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POST MARKETING EFFICACY AND SAFETY STUDY OF BOHECO'S SLEEP (FULL SPECTRUM HEMP LEAF EXTRACT BASED AYURVEDIC PROPRIETARY MEDICINE) FOR THE MANAGEMENT OF SLEEP AND STRESS

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ABSTRACT

Introduction: Cannabis leaf-based medicines have seen a recent jump to be considered for various ailments including management of sleep and stress. **Materials and Methods:** 50 patients who had been on the full spectrum cannabis leaf based Ayurvedic proprietary medicine manufactured by Bombay Hemp Company, Mumbai, India for sleep and stress were selected for the study. Separate structured multiple-choice questionnaires were used for the assessment of the safety and efficacy of BOHECO's SLEEP manufactured by BOHECO. **Results:** In terms of the overall effect of sleep management, out of 50 responses in this study, 8 patients (16%) reported complete relief, 37 patients (74%) reported marked improvement, 3 patients (6%) showed moderate improvement and 2 patients (4%) reported mild improvement. In the overall effect of stress management, out of 50 participants, 49 responses were received, in which 8 patients (16.3%) reported complete relief, 31 patients (63.3%) reported marked improvement, 7 patients (14.2%) showed moderate improvement and 3 patients (6.1%) reported mild improvement. **Conclusion:** Full Spectrum Hemp leaf extract-based Ayurvedic proprietary medicine sold under the brand name BOHECO SLEEP used for the management of sleep and stress has been observed to be effective and safe for long-term use.

Keywords: *SLEEP, Safety, Post-Marketing, Stress, Chronic, Hemp Leaf*

INTRODUCTION

The prevalence of mental stress has also alarmingly increased in the post-pandemic era as the vastness of physical, mental, emotional, and social damage caused due to the pandemic COVID-19 is being studied by scholars. Mental stress refers to the psychological experience of distress and anxiety due to the perception of events in the internal and external environment of a person.[5] The involvement of the CNS, along with the amygdala and endocrine mechanisms, contributes to the feeling of mental stress.[6] The last two years witnessed the emerging developments in the legalisation of cannabis-based medications in many countries, including India, following the conceptualization of the endocannabinoid system.[7] Cannabis has a long history of medicinal uses due to its main components that are found in higher concentrations, identified as Δ9 tetrahydrocannabinol (Δ9-THC) and cannabidiol (CBD). Among them, Δ9 tetrahydrocannabinol (Δ9-THC) is identified as the psychoactive component, which is a potential treatment for Pain and Sleep, and cannabidiol (CBD) has been identified as a potential treatment for pain and mental stress.[8,9] Having proven its efficacy, safety remains the next most important concern, as the indications of these medicines sometimes demand long-term usage. Bombay Hemp Company Pvt Ltd (BOHECO) developed sublingual Cannabis leaf-based Ayurvedic proprietary medicines under the brand name of BOHECO SLEEP for the management of sleep and stress having Cannabidiol (CBD) and Δ9 tetrahydrocannabinol (Δ9-THC) as the main component.

Aims and Objectives:

To study the post-marketing efficacy and safety of full-spectrum hemp leaf extract-based Ayurvedic proprietary medicines used for the management of stress and sleep and sold under the brand name BOHECO SLEEP.

Materials and Methods:

A retrospective observational analysis through a patient survey with the help of a questionnaire was carried out. We developed questionnaires to assess the broad characteristics of patients using Hemp/Cannabis Leaf based medicines. The survey consisted of structured questions answered by either yes/no or multiple-choice responses specifically designed for patients taking stress medications separately. Questions were focused on several key domains, like perceived efficacy, and adverse drug reactions, along with side benefits.

Data Source: Patient database created by doctor's team at CareAyu. The further patient consent form was collected before starting the survey.

Sample size: 50 patients who had been on a prescription-based product, BOHECO SLEEP (Full Spectrum Hemp leaf extract based Ayurvedic proprietary medicine) manufactured by BOHECO were selected irrespective of age, gender, or the underlying care.

Selection criteria: The cases were selected irrespective of Age, Gender, Acute or Chronic conditions, and Underlying causes. All the patients with no physical or mental disability to fill up the questionnaire were selected. The only inclusion criteria considered was the past or current use of BOHECO SLEEP for Sleep and Stress management.

Assessment criteria: A purely subjective grading with a 10-point Likert scale derived from the commonly used Numeric rating Scale of 1-10, was done for the assessment of the efficacy of Sleep and Stress, and no other subjective or objective clinical parameters were used.

Voluntary reporting of adverse events was encouraged during the survey where the patient was given a list of common side effects to select from and a column for reporting any unidentified adverse reactions. The probable side effects included in the questionnaire for reporting were dry mouth, somnolence, euphoria, sedation, and anxiety.

Table 1: 10-point scale for grading of SLEEP and STRESS

Improvement	Grading
No Improvement	0
Mild Improvement	1-3
Moderate Improvement	4-6
Marked Improvement	7-9
Complete Remission	10

Statistical Analysis:

A statistical analysis of the data collected from the 50 patients using BOHECO SLEEP was done using the Chi-Square test to look for relevant correlations by using Phi and Cramer's V to understand the strength of association. To maintain the sample size, an average value was counted as a response while tabulating the data.

DISCUSSION

Age Group: The medicine is mostly used by patients having their aged 21-30 (38%) followed by the age group of 31-40 (28%). 16% of the patients were between 41-50 and 12% of patients were in the age group of 51-60 and the rest were above 60. *Time administration of Medicine*: Out of 50 participants, 46 patients amounting to 92% preferred using the medicine at night whereas only 1 patient (2%) preferred day and 3 patients (6%) preferred both day and night. *No of drops prescribed*: Out of 50 participants, about 28 patients (56%) were taking 3-6 drops daily, 17 patients (34%) were taking 2-3 drops and 2 (4%) patients were taking only one drop, 2 patients (4%) were taking 8-10 drops and one patient (2%) was taking 12 drops.

Stress relief in chronic conditions: Out of 50 participants, 23 patients (46%) strongly agreed that the medicine provides relief in chronic cases, 23 patients (46%) agreed that the medicine provides relief in chronic cases, 3 patients (6%) disagreed that the medicine provides relief in chronic cases and only 1 patient (2%) strongly disagreed that the medicine provides relief in chronic cases. *Stress relief grading:* Out of 49 responses, 8 patients (16.3%) reported Complete relief from symptoms of stress, 31 patients (63.3%) reported marked improvement from symptoms of stress, 7 patients (14.2%) got Moderate Improvement and 3 patients (6.1%) reported mild improvement from symptoms of stress.

Sleep relief grading: Out of 50 responses, 8 patients (16%) reported Complete relief from sleep disorders, 37 patients (74%) reported marked improvement, 3 patients (6%) got Moderate Improvement and 2 patients (4%) reported mild improvement. *Anxiety grading:* Out of 35 patients with anxiety, 2 patients (5.71%) reported complete remission, 23 patients (65.71%) reported marked improvement, 7 patients (20%) reported Moderate improvement, and 3 patients (6%) reported mild improvement. *Panic Attack grading:* Out of 11 patients with Panic attacks 2 patients (18.2%) reported complete remission of symptoms, 5 patients (45.45%) reported marked improvement and 2 patients (18.2%) reported moderate improvement 2 patients (18.2%) reported mild improvement. *Reduction in frequency of getting stressed:* Out of 49 responses received, 43 patients (87.8%) reported a reduction in the frequency of getting stressed. Whereas 6 patients (12.2%) reported no reduction in the frequency of getting stressed. *Reduction in frequency of getting anxiety:* Out of 36 responses received 31 patients (86.1%) of patients reported a reduction in the frequency of the anxiety. Whereas 5 patients (13.9%) reported no reduction in the frequency of getting anxiety. *Reduction in frequency of panic attacks:* Out of 11 responses received, 8 patients (72.7%) of patients reported a reduction in the frequency of the panic attack. Whereas 3 patients (27.3%) reported no reduction in the frequency of getting panic attacks. *Enhances mood:*

Out of 50 responses received, 31 patients (62%) strongly agreed that the medicine enhances mood, 15 patients (30%) agreed that the medicine enhances mood and only 4 patients (8%) disagreed that the medicine enhances mood. *Aids restful sleep:* Out of 50 responses received, 40 patients (80%) strongly agreed that the medicine aids restful sleep, 6 patients (12%) agreed that the medicine aids restful sleep and only 4 patients (8%) disagreed that the medicines aid restful sleep. *Promotes relaxation:* Out of 50 responses received, 37 patients (74%) strongly agreed that the medicine promotes relaxation, 9 patients (18%) agreed that the medicine promotes relaxation and only 4 patients (8%) disagreed that the medicine promotes relaxation. *Soothes anxiety:* Out of 35 responses received, 20 patients (57.14%) strongly agreed that the medicine soothes anxiety, 13 patients (37.14%) agreed that the medicine soothes anxiety and only 2 patients (5.71%) disagreed that the medicine soothes anxiety. *Wakeup refreshed:* Out of 49 responses, 42 patients (85.71%) reported that they woke up refreshed with no difficulty after having the medicines at night in prescribed doses; only 7 patients (14.3%) disagreed that they woke up refreshed after having the medicine at night in prescribed doses. *Reduce the times of waking up at night:* 44 patients (88%) reported a reduction in the number of times waking up at night whereas only 6 patients (12 %) reported no reduction in the number of waking up at night. *Helps in getting deep sleep:* 45 patients (90%) of the patients reported getting deep sleep whereas 5 patients (10 %) reported no change from their normal sleep pattern.

Side effects observed: Out of 50 patients, 8 patients (16%) reported that the medicine has side effects whereas 42 patients (84%) reported no side effects or adverse reactions during the course of medicine. Out of the 8 responses the most common side effect observed was dry mouth in 5 patients and Somnolence in 5 patients

Table 2: Rare and bizarre adverse reactions reported

Side effects	No of patients
Dry throat	1
Constipation	1
Headache	1
Disturbed sleep	1

Cannabinoids present within the medicines such as Cannabidiol (CBD) have broad therapeutic properties across a range of neuropsychiatric disorders, stemming from diverse central nervous system actions.[12,13] There are studies toward a calming effect of CBD in the central nervous system.[14] The conducted survey on patients taking the medicine for stress and sleep disorders reveals that this medicine is also effective in the management of stress and is safe for long-term administration. 92% of the study population agreed that the medicine facilitates stress relief and 90% of the patients reported marked improvement in their sleep. Out of 49 responses, with 8 patients reporting complete relief from symptoms of stress, 31 patients reported marked improvement, 7 patients reported moderate improvement and 3 patients reporting mild improvement, BOHECO SLEEP for stress and sleep management are evidently efficacious. Its efficacy in managing disturbed sleep and other stress-related disorders, such as anxiety and panic attacks, is also indicative of the medicine's effect on the central nervous system. In addition to that, 87.8% of the study population reported that the frequency of getting stressed has been reduced, and of the 35 patients who had anxiety, 86.1% reported a reduction in the frequency of feeling anxious for no reason, and of the 11 patients having panic attacks, 72.7% reported a reduction in the frequency of getting panic attacks. Side effects reported were dry mouth and somnolence in 5 patients each, with no serious complications and no requirement for any medical intervention for its management.

CONCLUSION

Full Spectrum Hemp leaf extract-based Ayurvedic proprietary medicine sold under the brand name BOHECO SLEEP, used for the management of sleep and stress has been observed to be effective and safe for long-term use. It is observed to have reduced pain with no serious adverse reactions at prescribed doses.

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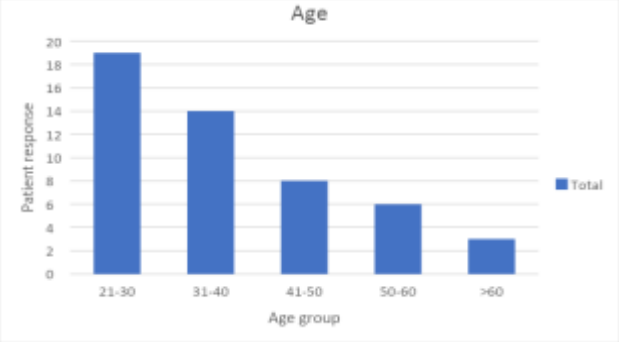
Fig. 1



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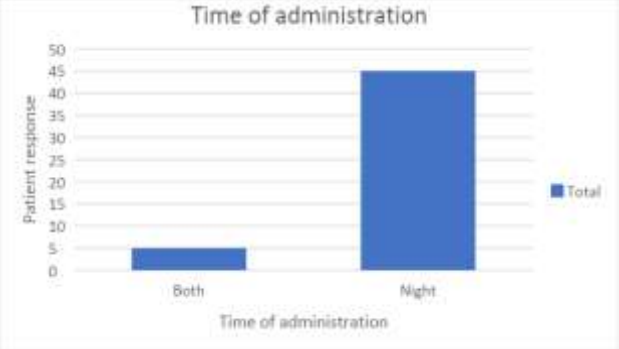

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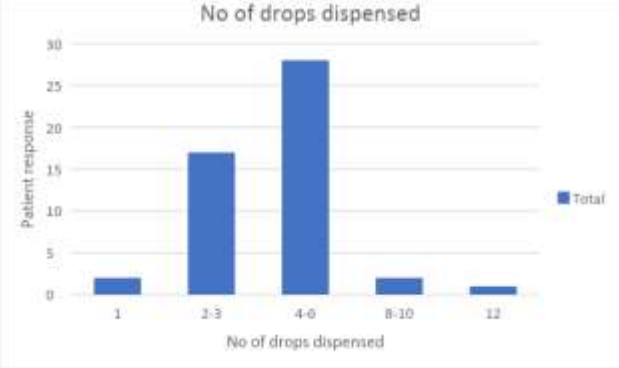

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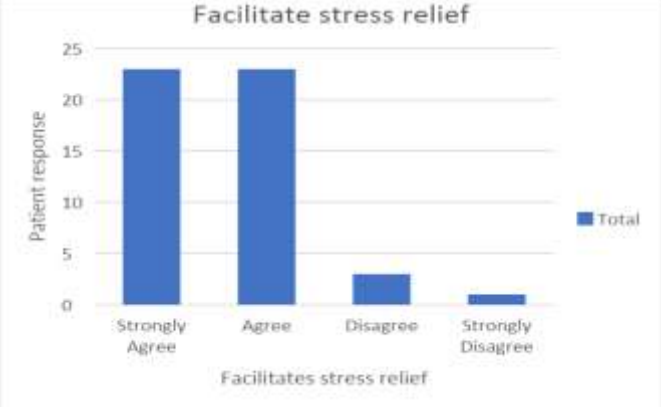

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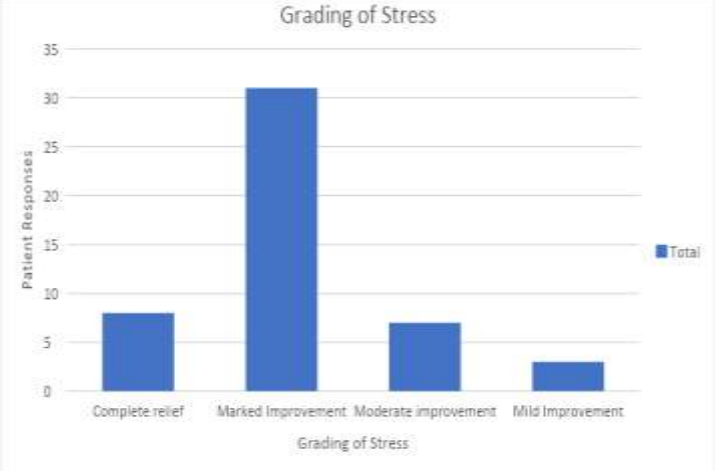

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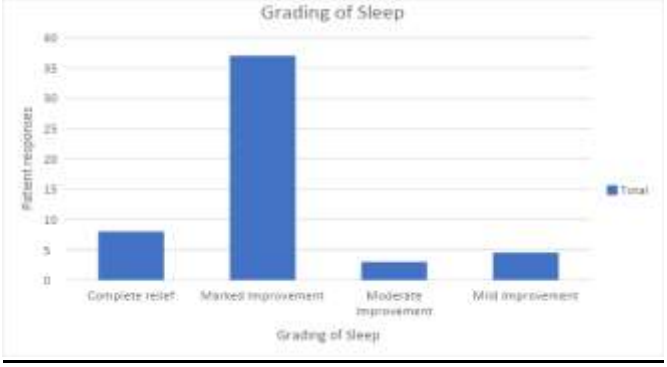

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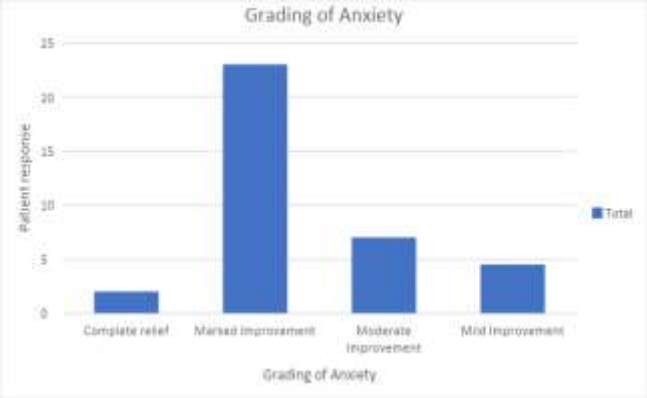

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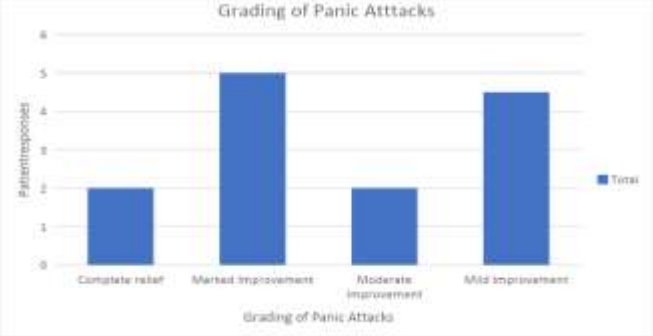

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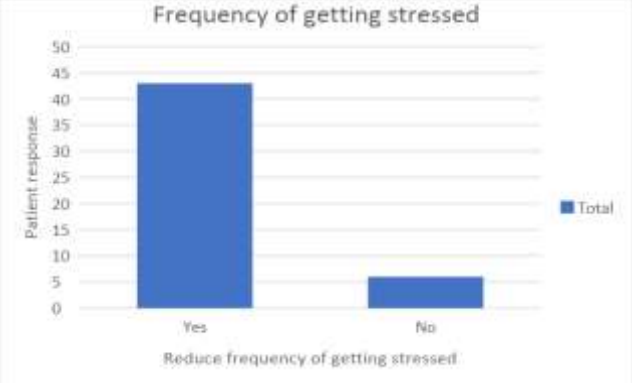

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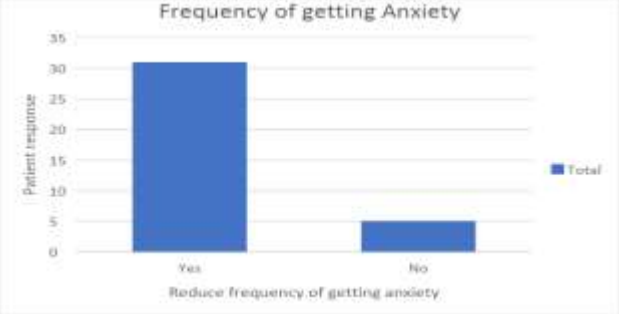

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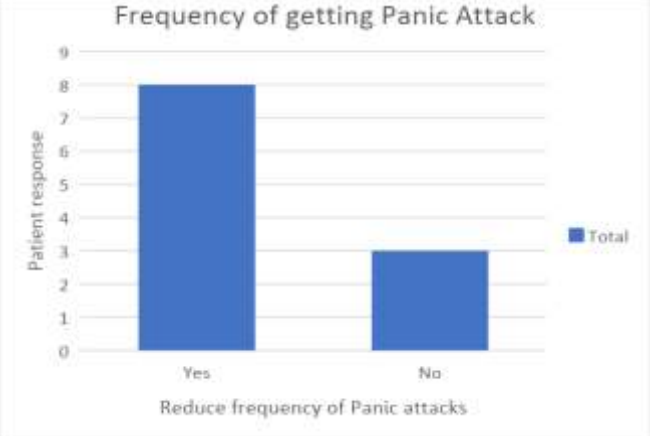

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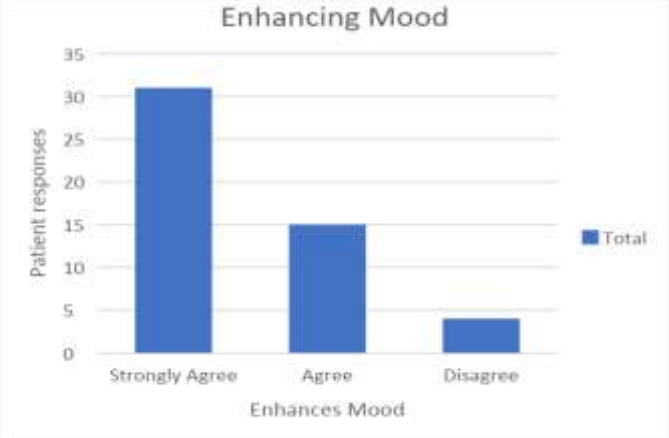

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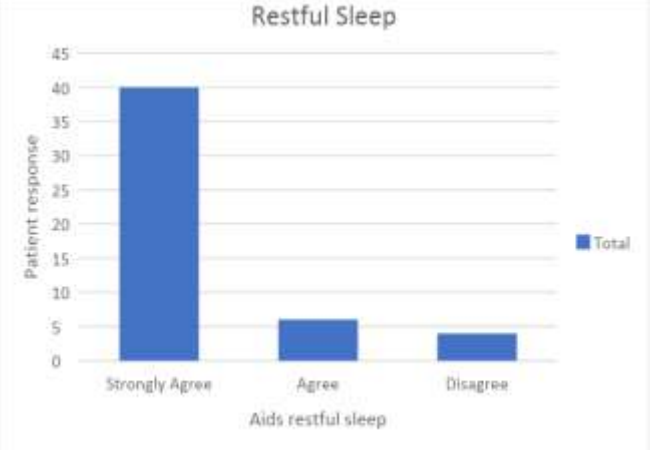

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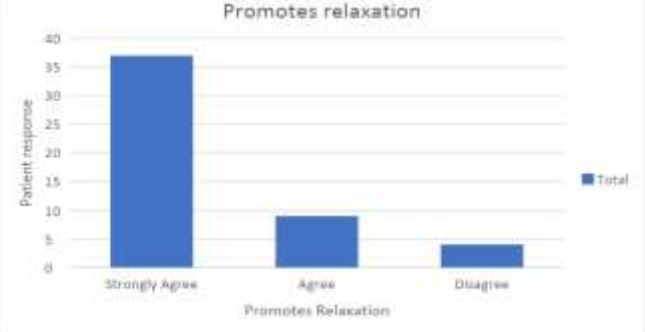

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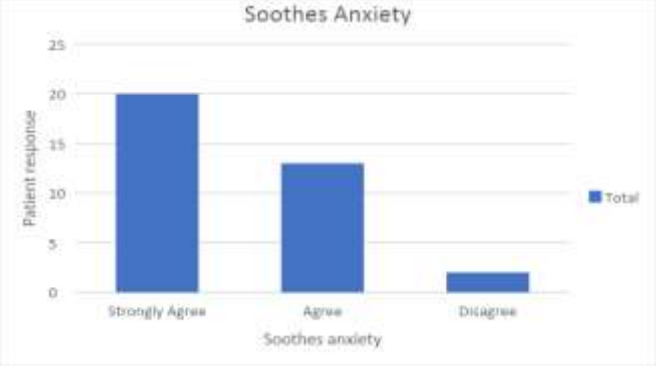

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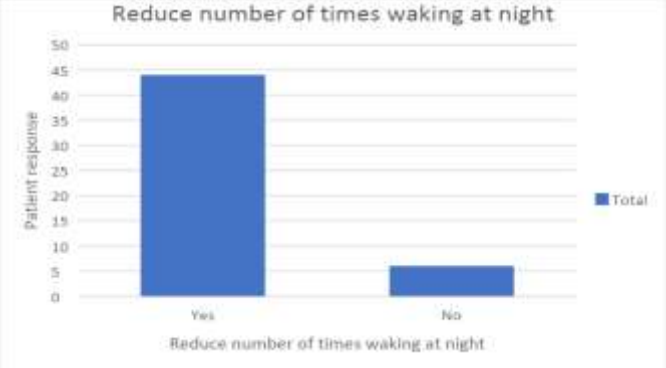
Fig. 17



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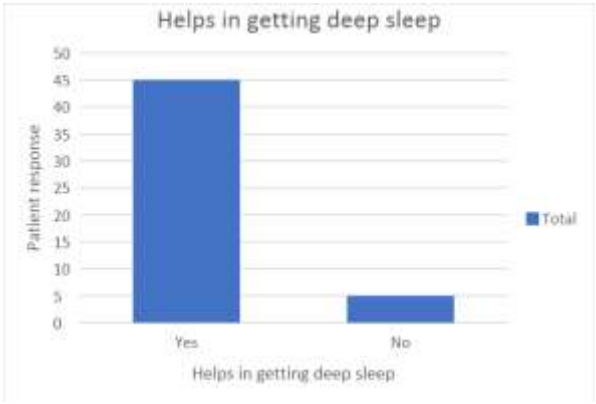
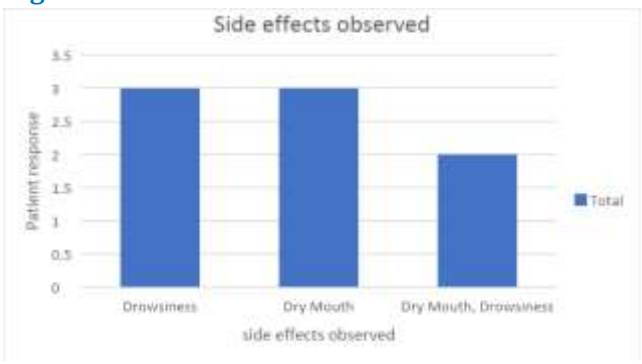
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