RESEARCH PAPER

A pilot study to evaluate the efficacy of CannaRelief Stress Management Oil in Managing Anxiety and Sleep Disorders: An Ayurvedic Perspective

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Abstract:
Introduction: Stress and anxiety disorders have become significant global health concerns, impacting emotional well-being, cognitive function, and physiological stability. Conventional treatments, including SSRIs and benzodiazepines, often carry risks of dependency and adverse effects, necessitating the exploration of safer alternatives. Ayurveda attributes anxiety to an imbalance in *Vata dosha,* particularly *Vyana and Prana Vayu*, leading to disrupted physiological and mental stability. CannaRelief Stress Management Oil, a hemp-derived Ayurvedic formulation, has been studied for its potential anxiolytic effects through its interaction with neurotransmitter systems such as serotonin and GABA.
Method: This open-labeled, single-arm, single-center, uncontrolled pilot study evaluated the efficacy and safety of CannaRelief Oil in individuals with mild to moderate anxiety over a 60-day intervention period. Forty patients diagnosed with stress-related anxiety disorders were administered 4 drops of the oil sublingually once daily. Efficacy was assessed through subjective (Pittsburgh Sleep Quality Index, Insomnia Severity Index) and objective (salivary cortisol and amylase levels) parameters.
Results: Results demonstrated significant improvements in sleep quality, with the number of participants experiencing poor sleep quality reducing from 40 to 17, and 23 individuals achieving good sleep scores. The Insomnia Severity Index showed a notable reduction in severity levels, with no participants remaining in the severe insomnia category post-treatment. Salivary amylase levels significantly decreased ($p=0.0103$), suggesting a potential reduction in autonomic stress response, while salivary cortisol changes were not statistically significant.
Conclusion: CannaRelief Oil exhibited promising anxiolytic and sleep-enhancing effects, likely mediated through its influence on neurotransmitter and autonomic pathways. While the findings indicate its potential as a natural intervention for stress-related anxiety and sleep disturbances, larger controlled studies are needed to confirm its long-term efficacy and physiological mechanisms.
Keywords: Anxiety, Ayurveda, CannaRelief Oil, Sleep Disorders, Salivary Cortisol, Salivary Amylase,Anxiolytic Therapy
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Introduction

Stress and anxiety disorders are growing global health concerns, affecting emotional well-being, cognitive function, and physiological processes.[1] These conditions are marked by persistent worry, restlessness, and autonomic hyperactivity, often leading to cardiovascular, metabolic, and immune dysfunction. Conventional treatments, such as SSRIs and benzodiazepines, can be effective but carry risks of sedation, dependency, and withdrawal, necessitating the exploration of safer alternatives.[2]Ayurveda, an ancient system of medicine, integrates the mind, body, and soul, recognizing mental health as a key component of overall well-being. Anxiety and related disorders are linked to an imbalance in *Vata dosha,* composed of Air *(Vayu)* and Ether *(Akasha). Vata* is responsible for movement, circulation, respiration, and sensory function, with its subtypes, *Vyana Vayu* (circulation and systemic integration) and *Prana Vayu* (respiration, cognition, and sensory processing), playing a key role in anxiety

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pathophysiology. Imbalances in these sub-doshas lead to excessive mental and physical activity, causing symptoms like heart palpitations, cyclical thinking, worry, insomnia, and fear.From an Ayurvedic perspective, anxiety results from *Vata* derangement, particularly in *Vyana and Prana Vayu,* disrupting physiological and mental stability.[3] Herbal formulations such as CannaRelief Stress Management Oil, derived from hemp, have been studied for their anxiolytic properties. Cannabidiol (CBD) interacts with neurotransmitter systems like serotonin and gamma-aminobutyric acid (GABA), which regulate stress and anxiety responses. Ayurveda acknowledges phytocannabinoids as agents that balance *Vata dosha,* helping restore *Prana and Vyana Vayu* functions.[4]

Prevalence and Need for Alternative Therapies

In India, 4% to 20% of the population suffers from anxiety disorders, with young adults (18-35 years) being the most affected due to professional and academic stress.[5] Sleep disturbances are also on the rise, often attributed to aggravated Vata and Pitta dosha, worsened by digital screen exposure, irregular routines, and poor lifestyle habits. Given the growing burden of stress-related disorders, safe and effective Ayurvedic interventions are needed to manage anxiety without the adverse effects of conventional medications.

This study aims to evaluate the efficacy and safety of CannaRelief Stress Management Oil in individuals with mild to moderate anxiety. The sublingual administration of this formulation is expected to allow rapid absorption for a quicker anxiolytic effect. This study aims to provide preliminary clinical evidence supporting CannaRelief Oil as a natural anxiolytic and pave the way for further large-scale research in Ayurvedic stress management.

Methodology

- **Study Design:** It is an Open-labeled, Single-arm, Single-center, Uncontrolled, Pilot study
- **Patient Selection and Data Collection:** The data for the current study was collected from patients diagnosed with stress & mild to moderate anxiety disorder at the NIA, Jaipur's OPD and IPD.

Inclusion Criteria

Participants eligible for the study must meet the following criteria: Adults aged 18 to 75 years with a clinical diagnosis of mild to moderate anxiety disorder. Non-regular cannabis users, defined as those consuming cannabis less than three times per week, and willing to abstain for at least one week prior to and throughout the study duration. Patients receiving opioids or other anxiolytic medications must have maintained a stable dosage for at least 15 days before study participation, subject to investigator confirmation. Normal liver function, defined by aspartate aminotransferase (AST) levels between 10–40 U/L and alanine aminotransferase (ALT) levels between 7–56 U/L. Normal renal function, defined as a serum creatinine level within the standard reference range.

Exclusion Criteria

Participants will be excluded if they meet any of the following criteria: Diagnosis of any sleep disorder other than anxiety-related conditions, History of bipolar disorder, psychotic disorder, post-traumatic stress disorder (PTSD), or any other psychiatric disorder requiring medication, Presence of ongoing clinical depression or generalized anxiety disorder. History of significant cardiac conditions, including unstable ischemic heart disease, heart failure, or severe uncontrolled hypertension, that may predispose the individual to arrhythmias or myocardial infarction. Lifetime history of schizophrenia, bipolar disorder, or psychosis, or any previous intolerance to cannabinoids. Pregnancy, confirmed by a positive urine pregnancy test (UPT), lactation, or plans for pregnancy during the trial period. Women of childbearing potential must agree to use effective contraception, as must their partners

- **Drug Preparation-** CannaRelief stress management oil for trial was produced from the Bombay Hemp Company, Cama Industrial Estate, Sunmill compound, lower Parel, Mumbai, Maharashtra, 400013.
- **Ethical Considerations:** Approval was obtained from the institutional ethics committee (IEC/ACA/2021/0277), and the trial was registered under CTRI (CTRI/2022/03/041165).
- **Informed consent:** Informed written consent was obtained from each participant prior to all trial related Procedure (physical examination, screening and laboratory studies). The participant were given full information about the study as well as description of any foreseeable risks and discomforts. He/she were also informed of his/her right to opt out of the study at any time without having to give reasons.
- **Treatment Protocol:**
  - **Intervention:** CannaRelief Stress Management Oil
  - **Dosage:** 4 drops, once daily (OD), administered sublingually after meals
  - **Duration:** 60 days
- **Efficacy and Safety end points**:

➢ Assessment of symptoms of stress and mild to moderate anxiety disorder by use of sleep quality scales (Pittsburgh sleep quality index[6], Insomnia severity index[7])

➢ Assessment of changes in Salivary Cortisol and Amylase[8]

- **Criteria for withdrawal:** The withdrawal criteria were set so that any patient who showed signs or symptoms of adverse reactions or deteriorated would be removed from the trial. Patients who do not follow the researcher's instructions.
- **Adverse drug reaction:** After taking medicine, some patients had symptoms like acidity, nausea, palpitations, excessive urination, and dizziness. After taking the rescue medication (Chew on black peppercorn, consume lemon juice, massage with lavender scents, Cinnamon oil, Lemongrass tea/soup) for two days, the symptoms subsided.

Assessment Parameters:

1. **Subjective parameters:** Sleep quality assessed using the Pittsburgh Sleep Quality Index and Insomnia Severity Index.
2. **Objective parameters:** Salivary Cortisol and Amylase

Observations & Results

Demographic data:

- **Age & Gender:** The majority of participants (35%) were aged 18-25 years, followed by 32.5% in the 26-35 age group, primarily due to academic, professional, and social stress. Males comprised 67.5% of the study population, likely influenced by financial and occupational pressures.
- **Habitat & Diet:** Urban residents made up 63.33% of the sample, reflecting the stress of fast-paced city life. Diet patterns showed 43.33% practicing Samasana (balanced eating), while 38.33% had irregular eating habits, contributing to digestive disturbances linked to mental stress. A high intake of Katu (78.33%), Lavana (63.33%), and Amla (61.66%) Rasa was observed, which may aggravate mental stress. The most common addiction was tea (55%), followed by tobacco (45%) and smoking (35%), all contributing to mental health imbalances.
- **Sleep & Digestion:** About 55% experienced disturbed sleep (Alpanidra), contributing to stress and nervous system imbalances. Vishamagni (irregular digestion) was reported in 60%, possibly leading to toxin accumulation (Ama) and further mental distress.
- **Physiological & Psychological Traits:** The majority had Vata-Pitta Prakriti (42%), Rajasika-Tamasika Manasika Prakriti (53%), and Avara Sattva (58%), making them more susceptible to mental disturbances.
- **Exercise & Physical Strength:** A significant portion (52%) did not engage in regular exercise, leading to metabolic imbalances. Most had Madhyama Samhanana (70%) and Madhyama Sara (77%), suggesting an average physical constitution without abnormalities. All patients (100%) exhibited Rasavaha and Manovaha Shrota Dushti, reinforcing the role of psychological factors in stress-related disorders.

Results: Total 40 patients completed the study.

Subjective parameters:

1. Pittsburgh Sleep Quality Index: The Pittsburgh Sleep Quality Index (PSQI) is a short self -report questionnaire and the most widely used subjective measure of sleep quality. The PSQI consist of 24 question or items measuring seven dimensions from 0 (best) to 3 (worst). These seven factors can be broadly categorised into sleep efficiency factors (sleep quality, sleep latency, sleep duration, and habitual sleep efficiency) and sleep disturbance factors (sleep disturbance, use of sleep medication, and daytime disturbance).

Range	**BT**	**AT**
Good sleep (0-4)	0	23
Poor sleep (5-21)	40	17
Mean ± SD	14.05±2.27529	5.65±2.1189

2. Insomnia Severity Index: - 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.)

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

Range	**BT**	**AT**
(0-7) no clinically significant insomnia	0	15
(8-14) subthreshold insomnia	18	25
(15-21) clinical insomnia- moderate severity	16	0
(22-28) severe.	6	0
Mean ± SD	15.775±4.00952	8.2±1.69766

Objective parameter:

1. Salivary Cortisol and Amylase

Variable	**Mean±SD**		**Mean**	**95% CI**	**SD±**	**SEM**	**T**	**p**	**s**
	Baseline Visit	Day 60							
Salivary cortisol	0.2517±0.1733	0.3058±0.2036	0.05413	-0.02533 to 0.1336	0.2484	0.03928	1.378	0.1761	**NS**
Salivary amylase	ns 13.2728±6.817	9.5631±6.0994	-3.710	-6.492 to 0.9270	8.701	1.376	2.697	0.0103	HS

Effect of study drug on Salivary cortisol and Salivary amylase Tests. In this table at Baseline visit Salivary cortisol Mean ± SD 0.2517±0.1733 and at Day 60 no reduction in Mean ± SD 0.3058±0.2036. In this table at Baseline visit Salivary cortisol Mean ± SD 13.2728±6.817 and at Day 60 reduction in Mean ± SD 9.5631±6.0994. P Value is not significant at Day 60 in Salivary cortisol parameter but significant for Salivary amylase.

Discussion

The current clinical study aimed to evaluate the efficacy and safety of CannaRelief Stress Management Oil in patients suffering from stress and mild to moderate anxiety disorder. The results provide valuable insights into its potential benefits in improving sleep quality, alleviating insomnia, and modulating biochemical stress markers such as salivary cortisol and amylase.

Sleep Quality Improvement

The Pittsburgh Sleep Quality Index (PSQI) was used to assess subjective sleep quality before and after treatment. The results indicate a significant improvement in sleep parameters over 60 days of intervention. At baseline, all 40 participants experienced poor sleep quality (PSQI score 5-21), but after the intervention, 23 participants shifted to the 'good sleep' category (PSQI score 0-4), leaving only 17 individuals in the 'poor sleep' group. The mean PSQI score decreased from 14.05±2.275 to 5.65±2.118, demonstrating a substantial improvement in sleep quality. These findings suggest that CannaRelief Oil plays a role in promoting sleep efficiency and reducing sleep disturbances, likely due to its anxiolytic and sedative properties.

Reduction in Insomnia Severity

The Insomnia Severity Index (ISI) was utilized to assess changes in sleep disorders. The findings demonstrated a remarkable shift in insomnia severity levels post-treatment. At baseline, 6 individuals had severe insomnia (ISI score 22-28), and 16 had moderate insomnia (ISI score 15-21). However, after the intervention, none of the participants remained in these severe categories. Instead, 15 individuals reported no clinically significant insomnia (ISI score 0-7), and 25 had only subthreshold insomnia (ISI score 8-14). The mean ISI score significantly declined from 15.77±4.009 to 8.2±1.697, reinforcing the oil's potential effectiveness in treating sleep disorders associated with anxiety and stress.

Salivary Biomarkers of Stress

Salivary Cortisol

Cortisol is a well-established biomarker of stress, typically elevated in individuals with anxiety disorders. In this study, salivary cortisol levels were assessed at baseline and at the end of the 60-day treatment period. Surprisingly, there was no statistically significant reduction in cortisol levels. The baseline mean cortisol level was 0.2517±0.1733, and at Day 60, it was 0.3058±0.2036, with a p-value of 0.1761, indicating a non-significant change. This suggests that while CannaRelief Oil demonstrated subjective improvements in sleep and anxiety, its effect on physiological stress markers like cortisol might be limited or require a longer duration to manifest.

Salivary Amylase

Salivary amylase is another biomarker linked to sympathetic nervous system activity and acute stress responses. Unlike cortisol, a significant reduction was observed in salivary amylase levels after the intervention. The mean salivary amylase level dropped from 13.27±6.81 at baseline to 9.56±6.09 at Day 60, with a statistically significant p-value of 0.0103. This indicates a potential stress-reducing effect of CannaRelief Oil, possibly mediated through mechanisms influencing autonomic nervous system activity.

The significant improvement in sleep quality and reduction in insomnia severity strongly support the anxiolytic and sedative effects of CannaRelief Oil. The findings suggest that the oil may be particularly beneficial for individuals experiencing stress-related sleep disturbances. While subjective improvements in stress levels were evident, the lack of a significant reduction in salivary cortisol raises questions about whether the intervention primarily impacts perceived stress rather than physiological stress markers. However, the significant decrease in salivary amylase suggests a potential regulatory effect on autonomic stress responses.

Mode of Action of CannaRelief Oil

CannaRelief Stress Management Oil exhibits its therapeutic effects through multiple mechanisms:

1. Anxiolytic & Sedative Effects:
   - The oil contains bioactive compounds that interact with the endocannabinoid system (ECS), modulating neurotransmitter release and promoting relaxation.
   - It enhances GABAergic activity, reducing neuronal excitability and calming the nervous system.[9]
2. Sleep Regulation:
   - It influences melatonin secretion, improving sleep onset and quality.
   - The sedative properties aid in reducing insomnia severity and promoting deep sleep cycles.[10]
3. Stress Modulation:
   - Regulates autonomic nervous system (ANS) activity, reducing sympathetic overactivation.
   - Lowers salivary amylase, indicating a reduction in acute stress response.
4. Neuroendocrine Balance:
   - While no significant change in cortisol levels was observed, the oil may contribute to perceived stress reduction rather than directly altering endocrine markers.
5. Digestive & Metabolic Influence:
   - Helps in balancing Agni (digestive fire) and reducing Ama (toxins), which are linked to mental well-being in Ayurveda.

The overall action of CannaRelief Oil suggests a synergistic approach in reducing stress, improving sleep, and modulating physiological stress responses, making it a potential natural remedy for anxiety and stress-related disorders.

Limitations and Future Directions

This study, being an open-label, single-arm pilot study, has inherent limitations, including the absence of a control group and small sample size. Further randomized controlled trials with larger populations and longer follow-ups are necessary to confirm these findings and establish the long-term efficacy of CannaRelief Oil. Additionally, investigating its mechanism of action through neurochemical and hormonal pathways could provide deeper insights into its therapeutic potential.

Conflict of Interest: None declared.

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