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A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED COMPARATIVE STUDY EVALUATING THE EFFICACY OF OCITUM™ (HOLY BASIL LEAF EXTRACT) ON DEPRESSION, ANXIETY, STRESS, AND SLEEP QUALITY

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ABSTRACT

Background: Stress, anxiety, and sleep disturbances negatively affect mental health and quality of life. Ocitum™ (Holy Basil Leaf Extract) has been explored for its anti-stress and anxiolytic properties. This study evaluates its efficacy and safety in improving depression, anxiety, stress, and sleep quality. **Methods**: This double-blind, randomized, placebo-controlled study enrolled 61 participants experiencing mild to moderate depression, anxiety, stress, and sleep disturbances. Participants were randomized 1:1 to receive either Ocitum™ or a placebo for 8 weeks. The primary endpoints included changes in Depression, Anxiety, and Stress Scale (DASS-21) scores, Stanford Sleepiness Scale (SSS) scores and sleep parameters. Secondary endpoints assessed cortisol levels and WHOQOL-BREF scores. Safety assessments included complete blood count (CBC), ALT, and serum creatinine levels. **Results**: Significant improvements were observed in the Ocitum™ group for DASS-21 scores (−14.34 vs. 1.80; $p < 0.001$) and SSS scores (−1.33 vs. +0.20; $p < 0.001$). Sleep efficiency improved markedly in the Ocitum™ group compared to placebo for both workdays (8.24% vs. −0.44%) and free days (7.2% vs. −0.5%). Serum cortisol, ALT, and WHOQOL-BREF scores demonstrated statistically significant improvements in the Ocitum™ group. No adverse events or serious adverse events were reported. **Conclusion**: Ocitum™ significantly improved psychological well-being, sleep quality, and safety markers, offering a promising natural intervention for managing stress-related conditions.

KEYWORDS: Mental Health, Depression, Anxiety, Stress, *Ocimum tenuiflorum* (Tulsi- Holy Basil), WHOQOL-BREF.

1.) INTRODUCTION[1-6]

Mental health disorders such as stress, anxiety, and depression, often accompanied by sleep disturbances, significantly affect individuals' well-being, productivity, and quality of life. Stress, sleep and anxiety are inter-related factors that affect the mental health and well-being of people in various settings and situations.[1]

Stress, a psychological response to perceived demands, can negatively affect physical health, leading to diseases like cardiovascular and immune system disorders, and mental health issues like mood disorders. Anxiety is a fear or apprehension about a potentially negative outcome, which can disrupt daily life, impact social interactions, work performance, and decision-making, and can worsen physical symptoms. Sleep is crucial for regulating circadian rhythm, immune system, and cognitive functions. Deprivation can impair alertness, creativity, and emotional regulation, increasing risk of health conditions.[2]

Individual, environmental, and situational factors influence stress, sleep, and anxiety levels. Common stressors include work pressure, financial difficulties, family conflicts, health issues, and traumatic events. Lifestyle habits like caffeine, alcohol, screen time, and physical activity affect sleep quality. Anxiety levels are influenced by personality traits, coping styles, self-efficacy, and social support.[3]

Optimal sleep, reduced anxiety, and stress are crucial for mental health, productivity, and quality of life. Good sleep enhances memory consolidation, creativity, and mood, while anxiety reduction boosts confidence and

motivation. Less stress reduces the risk of mental disorders. Current pharmacological treatments like anxiolytics and sedatives provide symptomatic relief but often carry risks of adverse effects, tolerance, and dependency. These limitations highlight the need for safer, natural alternatives.[4]

Ocitum™, derived from Holy Basil (*Ocimum tenuiflorum* / sanctum), is a promising adaptogen with anxiolytic and stress-modulating properties. Tulsi (Holy Basil) is rich in bioactive compounds such as Ursolic Acid, Eugenol, and Rosmarinic Acid, which interact with stress pathways and neurotransmitter systems. Ursolic Acid exhibits anti-inflammatory and neuroprotective effects, influencing stress modulation, while Eugenol demonstrates anxiolytic properties by modulating neurotransmitters like GABA. Rosmarinic Acid, known for its antioxidant and anti-inflammatory properties, may contribute to reducing stress-related damage.[5]

Ocitum™ exemplifies Ayurveda's comprehensive approach to promoting well-being. The Flavour profile of Tulsi (Holy Basil) is characterized by its hot and bitter taste, possessing the ability to penetrate deeply into tissues, regulate tissue secretions, and normalize *kapha* and *vata*, as described in Ayurvedic texts. *Kapha* and *Vata* both are acclaimed to have influence on mental stability and various neurological functions.[5]

K. Patel Phyto Extractions Pvt. Ltd. developed Ocitum™, a proprietary Branded Ingredient with calming properties. It is a standardized extract from *Ocimum tenuifolium* leaf, containing Total Ursolic Acid NLT 5%, Eugenol NLT 5%, and Rosmarinic Acid NLT 0.5%. The extract is made using water and ethanol, ensuring global acceptability and compliance. It also offers complete traceability from cultivation to final extract, ensuring safety for human consumption.
This study evaluates the efficacy and safety of Ocitum™ in adults experiencing mild to moderate depression, anxiety, stress, and sleep disturbances. The investigation aims to provide robust clinical evidence supporting Ocitum™ as a therapeutic intervention.[6]

2.) MATERIALS AND METHODS

Study Design: This was a prospective, double-blind, randomized, placebo-controlled clinical trial conducted over 11 weeks. Participants were randomly assigned in a 1:1 ratio to receive Ocitum™ or placebo.

Phase of development: II
Test product: "Ocitum™ (Holy Basil Leaf Extract) capsule" of K Patel Phytoextractions Pvt Ltd., Mumbai.

Name of Sponsor: K Patel Phytoextractions Pvt Ltd., Mumbai.
507, Eureka Tower, Mind Space, Off Link Road, Malad West, Mumbai-400064, Maharashtra, India.

Investigator(s) and Study centre(s): The study was conducted at a single centre in India. Subjects were enrolled and randomized at the below listed study centre.

Principal Investigator: Dr Sandeep Desai
Study Centre: Amit Hospital, Halar Road, Beside SBI Bank, Opp. Avabai High School, Valsad - 396001, Gujarat, India.
Ethics Committee: This study protocol was approved by the Dixit Hospital Institutional Ethics Committee on 05 Feb 2024.

Informed Consent: Participants were made fully aware of the Study Objectives, their rights and Procedure of the study, with the help of the patient information sheet, which was available in English, Hindi and Gujarati. Participants who gave written informed consent were included in study.

Participants: A total of 64 participants were screened in the study, from which 61 participants were randomized and 3 participants withdrew their consent before randomization.

Key Inclusion Criteria
- Adults aged 18 to 65 years.
- Experiencing mild to moderate stress and insomnia (DASS-21 and SSS scores within defined ranges).
- No significant comorbid conditions or substance use.

Key Exclusion criteria
- Severe psychiatric or chronic medical conditions.
- Pregnancy, lactation, or planning pregnancy.
- History of hypersensitivity to herbal products.

Intervention: Participants in the Ocitum™ group received 150 mg capsules twice daily for 8 weeks. The placebo group received visually identical capsules.

METHODOLOGY
- Individuals experiencing mild depression, stress, general anxiety, and sleep disturbances, and meeting all the previously mentioned inclusion and exclusion criteria, were identified.
- Subjects undergo screening phase of 7 days before first IP usage. All the tests performed during the screening (Visit 1) will be considered as baseline for further evaluation.
- Subjects were randomized on Day 1 (Visit 2: Enrollment / Randomization) to receive either test product or Placebo for a timeline of 8 weeks. Based upon the randomization schedule, subjects were received assigned product for a period of 4 weeks along with subject diary card (SDC) on Day 1 & Week 4 - Day 29.
- Interim follow up visits were conducted on Week 4 – Day 29 & Week 8 – Day 57 (Visit 3 & Visit 4). The subjects undergo following process: Physical examination, subjective assessment of depression,

stress, sleep and anxiety (DASS-21), assessment of Quality of Life (WHOQOL-BREF), Diary & IP compliance, and adverse event (AE) / serious adverse event (SAE) monitoring.

- Laboratory investigations were carried out at an interval of 4 weeks from baseline, i.e., Week 4 – Day 29 (Visit 3) and end of treatment visit on Week 8 – Day 57 (Visit 4).
- Treatment compliance was identified by documented information in SDC during the interim follow up visits on each monthly visit: Follow Up 1 on Week 4 – Day 29 ± 3 days (Visit 3) and at the end of treatment visit on Week 8 – Day 57 ± 3 days (Visit 4). Subjects were instructed not to miss the scheduled IP usage and complete all evaluations on designated monthly visits with no protocol deviations that could affect the treatment evaluation.
- Telephonic safety assessments were performed on Week 10 – Day 71 ± 2 days (Visit T1), which corresponds to the 14th day following the end of treatment visit (Visit 4), respectively, in order to assess and monitor the safety of the subjects.

Duration of study

The anticipated treatment duration was around 8 weeks, commencing from Day 1.

- **Screening (Visit-1):** Day -7 to -1
- **Enrolment / Randomization visit (Visit- 2):** Day 1
- **Follow Up 1 (Visit- 3):** Week 4 – Day 29 ± 3 days
- **Follow Up 2 - End of Treatment (Visit- 4):** Week 8 – Day 57 ± 3 days
- **Telephonic Follow Up 1 (Visit T1):** Week 10 – Day 71 ± 2days

Total expected study duration was approximately 11 Weeks – 77 Days ± 2 days (i.e., from screening phase to end of study visit). Telephone follow-up was conducted at T1 (2 weeks after treatment completion).

Primary Objective

- To assess the effect of Ocitum™ on severity of depression, anxiety & stress using Depression, Anxiety, Stress Scale (DASS-21) throughout the study period.
- To assess the effect of Ocitum™ on severity of sleep using Stanford Sleepiness Scale (SSS) throughout the study period.
- To assess the effect of Ocitum™ on various parameters of sleep: Sleep Latency, Sleep Efficiency & Sleep Duration throughout the study period.

Secondary objective

- To evaluate the effect of Ocitum™ on Serum Cortisol levels throughout the study period.
- To assess improvement in Quality of Life using WHOQOL-BREF throughout the study period.
- To assess the effect of Ocitum™ on CBC, ALT & S. Creatinine.
- To assess the safety of Ocitum™ throughout the study period.

Primary Efficacy Endpoints [Time Frame: Baseline to week 8-day 57]

- Improvement in domains of DASS-21 from baseline
- Improvement in SSS from baseline
- Improvement in various sleep parameters from baseline.

Secondary efficacy endpoints [Time Frame: Baseline to week 8-day 57]

- Change in S. Cortisol levels
- Improvement in WHOQOL-BREF score

Note: All the changes are considered from baseline to end of treatment.

Safety Endpoints [Time Frame: Baseline to week 8-day 57]

- Change in CBC (Complete Blood Count) parameters
- Change in S. Creatinine levels
- Change in ALT levels
- Number and type of Adverse Events (AEs) and serious adverse events (SAEs)

Statistical Analysis

Data were analysed using descriptive and inferential statistics. Paired t-tests assessed within-group changes, while independent t-tests compared differences between groups. Statistical significance was set at $p < 0.05$.

Statistical method

Descriptive Statistics was performed using IBM SPSS statistical software (Version 30) post database lock, including means, variability, and minimum and maximum values. All statistical tests were conducted at the 5% significance level. The identification of primary, secondary endpoints, safety endpoints, and demographics of the population were part of this comprehensive analysis.

The continuous data were summarized by treatment groups using descriptive statistics (number of subjects (n), mean, standard deviation (SD), median, minimum and maximum). Categorical data were summarized by treatment groups using frequency count (n) and percentages (%). The detailed statistical aspects of the efficacy and safety analysis were included, and it was prepared and finalized before the database lock.

Baseline Characteristics

Both groups (Ocitum™: n=30; Placebo: n=31) were compared in baseline demographics, DASS-21 scores, SSS scores, and sleep efficiency metrics.

Table 1: Subject Disposition

NUMBER OF SUBJECTS (PLANNED AND ANALYZED) :				
Category	**Statistics**	**Treatment Groups**		**Overall (N=61)**
		Test Group (N=30)	**Placebo Group (N=31)**	
Subjects Screened	n	-	-	64
Subjects Rescreened	n	-	-	0
Subject screen failure	n	-	-	0
Subject discontinued before randomization	n	02	01	03
Lost to follow up	n	-	-	0
Physician decision	n	-	-	0
Withdrawal of consent	n	02	01	03
Subjects Randomized	n(%)	30(49.2%)	31(50.8%)	61(100%)
Subjects Dosed	n(%)	30(49.2%)	31(50.8%)	61(100%)
Subjects Completed	n(%)	30(49.2%)	31(50.8%)	61(100%)
Subjects Discontinued	n(%)	02(3.1%)	01(1.6%)	03(4.7%)

*N: The number of subjects in the safety population for each sequence; n: The number of subjects in the specific category; %: calculated using the number of subjects in the safety population for each sequence, or the safety population for the overall, as denominator (n/N*100).*
A: Test Product: Ocitum™ (Holy Basil Leaf Extract) capsule" of K Patel Phytoextractions Pvt Ltd.
B: Placebo

3.) RESULTS

I.) Primary Outcomes

i.) DASS-21 Scores: The DASS-21 (Depression, Anxiety, and Stress Scale – 21 items) is a self-report questionnaire designed to measure negative emotional states of depression, anxiety, and stress. It comprises 21 items, divided equally into three scales—7 items each for Depression, Anxiety, and Stress. Respondents rate the application of each statement on a 4-point Likert scale, ranging from 0 to 3.[7] The baseline DASS-21 scores were 48.07 ± 6.16 for the test group (N=30) and 44.25 ± 5.56 for the placebo group (N=31). At the endpoint (EOT), the mean DASS-21 score in the test group reduced to 33.73 ± 5.60, whereas the placebo group increased to 46.06 ± 9.64.

The test group demonstrated a significant reduction in DASS-21 scores (−14.34 ± 8.32) compared to placebo (1.81 ± 11.2). This reflects a 29.8% improvement in psychological distress for test group versus 4.1% deterioration for placebo group. The test group showed a highly significant improvement in DASS-21 scores compared to the placebo group, with an intragroup p-value of <0.001, as determined by an independent sample t-test.

Table 2: Improvement in DASS-21 Score within each group: Test and Placebo

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	44.25±5.56	-	-	-	-	-
	Visit 4	46.06±9.64	1.81±11.2	-4.1	0.18	-	-
Test (n=30)	Baseline	48.07±6.16	-	-	-	<0.05	-
	Visit 4	33.73±5.60	-14.34±8.32	-29.83	<0.001*	<0.001*	<0.05

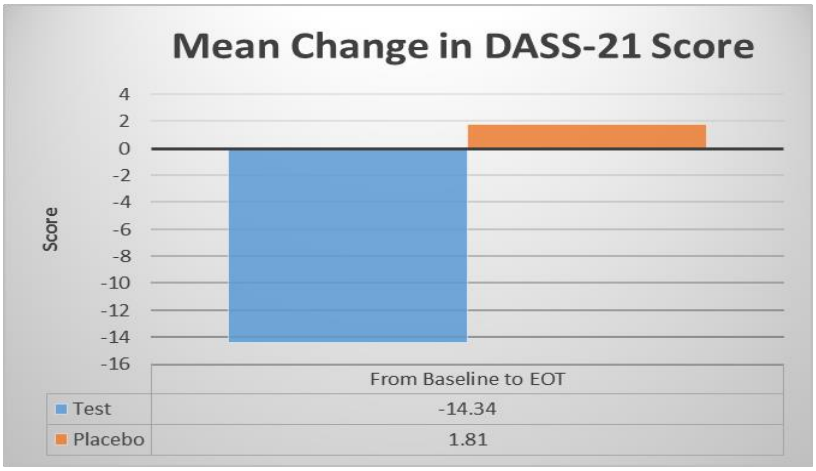

Figure 1: Mean Improvement in DASS-21 Score from baseline to EOT.

DASS-21 Scale

DASS21 *Name:* *Date:*

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

ii.) SSS Scores: The Stanford Sleepiness Scale (SSS) is a widely used tool for assessing subjective sleepiness, used in studies involving sleep deprivation, circadian rhythms, or sleep disorders. It quantifies an individual's daytime alertness and is commonly used in research on sleep and performance.[8] At baseline, the mean SSS score was recorded as 4 ± 0.98 for the test group (N=30) and 3.06 ± 0.81 for the placebo group (N=31). By the endpoint (EOT), the mean SSS score in the test group decreased to 2.67 ± 0.71, indicating a highly significant improvement ($p<0.001$) in sleepiness levels, while the placebo group experienced an increase in the mean SSS score to 3.26 ± 0.82.

The test group demonstrated a significant reduction in SSS Scores from baseline to EOT (−1.33 ± 1.21) compared to placebo (+0.20 ± 1.15). This reflects a 33.2% decrease in SSS for test group compared to a 6.5% increase in the placebo group. The test group showed a highly significant improvement in the SSS score compared to the placebo group at EOT, with an intragroup p-value of <0.001, indicating highly statistical significance and supporting its efficacy compared to placebo.

Table 3: Improvement in SSS Score within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	3.06±0.81	-	-	-	-	-
	Visit 4	3.26±0.82	0.2±1.15	6.5	0.43	-	-
Test (n=30)	Baseline	4±0.98	-	-	-	<0.001*	-
	Visit 4	2.67±0.71	-1.33±1.21	-33.25	<0.001*	<0.001*	<0.001*

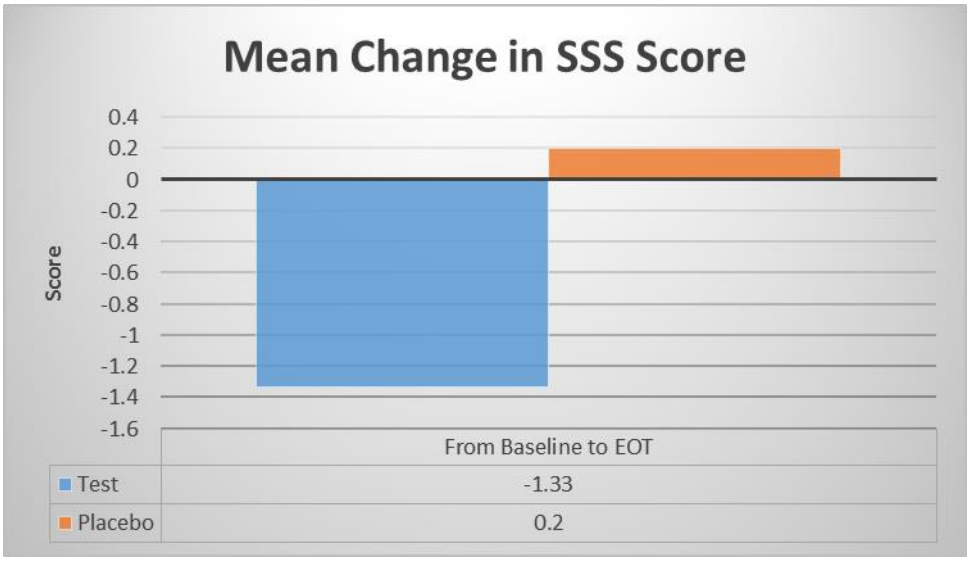

Figure 2: Mean Improvement in SSS Score from baseline to EOT.

SSS Scale

The Stanford Sleepiness Scale is a quick and easy way to assess how alert you are feeling. Discover your own pattern of alertness by recording your "degree of sleepiness" at different times throughout the day.

Using the 7-point scale below pick what best represents how you are feeling and note the corresponding number on the chart below.

Degree of Sleepiness	Scale Rating
Feeling active, vital, alert, or wide awake	1
Functioning at high levels, but not fully alert	2
Awake, but relaxed; responsive but not fully alert	3
Somewhat foggy, let down	4
Foggy; losing interest in remaining awake; slowed down	5
Sleepy, woozy, fighting sleep; prefer to lie down	6
No longer fighting sleep, sleep onset soon; having dream-like thoughts	7
Asleep	X

iii.) Improvement in Sleep Latency (On Work Days) from Baseline: Sleep latency refers to the amount of time it takes to transition from full wakefulness to sleep, typically measured from the time a person tries to fall asleep (lights off) to the onset of sleep.[9] At baseline, the mean sleep latency (in minutes) on work days was recorded as 66.5±39.54 for the test group (N=30) and 39.19±31.57 for the placebo group (N=31). By the endpoint (EOT), the mean sleep latency in the test group decreased to 31.5±19.34, indicating a reduction in sleep latency. Conversely, the placebo group exhibited an increase in mean sleep latency, with a final value of 42.25±31.43.

The test group demonstrated a significant decrease in sleep latency from baseline to EOT (-35±7.90), compared to placebo (3.06±8.13). This reflects a 52.6% improvement in sleep latency for test group versus 7.8%

deterioration in placebo group. The test group showed a highly significant improvement in sleep latency compared to the placebo group at EOT, with an intragroup p-value of <0.0001, indicating its efficacy compared to the Placebo group.

Table 4: Improvement in Sleep Latency (On Workdays) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	39.19±31.57	-	-	-	-	-
	Visit 4	42.25±31.43	3.06±8.13	7.80	>0.05	-	-
Test (n=30)	Baseline	66.5±39.54	-	-	-	<0.002	-
	Visit 4	31.5±19.34	-35±7.90	-52.63	<0.0001*	≤0.05	<0.001*

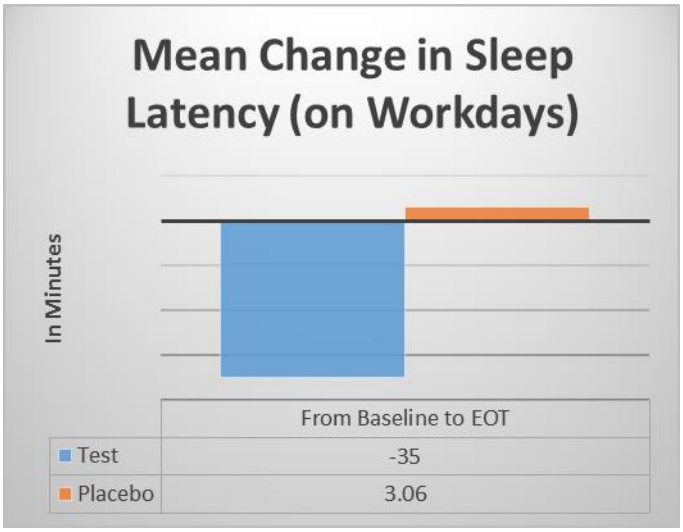

Figure 3: Mean Improvement in Sleep Latency (On Workdays) from baseline to EOT.

iv.) Improvement in Sleep Latency (On Free Days) from Baseline: Sleep latency is often used as an indicator of sleep initiation and can be influenced by stress, environment, and sleep disorders.[9] At baseline, the mean sleep latency (in minutes) on free days was recorded as 66.83±39.18 for the test group (N=30) and 40.64±34.34 for the placebo group (N=31). By the endpoint (EOT), the mean sleep latency in the test group decreased to 32.5±20.03, indicating a reduction in sleep latency. Conversely, the placebo group exhibited an increase in mean sleep latency, with a final value of 42.25±31.43.

The test group demonstrated a significant decrease in sleep latency from baseline to EOT (-34.33±7.91), compared to placebo (1.61±8.49). This reflects a 51.3% improvement in sleep latency for test group versus 3.9% deterioration in placebo group. The test group showed a highly significant improvement in sleep latency compared to the placebo group at EOT, with an intragroup p-value of <0.0001, indicating its efficacy compared to the Placebo group.

Table -5: Improvement in Sleep Latency (On Free days) within each group: Test and Placebo

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	40.64±34.34	-	-	-	-	-
	Visit 4	42.25±31.43	1.61±8.49	3.96	>0.05	-	-
Test (n=30)	Baseline	66.83±39.18	-	-	-	≤0.007	-
	Visit 4	32.5±20.03	-34.33±7.91	51.36	<0.0001*	>0.05	<0.00001*

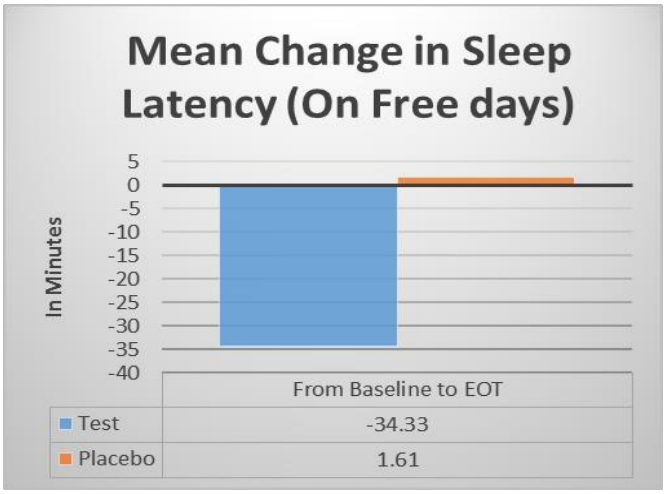

Figure 4: Mean Improvement in Sleep Parameters (On free days) from baseline to EOT.

v.) Improvement in Sleep Duration (On Work Days) from Baseline

Sleep duration refers to the total amount of time a person spends sleeping during a 24-hour period. The optimal sleep duration varies depending on age, lifestyle, and individual needs.[10]

At baseline, the mean sleep duration (in min) on workdays was recorded as 366±52.30 for the test group (N=30) and 393.90±55.50 for the placebo group (N=31). By the endpoint (EOT), the mean sleep duration in the test group increased to 426.5±45.88, indicating an improvement in sleep duration. Similarly, the placebo group exhibited an increase in mean sleep duration, with a final value of 400.64±51.11.

The test group demonstrated a significant increase in sleep duration from baseline to EOT (60.5±12.50) compared to placebo (6.74±13.77). This reflects a 16.5% improvement in sleep duration for test group and 1.7% deterioration for placebo group. The test group showed a highly significant improvement in sleep duration compared to the placebo group at EOT, with an intragroup p-value of <0.00002, indicating its efficacy compared to the Placebo group.

Table 6: Improvement in Sleep Duration (On Workdays) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	393.90±55.50	-	-	-	-	-
	Visit 4	400.64±51.11	6.74±13.77	1.71	>0.05	-	-
Test (n=30)	Baseline	366±52.30	-	-	-	<0.05	-
	Visit 4	426.5±45.88	60.5±12.50	16.53	<0.00002*	<0.05	<0.05*

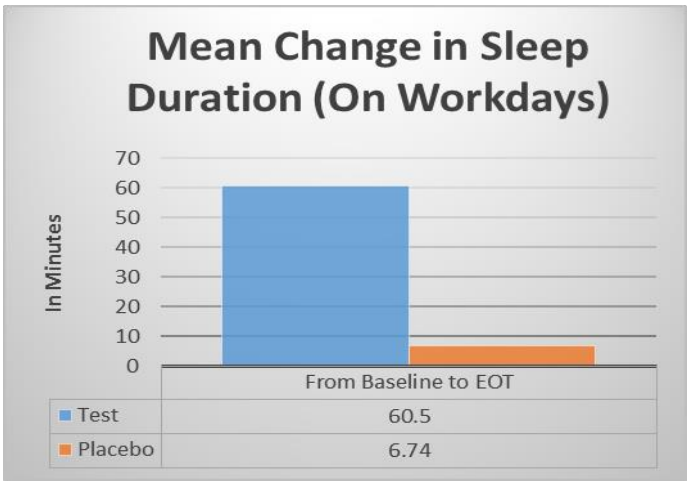

Figure 5: Mean Improvement in Sleep Duration (On Workdays) from baseline to EOT.

vi.) Improvement in Sleep Duration (On Free Days) from Baseline

At baseline, the mean sleep duration (in min) on free days was recorded as 401±69.79 for the test group (N=30) and 434.51±52.46 for the placebo group (N=31). By the endpoint (EOT), the mean sleep duration in the test group increased to 433.5±46.66, indicating an improvement in sleep duration. Similarly, the placebo group exhibited an increase in mean sleep duration, with a final value of 438.38±52.92.

The test group demonstrated a significant increase in sleep duration from baseline to EOT (32.5±15.33) compared to placebo (3.87±13.59). This reflects an 8.1% improvement in sleep duration for test group and 0.8% deterioration for placebo group. The test group showed a statistically significant improvement in sleep duration compared to the placebo group at EOT, with an intragroup p-value of <0.05, indicating its efficacy compared to the Placebo group.

Table -7: Improvement in Sleep Duration (On free days) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	434.51±52.46	-	-	-	-	-
	Visit 4	438.38±52.92	3.87±13.59	0.89	>0.05	-	-
Test (n=30)	Baseline	401±69.79	-	-	-	>0.05	-
	Visit 4	433.5±46.66	32.5±15.33	8.10	<0.05	>0.05	<0.00001*

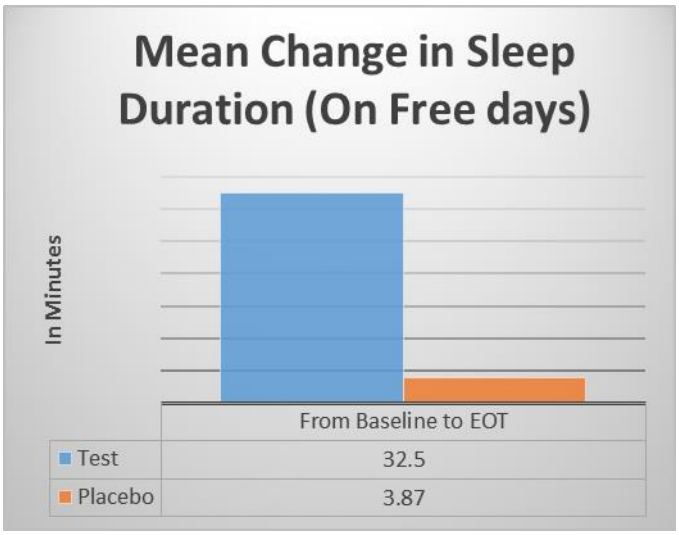

Figure 6: Mean Improvement in Sleep Duration (On Free days) from baseline to EOT.

vii.) Improvement in Total time in bed (On Workdays) from Baseline: Total time in bed is the duration from when a person lies down intending to sleep to when they get up in the morning. It provides insights into sleep opportunities and routines and becomes especially valuable when analysed alongside sleep latency and total sleep time to evaluate sleep quality and habits.[11] At baseline, the mean total time spent in bed (in min) on workdays was recorded as 432.5±57.69 for the test group (N=30) and 432.09±51.79 for the placebo group (N=31). By the endpoint (EOT), the mean total time spent in bed in the test group increased to 457.83±49.56, indicating an improvement in total time spent in bed. Similarly, the placebo group exhibited an increase in mean total time spent in bed, with a final value of 442.90±47.13.

The test group demonstrated a significant increase in total time spent in bed from baseline to EOT (25.33±13.65) compared to placebo (10.81±12.77). This reflects a 5.85% improvement in total time spent in bed for test group and 2.50% for placebo group. The test group showed a statistically significant improvement in total time spent in bed compared to the placebo group at EOT, with an intragroup p-value of <0.05, indicating its efficacy compared to the Placebo group.

Table 8 Improvement in Total time in bed (On Workdays) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	432.09±51.79	-	-	-	-	-
	Visit 4	442.90±47.13	10.81±12.77	2.50	>0.05	-	-
Test (n=30)	Baseline	432.5±57.69	-	-	-	>0.05	-
	Visit 4	457.83±49.56	25.33±13.65	5.85	<0.05	>0.05	≤0.0001*

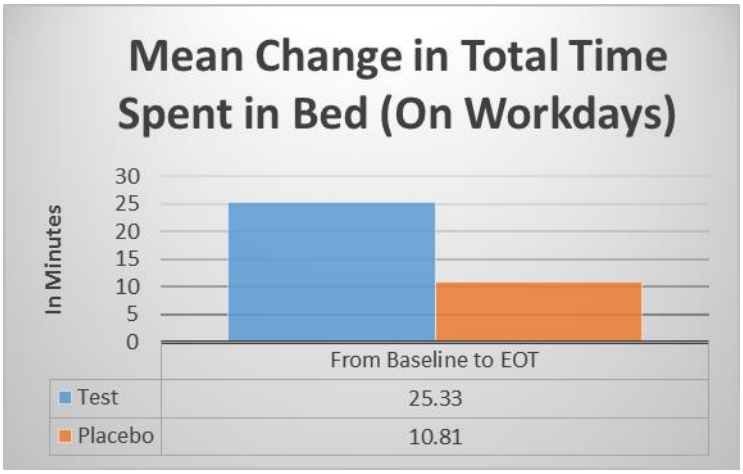

Figure 7: Mean Improvement in Total time in bed (On Workdays) from baseline to EOT.

viii.) Improvement in Total time in bed (On Free Days) from Baseline

At baseline, the mean total time spent in bed (in min) on workdays was recorded as 451.16±86.67 for the test group (N=30) and 475.16±54.42 for the placebo group (N=31). By the endpoint (EOT), the mean total time spent in bed in the test group increased to 451.16±86.67, indicating an improvement in total time spent in bed. Conversely, the placebo group exhibited a decrease in mean total time spent in bed, with a final value of 461.61±91.54.

The test group demonstrated a significant increase in total time spent in bed from baseline to EOT (14.67±18.31) compared to placebo (-13.75±19.43). This reflects a 3.25% improvement in total time spent in bed for test group and placebo group showed a decrease of 2.89%. The test group showed a statistically insignificant improvement in total time spent in bed compared to the placebo group at EOT, with an intragroup p-value of >0.05, indicating its efficacy compared to the Placebo group.

Table -9: Improvement in Total time spent in bed (On Free days) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	475.16±54.42	-	-	-	-	-
	Visit 4	461.61±91.54	-13.75±19.43	-2.89	>0.05	-	-
Test (n=30)	Baseline	451.16±86.67	-	-	-	>0.05	-
	Visit 4	465.83±53.67	14.67±18.31	3.25	>0.05	>0.05	>0.05

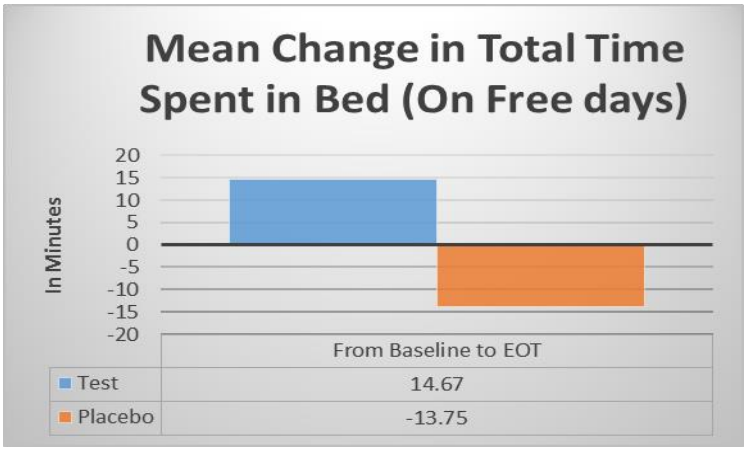

Figure 8: Mean Improvement in Total time in bed (On Free days) from baseline to EOT.

ix.) Improvement in Sleep Efficiency (On Work Days) from Baseline

Sleep efficiency is the percentage of time spent asleep to bedtime, crucial in sleep studies for understanding sleep quality and its impact on daily functioning, especially workdays. A higher percentage indicates better sleep quality, while a lower percentage suggests insomnia or difficulties in sleep.[12] At baseline, the mean sleep efficiency (on workdays) was measured at 84.92 ± 8.5% for the test group (N=30) and 90.91 ± 7.2% for the placebo group (N=31). By the endpoint (EOT), the test group exhibited a significant increase in mean sleep efficiency, rising to 93.16 ± 3.9%, which indicates a marked improvement in their overall sleep quality. In contrast, the placebo group showed a slight decrease in mean sleep efficiency to 90.47 ± 6.8%.

Sleep efficiency calculated by,

Sleep Efficiency (%) = (Total Sleep Time / Total Time in Bed) × 100

The test group demonstrated a significant improvement in sleep efficiency (on workdays) from baseline to EOT (8.24 ± 9.34) compared to placebo (-0.44 ± 9.9). This reflects a 10% improvement in sleep efficiency (on workdays) for test group versus 0% deterioration for placebo group. The test group showed a highly significant improvement in sleep efficiency (On workdays) compared to the placebo group at EOT, with an intragroup p-value of <0.001, indicating its efficacy compared to the placebo group.

Table 10: Improvement in Sleep Efficiency (On Workdays) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	90.91±7.2	-	-	-	-	-
	Visit 4	90.47±6.8	-0.44±9.9	-0.49	0.40	-	-
Test (n=30)	Baseline	84.92±8.5	-	-	-	<0.005	-
	Visit 4	93.16±3.9	8.24±9.34	9.7	<0.001*	<0.001	0.003*

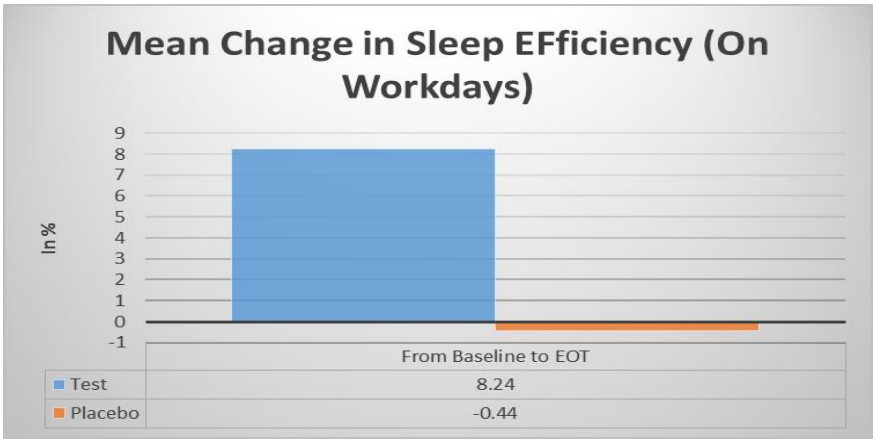

Figure 9: Mean Improvement in Sleep Efficiency (On Workdays) from baseline to EOT.

x.) Improvement in Sleep Efficiency (On Free Days) from Baseline

Sleep efficiency is the ratio of time spent asleep to time spent in bed, indicating better sleep quality. Higher efficiency indicates more deep, restorative sleep.[13-16] Free days, such as weekends or vacations, can significantly differ from workdays due to fewer disruptions and lower stress levels.[13-14]

At baseline, the mean sleep efficiency (on free days) was recorded as 85.7 ± 8.6% for the test group (N=30) and 91.6 ± 6.5% for the placebo group (N=31). By the endpoint (EOT), the mean sleep efficiency in the test group increased to 92.9 ± 4.1%, indicating a notable improvement in sleep efficiency. In contrast, the placebo group exhibited a slight decrease in mean sleep efficiency, reaching 91.1 ± 6.4%.

The test group demonstrated a significant Improvement in sleep efficiency (on free days) from baseline to EOT (7.2 ± 9.53) compared to placebo (-0.5 ± 9.1). This reflects an 8.4% improvement in sleep efficiency (on free days) for test group versus 0.5% deterioration for placebo group. The test group showed a highly significant improvement in sleep efficiency (On Free Days) compared to the placebo group at EOT, with an intragroup p-value of <0.001, indicating its efficacy compared to the placebo group.

Table 11: Improvement in Sleep Efficiency (On Free Days) within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	91.6±6.5	-	-	-	-	-
	Visit 4	91.1±6.4	-0.5±9.1	-0.5	0.38	-	-
Test (n=30)	Baseline	85.7±8.6	-	-	-	<0.005	-
	Visit 4	92.9±4.1	7.2±9.53	8.4	<0.001*	<0.001	<0.01*

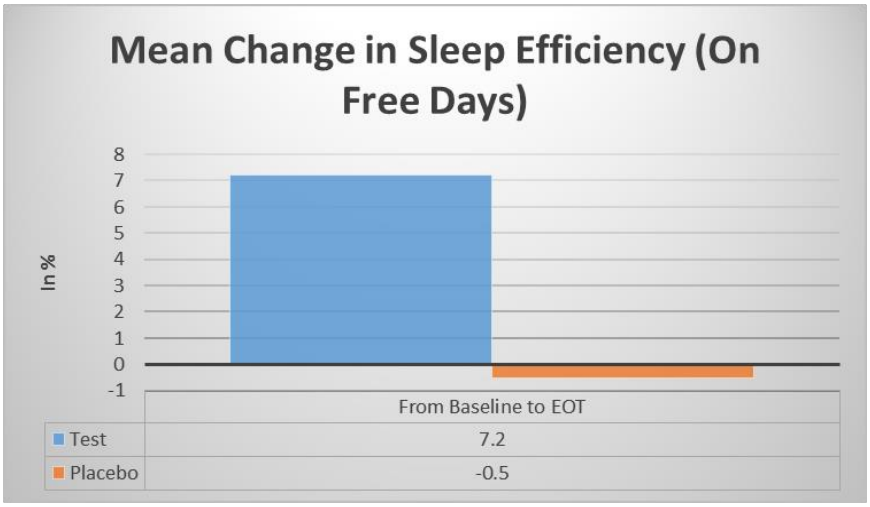

Figure 10: Mean Improvement in Sleep Efficiency (On Free Days) from baseline to EOT.

xi.) Improvement in Sleep Debt from Baseline

Sleep debt refers to the discrepancy between an individual's actual and required sleep levels, which can affect psychological well-being and cognitive function. Recovery is often difficult due to sleep limitations, such as working late or early.[14] Prolonged or recurrent sleep debt can lead to negative long-term health outcomes, such as increased risk for cardiovascular disease, obesity, and diabetes.[17]

At baseline, the mean sleep debt (in hours) was recorded as 0.02 ± 0.03 for the test group (N=30) and 0.03 ± 0.03 for the placebo group (N=31). By the endpoint (EOT), the mean sleep debt in the test group decreased to 0.00 ± 0.01, indicating a reduction in sleep debt. Conversely, the placebo group exhibited no changes in mean sleep debt, with a final value of 0.03 ± 0.03.

The test group demonstrated a significant decrease in sleep debt from baseline to EOT (-0.02 ± 0.03) compared to placebo (0.00 ± 0.04). This reflects a 100% improvement in sleep debt for test group versus 0% for placebo group. The test group showed a highly significant improvement in sleep debt compared to the placebo group at EOT, with an intragroup p-value of <0.001, indicating its efficacy compared to the Placebo group.

Table 12: Improvement in Sleep Debt within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	0.03±0.03	-	-	-	-	-
	Visit 4	0.03±0.03	0.00±0.04	0.00	1.0	-	-
Test (n=30)	Baseline	0.02±0.03	-	-	-	0.1	-
	Visit 4	0.00±0.01	-0.02±0.03	-100	<0.001*	0.1	≤0.05

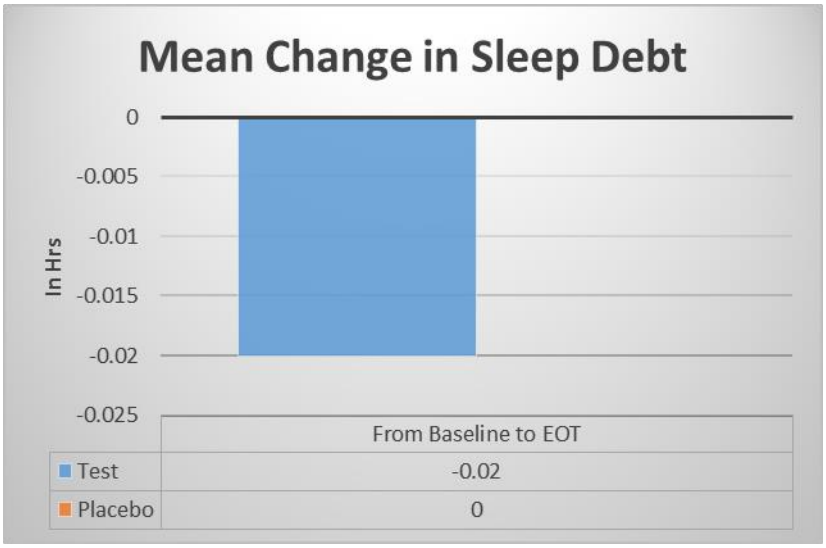

Figure 11: Mean Improvement in Sleep Debt from baseline to EOT.

II.) Secondary Outcomes

i.) Serum Cortisol Levels

Cortisol, a steroid hormone produced by the adrenal cortex, is crucial for various physiological processes like metabolism, immune response, and stress adaptation. It's often called the "stress hormone" as its level fluctuates in response to the stress. Cortisol also regulates blood sugar levels, blood pressure, and inflammatory responses.[18]

At baseline, the mean cortisol levels were recorded at 8.89 ± 4.27 mg/dL for the test group (N=30) and 9.88 ± 4.81 mg/dL for the placebo group (N=31). By the endpoint (EOT), the mean cortisol level in the test group decreased to 5.79 ± 4.9 mg/dL. In contrast, the placebo group experienced an increase in mean cortisol levels, which rose to 11.32 ± 4.57 mg/dL.

The test group demonstrated a significant reduction in serum cortisol levels from baseline to EOT (-3.1 ± 6.4) compared to placebo (+1.44 ± 6.6). This reflects a 34.8% improvement in psychological distress with decrease in serum cortisol level for test group versus 14.6% deterioration with increase in serum cortisol level for placebo group. The study found a significant difference in cortisol levels in the test group at an intragroup p-value of ≤0.01, indicating a higher central tendency of cortisol decrease compared to the placebo.

Table 13: Change in Cortisol level from baseline within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	9.88±4.81	-	-	-	-	-
	Visit 4	11.32±4.57	1.44±6.6	14.6	>0.05	-	-
Test (n=30)	Baseline	8.89±4.27	-	-	-	>0.05	-
	Visit 4	5.79±4.9	-3.1±6.4	-34.87	≤0.01	<0.0001	<0.01

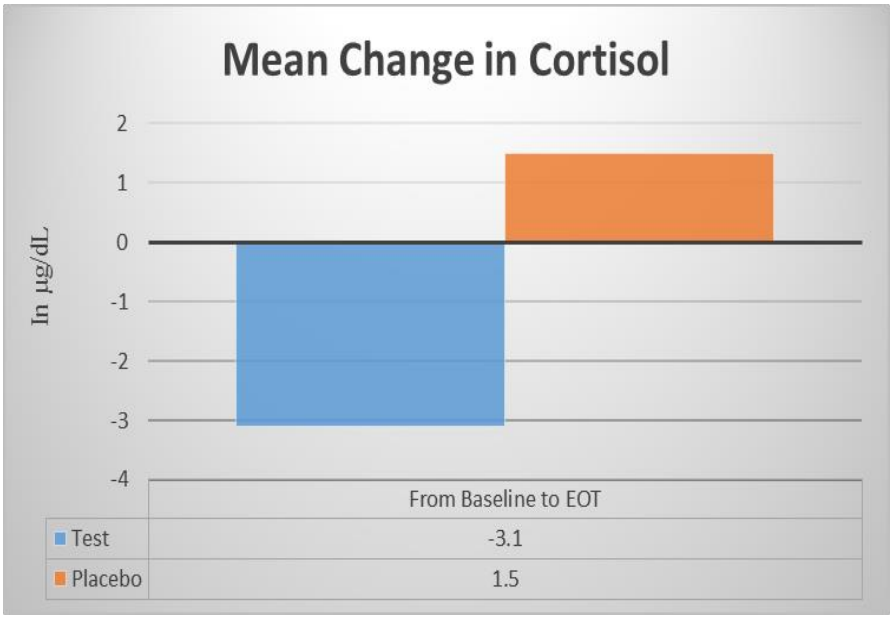

Figure 12: Mean Improvement in Cortisol levels from baseline to EOT.

ii.) WHOQOL-BREF Scores

The WHOQOL is an internationally recognized framework for assessing quality of life (QoL). It was developed by the World Health Organization (WHO) to provide a comprehensive tool for evaluating an individual's well-being across several domains. The WHOQOL aims to assess both physical health and mental well-being, considering the cultural, social, and environmental factors.[19]

At baseline, the mean WHOQoL-BREF scores were recorded as 71.4 ± 10.33 for the test group (N=30) and 78.65 ± 7.98 for the placebo group (N=31). By the endpoint of the study (EOT), the test group demonstrated a notable improvement in their mean WHOQoL-BREF score, which increased to 83.7 ± 9.44. In stark contrast, the placebo group experienced a deterioration in their mean WHOQoL-BREF score, which declined to 76 ± 8.75.

The test group demonstrated a significant mean increase in WHOQOL-BREF Scores from baseline to EOT (12.3 ± 2.55) compared to placebo (-2.65 ± 2.16). This reflects a 17.2% improvement in psychological distress for test group versus 3.3% deterioration in the placebo group. The study reveals that Ocitum™ significantly improved participants' perceived quality of life, while placebo led to a decline, with an intragroup p-value of <0.001, indicating a highly significant difference.

Table 14: Change in WHOQOL-BREF Score from baseline within each group: Test and Placebo.

Group	Evaluation	Mean ± SD	Mean Change± SD	Mean change from baseline (%)	p, Intragroup comparison, (vs. baseline)	p, Intergroup comparison (vs. placebo)	p, Intergroup comparison of change from baseline (vs. placebo)
Placebo (n=31)	Baseline	78.65±7.98	-	-	-	-	-
	Visit 4	76±8.75	-2.65±2.16	-3.37	0.22	-	-
Test (n=30)	Baseline	71.4±10.33	-	-	-	<0.01	-
	Visit 4	83.7±9.44	12.3±2.55	17.23	<0.001	<0.0001	<0.0001*

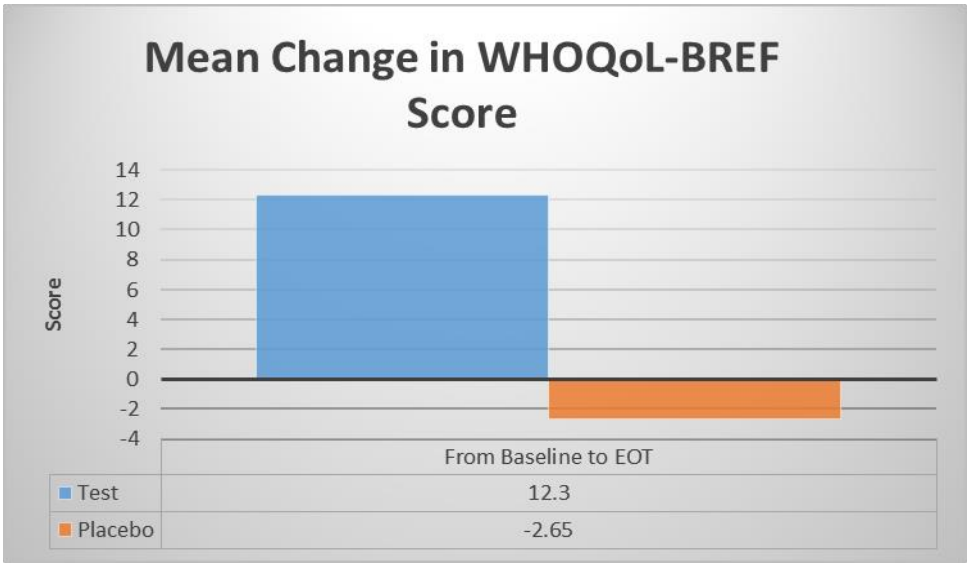

Figure 13: Mean Improvement in WHOQoL-BREF Score from baseline to EOT.

WHOQoL-BREF Scale

Please read the question, assess your feelings, for the last two weeks, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Fairly Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the **last two weeks**.

		Not at all	A Small amount	A Moderate amount	A great deal	An Extreme amount
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5	How much do you enjoy life?	1	2	3	4	5
6	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
7	How well are you able to concentrate?	1	2	3	4	5
8	How safe do you feel in your daily life?	1	2	3	4	5
9	How healthy is your physical environment?	1	2	3	4	5

		Not at all	Slightly	Somewhat	To a great extent	Completely
10	Do you have enough energy for everyday life?	1	2	3	4	5
11	Are you able to accept your bodily appearance?	1	2	3	4	5
12	Have you enough money to meet your needs?	1	2	3	4	5
13	How available to you is the information you need in your daily life?	1	2	3	4	5
14	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Not at all	Slightly	Moderately	Very	Extremely
15	How well are you able to get around physically?	1	2	3	4	5

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the **last two weeks**.

		Very Dissatisfied	Fairly Dissatisfied	Neither Satified nor Dissatisfied	Satisfied	Very satisfied
16	How satisfied are you with your sleep?	1	2	3	4	5
17	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18	How satisfied are you with your capacity for work	1	2	3	4	5
19	How satisfied are you with yourself?	1	2	3	4	5
20	How satisfied are you with your personal relationships?	1	2	3	4	5
21	How satisfied are you with your sex life?	1	2	3	4	5
22	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24	How satisfied are you with your access to health services?	1	2	3	4	5
25	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Infrequently	Sometimes	Frequently	Always
26	How often do you have negative feelings such as blue mood, despair, anxiety or depression?	1	2	3	4	5

III.) Safety Results

Similar exposure and treatment compliance observed in both treatment arms.

1. The study found no significant changes in CBC parameters between the test and placebo groups, indicating no negative impact of the test product on these parameters.
2. A significant difference in serum creatinine levels was found between the Ocitum™ treatment group and the placebo, with a p-value of ≤0.01, suggesting a meaningful difference.
3. A significant difference in ALT levels was observed between the Ocitum™ treatment group and the placebo group, with a p-value of <0.05, indicating a notable difference.
4. No adverse events were reported in either group.
5. No dose adjustments were necessary for any investigational product (IP) treatment.
   All treatments were well tolerated, with no adverse events, supporting the overall long-term safety of the test product.

4.) DISCUSSION

The study evaluated the safety and efficacy of the " Ocitum™ Capsule" test product in healthy volunteers over an 11-week period. It assessed changes in depression, stress, and anxiety, and their associated biomarkers. Subjective measures included the DASS-21 scale for psychological distress, the Stanford Sleep Scale to assess sleepiness, Various Sleep Parameters to determine overall sleep quality, and the World Health Organization Quality of Life score. Laboratory tests were conducted to assess the product's impact on physical and mental health, immunity, and vital organ function. The study meticulously recorded adverse events to evaluate the safety profile of "Ocitum™ Capsule" in the treatment population, providing a comprehensive understanding of its therapeutic effects and safety considerations.

A study involving 64 participants was conducted in India, with 61 randomized into treatment arms: 30 to the Ocitum™ Capsule group and 31 to the placebo group. All participants completed the study, contributing to the safety population. This study aimed to assess the efficacy and safety of Ocitum™ Capsule, evaluating several primary and secondary efficacy endpoints, as well as safety parameters, over the 11-week duration from baseline.

The primary efficacy endpoints of the study focused on assessing improvements across multiple domains, specifically within the Depression, Anxiety, and Stress Scale (DASS-21), the Stanford Sleep Scale (SSS), and a range of sleep parameters from baseline measurements. The DASS-21 is a well-validated psychometric test meant to quantify emotional states related to depression, anxiety, and stress, providing a full overview of an individual's psychological well-being.[7] On the other hand, the Stanford Sleep Scale assesses the effects of different conditions, including sleep loss, on alertness and cognitive functioning. This scale provides a sophisticated knowledge of how perceived sleepiness connects with cognitive performance.[8] In addition, various sleep parameters were investigated, including sleep efficiency, which is the ratio of total time spent asleep to total time spent in bed, and sleep latency, which is the time it takes to transition from full wakefulness to sleep. Together, these endpoints provide a comprehensive picture of the interventions' effects on emotional and sleep-related outcomes.[20]

The study analyzed assessment reports from 30 test group subjects to identify trends in DASS-21, SSS, and sleep parameters. Results were quantified as improvement percentages. A comparable procedure was applied to the placebo group for comparative analysis. Here's a clearer and more professionally worded version of your sentence: The results demonstrated positive therapeutic outcomes, with the test group showing significant improvements in DASS-21 and SSS scores compared to the placebo group ($p < 0.001$). Additionally, various sleep parameters showed significant improvements in the test group relative to the placebo group.

In a clinical study evaluating the effects of "Ocitum™ Capsule" and placebo on several health metrics, secondary efficacy endpoints (serum cortisol, and WHOQoL-BREF scores) and safety endpoints (complete blood count parameters, serum creatinine, ALT) were assessed at baseline and Visit 4. These studies demonstrate that " Ocitum™ Capsule" had a positive impact on serum cortisol, WHOQoL-BREF scores, serum creatinine and ALT, indicating potential advantages for both physical and psychological health. These results indicate that the test product significantly improves stress hormone management, general quality of life, kidney function and liver enzyme levels. The data support the hypothesis that " Ocitum™ Capsule" may provide therapeutic benefits above placebo in managing these health parameters. The decrease in cortisol levels suggests that " Ocitum™ Capsule" may modulate the hypothalamic-pituitary-adrenal (HPA) axis, mitigating the physiological stress response. Enhanced WHOQOL-BREF scores indicate broader benefits, encompassing physical, psychological, and social well-being.

The study found no significant changes in CBC parameters between the test and placebo groups, indicating no adverse impact of the test product. Significant differences were observed in serum creatinine and ALT levels between the treatment group and placebo, with p-values of ≤0.01 and <0.05, respectively. No adverse events were reported, and no dose adjustments were necessary for any investigational product.

Tulsi (Holy Basil), a natural remedy with anti-stress and anxiolytic properties, has been observed to improve depression, anxiety, stress, and sleep parameters due to its bioactive compounds, including Ursolic acid,

Eugenol, and Rosmarinic acid, which interact with stress pathways and neurotransmitter systems.[21]

The study emphasizes the clinical importance of Tulsi (Holy Basil) in reducing stress pathways' effects. This clinical report indicates Ocitum™, a standardized extract from *Ocimum tenuiflorum* leaves, has been found to improve sleep quality, reduce anxiety, and alleviate stress, which are essential for mental health, productivity, and overall quality of life. The extract is standardized for a total ursolic acid content of not less than 5%, in accordance with United States Pharmacopeia (USP) guidelines, and contains key active compounds like eugenol (no less than 5%) and rosmarinic acid (no less than 0.5%). The extraction process uses ethanol, ensuring safety and acceptability. Ocitum's comprehensive traceability from cultivation to final extract supports its efficacy in promoting mood balance and immune health.[21]

Ursolic acid, a pentacyclic triterpenoid, has been found to have anti-inflammatory and neuroprotective properties, influencing stress modulation by inhibiting pro-inflammatory cytokines and enhancing neuroprotective factors, potentially reducing the negative effects of chronic stress on neuronal health.[21] Rosmarinic acid, a polyphenolic compound with antioxidant and anti-inflammatory properties, reduces oxidative stress and inflammation, potentially supporting the body's resilience to stress by scavenging free radicals and modulating inflammatory pathways.[22] Eugenol, a phenolic compound, has anxiolytic properties by modulating neurotransmitter systems like GABA, potentially calming the central nervous system and alleviating anxiety and stress-related symptoms.[23] Overall, the synergistic effects of these bioactive compounds in Ocitum™ Capsule underscore its potential as a therapeutic agent for stress management and neuroprotection.

The study found a clinically relevant trend towards improvement in certain parameters, despite weaker statistical significance, suggesting potential benefits due to potential variability in response or sample size. The placebo group's positive outcomes may be influenced by confounding factors like participants' conscious diet and lifestyle modifications, which complicates attributing observed effects solely to the intervention. The test group showed significant improvements in biomarkers and quality of life assessments, but lifestyle factors should be considered when interpreting clinical trial results.

This trial's strengths include its randomized, double-blind design and robust statistical analysis. However, limitations include the small sample size and single-centre study design.

5.) CONCLUSION

The Test product, showed highly significant improvement in DASS-21 Score, SSS. Sleep Latency, Sleep Duration, Sleep Frequency on work days and free days, Sleep dept and WHOQOL-BREF Score and also showed statistical significance improvement in serum ALT level, serum Creatinine level, Serum Cortisol Level. Overall, no significant changes were observed in the CBC parameters for either the test or placebo groups. All parameters remained stable throughout the study, indicating that the test product had no adverse effect on the CBC parameters. The test product did not adversely affect haematological or kidney function or liver function, confirming its safety profile for vital organs like the pancreas, heart, and kidneys.

This suggests it may be beneficial for individuals with mild to moderate depression, stress, and anxiety, but further clinical evaluation is needed to validate this hypothesis.

The test product demonstrated exceptional safety during 57 days of administration, with no adverse events reported. This suggests that regular consumption over an extended period may improve stress, depression, anxiety, and sleep quality. These findings suggest promising implications for the long-term safety and improvement in overall psychological health associated with the usage of Ocitum™ Capsules.

Ocitum™ demonstrated statistically significant efficacy in improving depression, anxiety, stress, and sleep quality while maintaining an excellent safety profile. These findings support its potential as a natural, effective intervention for managing stress-related disorders. Further research is warranted to explore its long-term benefits and broader applications.

6.) REFERENCES

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