its ability to scavenge free radicals and also calming effects [46].

Myristica fragrans

Myristica fragrans is used as stimulant, appetizer and to control flatulence. Studies also indicate its benefits on vigor, gastric mucosa and lipid metabolism [47].

Piper longum

Fruits of the plant *Piper longum* and its component *piperine* have immunomodulatory activity, which may help a person to maintain health [48].It also enhances the bioavailability that potentiates action of other ingredients [49].

Syzygium aromaticum

Syzygium aromaticum is used in common digestive symptoms; and also has an additional property of killing germs [50].

Elettaria cardamomum

It is used in treating various ailments of body and mind. The seed extract which contains the essential oils have potential applications as killing germs and antioxidant activities. It is used as general health supplement in expectant mothers [51].

***Carum copticum* (Syn:*Trachyspermum amni*)**

*Carum copticum*seed extract has various health benefits on heart and liver and its use in maintaining health [52].

Curcuma longa

Curcuma longa have shown beneficial effects in conditions related to liver, heart, and immunity [53].

Adhatoda vasica

Adhatoda vasica extracts contain alkaloids such as vasicine, vasicinone and a quinazoline-alkaloid, and peganin. These improve the immunity of an individual and help in maintaining respiratory health [54].

Eclipta alba

Eclipta alba helps promote liver health and also known to enhance memory. *Eclipta alba* helps reduce free radicals due to its anti-oxidant properties [55].

Celastrus paniculatus

Celastrus paniculatus seed enhances memory and reduces free radicals [56]. The plant extract reduces anxiety and keeps a person healthy [57].

Argyrei aspeciosa

*Argyrei aspeciosa*root helps improve the immunity of the person [58].

4.0 Conclusion

The findings from the clinical study clearly show that, StressCare is beneficial in improving the symptoms of emotional discouragement and enhancement of well-being in the subjects as shown by reduction in mean HRSD scores. It is also well tolerated and safe and compliance to the formulation was good. Hence it can be concluded that, StressCare is safe and effective in individuals with emotional encouragement, however further large scale studies are required to prove its efficacy in management of emotional discouragement.

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