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A pilot study to evaluate the safety and efficacy of 'Canna Relief' Stress Management Oil after oral consumption in patients with Stress and Mild to Moderate Anxiety Disorder

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ABSTRACT

Background: Clinical manifestation of Anxiety is included in as a *Mansik vyadhi* in Ayurveda. Anxiety disorders are the world's most common mental disorder affecting 4.05% of global population, translating to 301 million people. The prevalence of anxiety disorders has been rising over the last three decades. Due to the wide spectrum of diseases, much prevalence in society, and lack of effective medicines, the disease has been chosen for the trial. **Aim:** The aim of this study was to study the efficacy of CannaRelief stress management oil in the management of Anxiety. **Materials and Methods:** 40 clinically diagnosed patients were selected and administered CannaRelief stress management oil – 4 drops sublingual in night after food for 60 days. Study Design: It was a single-center, single arm, open-label, phase 4, pilot study. **Results:** The drug showed statistically significant results in terms of subjective parameters. It was found that after taking medicine sleep quality was increased in maximum no. of patients. 50% patient showed reduced level of salivary cortisol level and 60% patient showed reduced level of salivary amylase. salivary amylase showed significant result after treatment. **Conclusion:** CannaRelief stress management oil is effective in the management of Anxiety disorder.

Key words: *Anxiety, Mansik Vyadhi, Canna Relief stress management oil.*

INTRODUCTION

Anxiety is defined as a state of apprehension, uncertainty, and fear resulting from anticipation of a realistic or imagined threatening event or situation.[1]

Anxiety is a normal and necessary basic emotion without which individual survival would be impossible.

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Everyone experiences anxiety from time to time. This is normal. Anxiety becomes a disorder when it and its symptoms and feelings interfere with a normal lifestyle.[2] Anxiety activates the stress response, also known as the *fight, flight, or freeze response*. This survival reaction immediately stimulates the body into emergency action.[3] Therefore, anxiety disorder symptoms are symptoms of stress. They are called anxiety symptoms because anxiety is the main source of the stress that causes the body to become stressed and symptomatic. According to WHO In 2019, 301 million people were living with an anxiety disorder including 58 million children and adolescents.[4] Anxiety disorders are characterised by excessive fear and worry and related behavioural disturbances. Symptoms are severe enough to result in significant distress or significant impairment in functioning. Anxiety disorders are the most prevalent psychiatric disorders (with a current worldwide prevalence of

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7.3% [4.8% - 10.9%] Among them, specific phobias are the most common, with a prevalence of 10.3%, then panic disorder (with or without agoraphobia) is the next most common with a prevalence of 6.0%, followed by social phobia (2.7%) and generalized anxiety disorder (2.2%). Evidence is lacking as to whether these disorders have become more prevalent in recent decades. Generally speaking, women are more prone to develop emotional disorders with an onset at adolescence; they are 1.5 to 2 times more likely than men to have an anxiety disorder.[5] Within the Charaka Samhita, an ancient Ayurvedic text, it is said "The body and that which is called the mind are both considered to be abodes of disease, likewise of well-being. The cause of well-being is their harmonious or concordant interaction." From this perspective, we can regard anxiety as being an act of *Prajnaparada (Dhee Dhriti Smriti Vibhrisht*) or a crime against our intellect, expounded up on here from the Charaka Samhita "An unrighteous act done by one who is ignorant and of impaired memory is to be regarded as a volitional transgression (*Prajnaparadha).*[6] Sleep is a proprietary ayurvedic

Rationale

My research is on the anxiolytic effect of Cannarelief oil and the effect on quality of life and sleep to evaluate the safety of the product. CannaRelief have full spectrum Cannabis leaf extract with each 1 ml containing 22.5 mg of major cannabinoids in a 1:2 ratio (7.5 mg CBD) along with minor Cannabinoids (CBG, CBN etc) which provides natural healing for symptomatic pain relief.

The compounds present in the Vijaya leaf extract increase the level of endogenous cannabinoids which in turn help reduce stress by promoting CB1 binding by the endogenous cannabinoids. Further, a proprietary blend of *Tagar* (Valerian), *Jatamansi* (Spikenard), and *Musta* (Nut grass) delivers calming effects.

Aim

This study aimed to evaluate the safety and efficacy of "CannaRelief stress management oil" in the management of After Oral Consumption in Patients with Stress And Mild To Moderate Anxiety Disorder".

Materials and Methods

The Ethics Committee of National Institute of Ayurveda, Jaipur, India approved the study with No. IEC/ACA/2021/02-77 on 1-09-2021. The study was registered on Clinical Trial Registry India (CTRI) vide registration number, CTRI/2022/03/052280 registered on Jan 20, 2022. Patients visiting the out-patient and in-patient department of Rognidana Department of National Institute of Ayurveda, Jaipur were thoroughly examined for clinical signs and symptoms of mild to moderate anxiety disorder. Subjects were enrolled for the study considering the criteria of inclusion and consent was obtained from each patient in the study. The registered patients were given CannaRelief stress management oil for orally. CannaRelief oil was used 4 drops sublingually for two months. Study evaluation visits were made at baseline and screened subjects were asked to visit after every 15th day i.e., visit 1 (day 0), visit 2 (day 15), visit 3 (day 30), visit 4 (day 45), visit 5 (day 60). The study was conducted in compliance with Good Clinical Practice guidelines (ICH) and the declaration of Helsinki and national regulations.

This was an open label, single arm, single centre, uncontrolled, pilot study, investigator initiated drug trial in phase-4, comparing the efficacy and safety of the drug before and after intervention, and also studying the same at every follow-up of the patient.

Diagnostic Criteria

Patient with clinical sign and symptoms of mild to moderate anxiety like Insomnia problem, anxious mood, tension, fear, fatigue, low concentration and memory were screened in OPD and IPD of NIA, hospital. Patient enrolment began in January 2023 and the last follow-up was completed in July 2023.

Inclusion Criteria

a) Voluntary patients clinically diagnosed for mild to moderate anxiety disorder between 18 and 75 years of age.

b) Ability to consent to the study and able to read and write in English or local language.

c) Patients who are non-regular users of cannabis in any form (three times per week or more) and are

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willing to abstain for 1 week prior and during the study;

d) Normal liver function (defined as aspartate aminotransferase 10-40 U/L and alanine aminotransferase 7-56 U/L)

e) Normal renal function (defined as serum creatinine level <133 µmol/L and Estimated Glomerular Filtration Rate (eGFR) equal or higher than 60)

f) Patients willing to stop alcohol, caffeine and nicotine consumption during the study duration

Exclusion Criteria

a) Patients with history of diagnosis of another sleep disorder other than anxiety like history of bipolar disorder, schizophrenia, psychotic disorder, or posttraumatic stress disorder or current psychiatric disorder that requires medication

b) Previous serious adverse event or hypersensitivity to cannabis or cannabinoids.

c) Presence of significant cardiac disease (history of unstable ischemic heart disease, heart failure, severe and uncontrolled hypertension) patient at risk of a clinically significant arrhythmia or myocardial infarction;

d) Life-time history of dependence on cannabis or diagnosis of cannabis use disorder

e) Pregnant women tested positive in UPT and lactating women or women planning pregnancy during the trial period.

f) Any clinically significant systemic or cutaneous disease, which may interfere with study procedures.

Investigational Product

CannaRelief oil is composed of in every 1ml *Vijaya (Cannabis Sativa*) 100 mg (10%), *Tagar* (*Valerinawallichi)* 80 mg (8%), *Jatamansi* (*Nardostychus jatamansi*) 85mg (8.5%), *Musta* (*Cyperus rotundus*) 20 mg (2%). The formulation of drug was kept confidential as per the protocol of the company.

All the subjects were asked to use CannaRelief oil sublingually by following the process described in the protocol 4 drops of oil was used. The oil was kept at room temperature. The oil is used in night after food (before going to bed). Other than study drug, no other Allopathic, Ayurvedic, Homeopathic, Siddha, Unani drug(s) or any other traditional or folklore medicine or therapy was permitted for the said indications during study period. All the subjects were advised to continue their regular diet and yoga, pranayam.

Study Variables and Measurement

A structural questionnaire was used to collected information about participants socioeconomic graphics including age, gender, chief complains, past history, history of present illness, personal history, menstrual history, general physical examination, *Ashtwidh Pariksha, Dashwidh Pariksha.*

Sleep quality -

- Hamilton anxiety scale
- Insomnia severity index
- Pittsburgh sleep quality index
- Athens Insomnia scale

And criteria of assessment are Hamilton anxiety scale, Athens insomnia scale, Pittsburgh sleep quality index, Insomnia severity index.

The Hamilton anxiety scale assess a range of symptoms like anxious mood, tension, fears, insomnia, intellectual, depressed mood, somatic muscular and sensory symptoms, cardiovascular symptoms, respiratory system, gastrointestinal, genitourinary symptoms, behaviour of interview. The higher level of anxiety, categorized by scores as mild (<17), 18-24 mild to moderate, 25-30 moderate to severe.

Insomnia severity index has seven questions about current severity of last 2 weeks like Insomnia problem (difficulty falling asleep, difficulty staying sleep, problems waking up too early), satisfied with your current sleep pattern, quality of life, distressed about your current sleep pattern, sleep problem interfere with your daily function (eg. Day time fatigue, mood, ability to function, concentration, memory, mood etc.),

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Scores are classified (0-7) no clinically significant insomnia, (8-14) subthreshold insomnia, (15-21) clinical insomnia (moderate severity), (22-28) severe.

Pittsburgh sleep quality index (PSQI) have seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality.

Athens Insomnia scale provided that it occurred at least three times per week, during the last month, about sleep induction, awakens during the night, final awakening earlier than desired, total sleep duration, overall quality of sleep, sense of well-being during the day, functioning (physical and mental) during the day, sleepiness during the day.

Objective Parameters

Biomarkers: a) Salivary cortisol level (b) Salivary alpha amylase.

Lab investigation: CBC, RFT, LFT, BSL Fasting &PP, Lipid profile, DHEA, Urine R&M, UPT.

Statistical Analysis Plans

Data were transferred from Google forms to an Excel sheet and exported to SPSS version for the analysis. Clinical statistics were used to determine the frequencies, mean and standard deviation and to describe the effect of "CannaRelief stress management oil" in mild to moderate anxiety disorder.

Observations and Results

The present study has shown that 14 patients were in age group 18-25 years, 13 patients in the age group 26-35 years, 9 patients in the age group 36-45 years and 4 patients in the age group 46-65 years. Incidence of the disease is found notably higher in males (67%) than in females (33%). About 60% of patients were unmarried. Patients from the middle-class account for up to 30% of the total, with the poor accounting for 10% of the total. 17 Patients with *Vata-Pittaja Prakriti* make up the majority of patients, followed by 16 patients *Vata-Kaphaja Prakriti* and 7 patients were *Pitta-Kaphaja Prakriti* which is linked to the development of anxiety disorder. About 49% of patients showed *Madhyama Ahara Shakti*, followed by 38% patients had *Avara Ahara Shakti*. About 12% of patients had *Pravara Koshtha*, whereas 7% of patients *had Mrudu Koshth. Mandagni* was reported by 22% of the patients, whereas *Vishamagni* was reported by 11% of the cases. About 22% of patients had *Sattvik-Rajasik Prakriti*, whereas 25% of patients had *Sattvik-Tamasik Prakriti* and *Rajasik-Tamasik* was reported by 53% of the cases. Majority of patients had taken *Alpnidra* (80%) and 20% had taken *Samyak Nidra*. Maximum number of subjects were *Avara Sattva* 58%, 30% subjects were *Madhyama Sattva* and 12% subjects were *Pravara Sattva.* Duration of illness < 1 year was found in a maximum 68% of the patients, followed by 32% of patients were in having a duration of illness between 8 to 3 months. 40% of patients informed drug history of allopathic medicines.

Results

The data were analyzed using Instat graph pad - free trial version, GraphPad by Dotmatics. For nonparametric data, Wilcoxon matched -pairs signed ranks test is used, while for parametric data, paired t-test is used.

Effect of therapy in subjective parameters

(A) Effect of therapy on HAM-A Scales:

Assessment of change in HAM-A scale showed that there was a significant reduction in the score of baselines to visit 4. Table no. 1 - In this table at Baseline visit HMA scale Mean ± SD 18 ± 3.13786 and at visit 4 reduction in Mean ± SD 7.025± 2.0567.

Table 1: Hamilton anxiety scale assessment.

Average of HMA-S	%Average of HMA visit 4	Difference of the average	%relief	p-value	Significance
18±3.13786	7.025±2.05673	10.975	61%	<0.0001	**HS**

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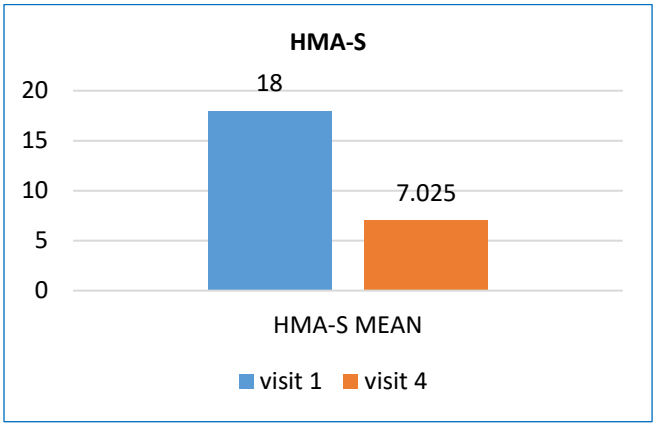


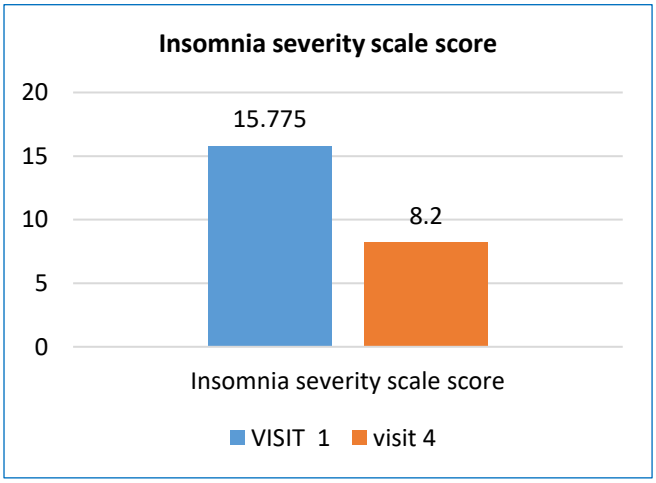
(B) Effect of therapy on Insomnia Severity Index.

Assessment of change in Insomnia Severity Index showed that there was a significant reduction in the score of baselines to visit 4.

Table No. 2 - In this table at Baseline visit Insomnia Severity Index Scale Mean ± SD 15.775± 4.0095 and at visit 4 reduction in Mean ± SD 8.2± 1.6976. CannaRelief stress management oil has better improvement in Insomnia problems.

Table 2: Insomnia severity scale assessment.

Average of Insomnia severity scale score Visit 0	Average of Insomnia severity scale score Visit 4	Difference of the average	%relief	p-value	Significance
15.775±4.00952	8.2±1.69766	7.575	48 %	<0.0001	**HS**

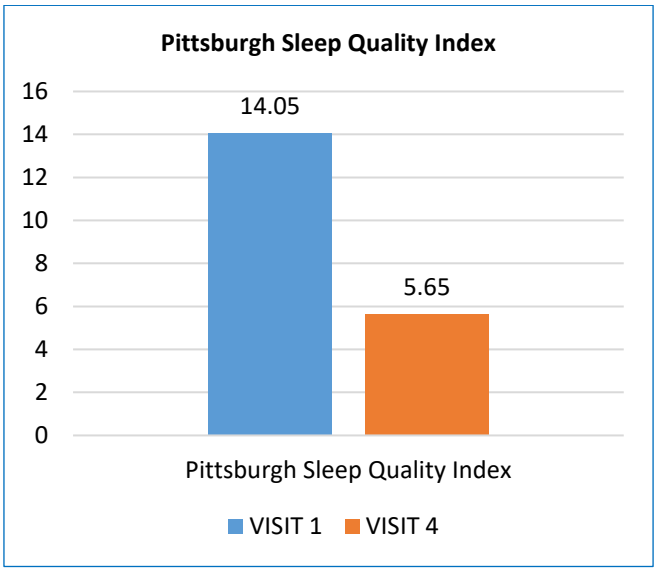


(C) Effect of therapy on Pittsburgh Sleep Quality Index.

Assessment of change in Pitsburgh sleep quality index showed that Table no. 3 there was a significant reduction in the score of baselines to visit 4. In this table at Baseline visit Insomnia Severity Index Scale Mean ± SD 14.05± 2.2752 and at Day 60 reduction in Mean ± SD 5.65± 2.1189.

Table 3: Pittsburgh Sleep Quality Index assessment.

Average of Pittsburgh Sleep Quality Index Visit 0	Average of Pittsburgh Sleep Quality Index Visit 4	Difference of the average	% relief	p-value	Significance
14.05±2.27529	5.65±2.11189	8.4	60 %	<0.0001	**HS**



(D) Effect of therapy on Athens Insomnia Scale

Assessment of change in Athens Insomnia scale showed that Table no. 4 there was a significant reduction in the score of baselines to visit 4. In this table at Baseline visit of Athens Insomnia Scale Mean ± SD 13.4± 2.9595 and at visit 4 reduction in Mean ± SD 6.55± 1.3577.

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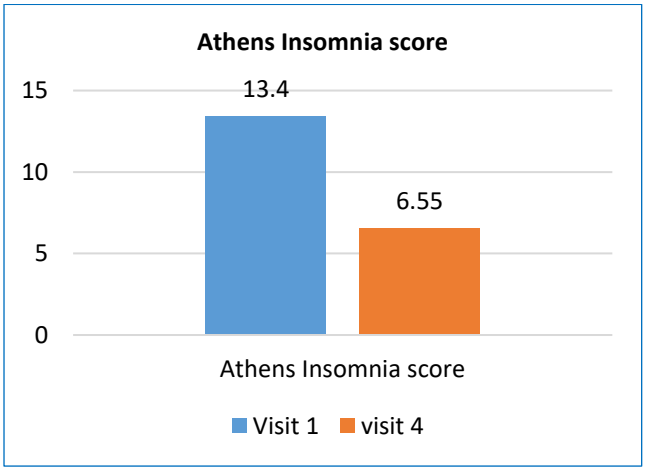
Table 4: Athens Insomnia scale assessment.

Average of Athens Insomnia score Visit 1	Average of Athens Insomnia score Visit 4	Difference of the average	% relief	p-value	Significance
13.4±2.95956	6.55±1.35779	6.85	51.1 %	<0.0001	HS



Effect of therapy in objective parameters (lab investigations)

There was significant change in these CBC parameters from baseline to visit 4. All the parameters remained within the normal range both at baseline and visit 4**.**

1. CBC Parameters: CBC parameters remained within the normal range both at baseline and final visit. So there was no significant result at visit 4
2. Cholesterol Parameters: All cholesterol parameters (total cholesterol. Serum triglyceride, LDL. HDL, VLDL, total cholesterol ratio showed significant result at visit 4.
3. LFT & RFT: Both parameters remained within the normal range both at a baseline and final visit. So, there was no significant result at visit 4.
4. Fasting blood sugar: At the time of screening all patient was selected in normal range of blood sugar.
5. DHEA (Dehydroepindiosterone): The level of DHEA had reduced in some patients after treatment,
6. Salivary cortisol & Salivary amylase: 50% patient showed reduced level of salivary cortisol level and salivary amylase showed significant result after treatment.

Discussion

The study was conducted to evaluate the efficacy and safety of CannaRelief oil in patients suffering from mild to moderate anxiety disorder. After the evaluation of inclusion / exclusion criteria, subjects with clinical sign and symptoms of anxiety were recruited into the study for a period of two months with six visits at an interval of 15 days. Bhanga (Vijaya) has been neglected earlier due to its psychoactive effect. But In small dose is beneficial in insomnia problem and other symptoms of anxiety.

Probable mode of action of the drug

Probable mode of action of CannaRelief stress management oil contents: Ingredients of CannaRelief stress management oil of Vijaya *(Cannabis sativa* 100mg*), Mustak (Cyperus rotandus* 85mg*). Jatamansi (Nardostachys jatamansi* 20mg*), Tagara (Valeriana wallachii* 80mg*).*

In this combination, *Tikta-Katu* dominant *Rasa* of the ingredients help in digestion of *Ama* and ultimately break the pathogenesis due to *Nidana Seven* of the related disease because play important role in manifestation of disease.[7] This formulation dominantly has two *Dravyas* with *Ushna Virya* and two *Dravya* with *Sheeta Virya* which helps to pacify the *Vata Dosha* while *Deepana* and *Pachana* properties of the ingredients help to digest the *Ama* and control the *Vata Dosha*. Besides this, there is dominancy of *Laghu, Snigdha Gunas* in which also helps in *Kaphhar (Tama)* and *Vatahar (Raja)* property. Most of ingredients have *Tridhosha Shamak* property which help in pacify *Tridosha. Atichinta* have both psychic and somatic manifestation.

Vijaya (*Cannabis sativa*) was chosen for the study. It has *Grahi, Nidrājanana Vājikara, Viryavardhana, Vyavāyi* and *Madakari* Effect. *Vijaya* pacifies *Kapha* and *Vata Doshas* increase *pitta dosha* and has *Dipana, pachan, Ruchya, Mdakari* and *Vyavayi*. It has also been

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attributed will *Grahi, Medhya* and *Rasayan Ushna Veerya* acts as *Vatashamak.*[8]

Active compounds in the cannabis plant indirectly influence the human endocannabinoid system (ECS), which is an extensive system of receptors and regulators. Intake of cannabinoids such as CBD can increase the level of joy neurotransmitter, anandamide. In addition to elevating your moods, this change in body chemicals can soothe your nerves and muscles, allowing you to relax.[9]

Tagara has *Prabhava* like *Vedanasthapana, Vishanasak, Akshi Rognasak, Shira-Rognasak, Bhut Rognasak, Unmad-Apasmarnasak.* Previous studies indicated that the roots and rhizomes are highly aromatic and contain valerenic acid that has been shown to inhibit the breakdown of neurotransmitter gamma-aminobutyric acid (GABA) that results in sedation. Valeranone and valepotriates are present in *Tagara* with percentage of active chemical constituents are 2% and 3-6% respectively. Valepotriates are responsible for chief effect of valerian as a potent sedative.[10]

Jatamansi was chosen for the study. The medicine improves intelligence, recall capability, memory, and cognitive abilities. *Medhya* drugs are believed to have a special influence on mental performance by enhancing the activities of '*Buddhi* and '*Mana*,[11] which aids in anxiety relief.

Jatamansi action on *Dosha* - The principal *Dosha* involved, according to the *Mansik Vikara Samprapti*, is *Tridosa*. *Jatamansi* has *Medhya Karm* due to *Prabhava* and is *Tridoshshamaka*.

In different study its proved that *Nardostachys jatamansi* extract (NJE) act as sedative. due to sedative action of *Jatamansi* its further work on increase GABA and monoamine neurotransmitter level in brain. GABA's main function in the body is to reduce neuronal activity in the brain and central nervous system.[12]

Mustak has *Prabhav* like *Shothahara, Krimighna, Vishaghna Sthoulyahar Trishnanigrahana, Tvakadoshahara Jvaraghna.*

Chemical composition of *Cyprus rotundus,* Scopolamine produced significant improvement in memory dysfunction. Ethanol extract of *Cyperus Rotandus* rhizomes and the flavonoids present in ethanol extract is essential for treatment of epilepsy and could be attributed for anticonvulsant activity.[13]

Conclusion

At the verge of completion of this study, the final conclusion can be drawn from the deductive reasoning of the relevant information. It is evident from the study that Anxiety is a *Manashika Vyadhi* sited in ayurveda which can be correlated with anxiety disorder as symptomatology and etiopathogenesis of both the diseases are quite similar. *Vata Dosha* helped by other two *Shareerika Dosha* and *Manashika Dosha* i.e*., Raja* and *Tama* are responsible for the occurrence of the disease. *Rasavaha* and *Manovaha Srotas* are the *Srotas* found to be affected in the disease.

Clinical part of the study showed that the drug showed statistically significant results in terms of subjective parameters. It was found that after taking medicine sleep quality was increased in maximum no. of patients. But in clinical study maximum patient's lab parameters are already in the normal range so maximum lab parameter was non -significant. 50% of patient's salivary cortisol level decreased after taking medicine and 60% of patient's salivary amylase level decreased after taking medicine.

Hence, it can be concluded at last that CannaRelief stress management oil proved to be safe and effective medication in the management of stress and mild to moderate anxiety disorder.

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