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A Pilot Study to Evaluate the Effectiveness of *Dalk* (Massage) with *Roghan Labub-E-Saba* in the Control of Insomnia Disorder

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ABSTRACT

Background: This pilot study was undertaken to evaluate the effectiveness of *Dalk* (massage) with *Roghan Labub-e-Saba* (a local Unani formulation) in the control of Insomnia Disorder.

Methods: This Pilot study was done in the months of March and April of the year 2019. A before and after interventional study was done in which total 6 patients of Insomnia Disorder were selected, 3 patients were selected from the OPD of Majeedia Unani Hospital, Jamia Hamdard, New Delhi, India and 3 patients were selected from the community of South Delhi, India. Patients were selected on the basis of subjective parameters and objective parameters of Insomnia Disorder as mentioned in DSM- V. The Patients were provided *Dalk* (Massage) with *Roghan Labub- e- Saba* on forehead and temporal region for 15 minutes daily for two weeks. The assessment was done before and after the intervention on the basis of standard methods of scoring specified for insomnia scales i.e. Athens Insomnia Scale and Pittsburgh Sleep Quality Index.

Results: Out of total 6 participants, 4 were male and 2 were female. The mean age of the participants was 30.67 years. All the participants showed significant improvement. . Massage with *Roghan Labub-e-Saba* was found effective in reducing insomnia and it was found statistically significant (0.0040* and 0.0003*).

Conclusions: *Dalk* (massage) therapy is the safe and good alternative modality of conventional sedative hypnotic medications in the control of Insomnia Disorder. It has also not been noted any adverse and addictive effects, therefore it can be used in long-term therapeutics.

Keywords: Insomnia Disorder, Sehar, Dalk, Massage, Ilaj Bil Tadbeer & DSM-V.

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INTRODUCTION:

The condition of insomnia is called *Sehar* or *Bekhaabi* in Unani medicine. According to Unani Medicine, there are six essential factors (*Asbabe-Sitta Zarooriyah*) which are necessary at its optimum to maintain the healthy life. Fifth one of them is *Naum wa Yaqza* which means 'sleep and awakening'. Imbalance between these two conditions causes the disease state known as *Sehar* (Insomnia). Normal sleep is because of *ratoobat wa baroodat* i.e. wetness and coldness in our brain and if there is derailment of balance in sleep and wakefulness, it implies the predominance of *yaboosat wa hararat* i.e. dryness and hotness widespread in the brain. [1]

Insomnia is defined not simply by total sleep time but rather by difficulty in initiation and maintenance of sleep, poor quality of sleep and an insufficient duration of sleep, such that functioning in the awake state is impaired. Insomnia is the most prevalent sleep complaint, affects up to 10 to 45% of the adult population and is second only to the complaint of pain as a reason to seek medical attention.[2]

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) describes it as Insomnia Disorder under the heading of Sleep-Wake Disorders.

In DSM- V, Insomnia disorder is characterized by poor sleep quality or quantity, including having difficulty falling asleep, remaining asleep, or returning to sleep after awakening and insomnia is experienced at least 3 nights per week for at least 3 months.[3,4]

DSM-V- Diagnostic Criteria for Insomnia Disorder:

Criteria A-H must be met

A. A predominant complaint of dissatisfaction with sleep quantity or quality, associated with one or more of the following symptoms:

1. Difficulty initiating sleep (in children, this may manifest as difficulty initiating sleep without a caregiver intervention).

2. Difficulty maintaining sleep, characterized by frequent awakenings or problems returning to sleep after awakenings (in children, this may manifest as difficulty returning to sleep without a caregiver intervention).

3. Early morning awakening with inability to return to sleep.

B. The sleep disturbance causes clinically significant distress or impairment in social, occupational, educational, academic, behavioral or other important areas of functioning.

C. The sleep difficulty occurs at least three nights per week.

D. The sleep difficulty is present for at least three months.

E. The sleep difficulty occurs despite adequate opportunity for sleep.

F. The insomnia is not better explained by and does not occur exclusively during the course of another sleep disorder (e.g., narcolepsy, a breathing related sleep disorder, a circadian rhythm sleep-wake disorder, parasomnias).

G. The insomnia is not attributable to the psychological effects of a substance (e.g., drug abuse or a medication.)

H. Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia. [3,4,5]

***Dalk* (Massage)**

Dalk (Massage) is one of the most important part of Unani System of Medicine and widely practiced method of *Ilaj Bil Tadbeer*. *Dalk* (Massage) evoke some physiological and psychological effects which serve to achieve the therapeutic, restorative or preventive goals.

"*Dalk* (Massage) is a type of *Riyazat* (exercise) practiced with palm and digits by a skilled person on the body surface in varieties of ways to dissolve the morbid matters and to assist the quwa (faculties) for therapeutic and preventive purpose." (Dr. Mohd. Zulkifle, Dr.Abdul Haseeb Ansari & Md Tanwir Alam).[6,7]

Dalk e Layyin Mo'atadil is a type of massage which is composite in nature, and done lightly or softly for the moderate duration. [8]

Roghan Labub- e –Saba: *Roghan Labub- e -Saba* is an effective Unani remedy. It is the composition of *Maghaz- e- Akhrot (Juglans regia), Maghaz- e- Badam shirin (Prunus amygdalus), Maghaz-- e Tukhm- e- Kahu (Lactuca sativa), Maghaz-- e Tukhm -e- khashkhash (Papaver somniferum), Maghaz- e- Tukhm e kaddu shirin (Cucurbita maxima), Maghaz- e- pista (Pistacia vera), Maghaz- e- Tukhm- e Tarbuz (Citrulus vulgare)* and *Kunjad safaid Muqasshar* (*Sesamum indicum)* in equal amount. It strengthens the brain and act as *murattib,* thus removes the dryness of brain. It is used in the management of insomnia. In National Formulary of Unani Medicine *Roghan Labub e Saba* is indicated for topical use and its therapeutic dose is Q. S. (quantum sufficit) means sufficient quantity.[9,10]

Need of the study: The role of the *Dalk* (massage) therapy in the management of insomnia is well documented in the classical Unani medicine literature but it needs scientific validation.

Objectives of the study:

To evaluate the effectiveness of *Dalk-e-Laiyyin Mo'atadil* (massage done softly in moderate durations) with *Roghan Labub-e-Saba* in the control of Insomnia Disorder.

MATERIAL AND METHODS

Sample Size:

On the basis of previous intervention study done on insomnia, it is found that relief percentage is 50% in intervention group and 39% in non- intervention group. [11] Assuming 5% level of significance and 80% of power, the sample size is calculated by

$$n = \frac{\left(Z_{\alpha/2} + Z_{\beta}\right)^2 [p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2}$$

Where,

n= sample size

p_1= expected sample proportion of one group

p_2= expected sample proportion of another group

Z_{β}= Corresponds to power (0.84= 80% power)

$Z_{\alpha/2}$= Corresponds to two-tailed significance level (1.96 for α=0.05)

Sample Size = 53

Sample size for the main study is 53. Sample size for the Pilot study should be 10% of the sample size of main study which is calculated 5.3. So, we have taken the sample size for the pilot study (n) = 6

So the **Sample size for pilot study (n) = 6**

Source of data: In this study total 6 patients of Insomnia Disorder were selected, 3 patients were selected from the OPD of Majeedia Unani Hospital, Jamia Hamdard, New Delhi, India, and 3 patients were selected from the community of South Delhi, India.

Subjective parameters:

1. An inability to fall sleep
2. An inability to continue / maintain sleep
3. Restless wakening after night sleep
4. Sleepiness or tiredness during the day

Objective parameters:

1. Pittsburgh Sleep Quality Index (PSQI)
2. Athens Insomnia Scale (AIS)

Inclusion criteria:

Patients with

1. Age between 18 to 60 years.
2. Males, Females and Trans-genders.
3. Patients complaining of insomnia who fulfill the diagnostic criteria of Insomnia Disorder of DSM –V.

Exclusion criteria:

1. Patients not fulfilling the diagnostic criteria of Insomnia Disorder of DSM-V.
2. Acute illness, fevers or painful conditions.
3. Known patients of Obstructive sleep apnea syndrome, Central Sleep-Apnea Syndrome, Narcolepsy, Breathing related sleep disorder, Circadian rhythm sleep-wake disorder, Parasomnia.
4. Known cases of Restless Leg Syndrome, Periodic Limb Movement Disorder.
5. Alcohol or drug abuse with in past six months.
6. Pregnant and Lactating Women.
7. Patients with drug abuse and medication.
8. Known patients of Asthma.
9. Known Patients of Migraine or Headache.
10. Known Drug users of Glucocorticoids.
11. Known cases of Parkinson, Chorea, Epilepsy and Dementia.
12. Known patients of skin diseases like Eczema, Scabies and Psoriasis.
13. Known cases of Chronic Obstructive Pulmonary disease.
14. Known patients of mental diseases.
15. Known patients of Cardiac disease.
16. Any other specific disease.
17. Participation in another study or previous participation in similar study.

Withdrawal criteria:

1. If the subject not willing to continue.

2. Any acute systemic illness during the therapy.

3. Failure to follow the study protocol.

Study type: Intervention type

Study design: Before and after experimental study.

Assessment Tools: Assessment was done before and after the intervention by the following Insomnia scales:

1. Sleep Quality Index (Pittsburgh) **-** The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in the adult. It differentiates "poor" from "good" sleep by the measurement of seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the last month. The client self-rates these seven areas of sleep. Scoring of answers is based on a 0 to 3 scale, where 3 reflects the negative extreme on the Likert Scale. A global sum of "5" or greater is the indicator of "poor" sleep. Pittsburgh Sleep Quality Index has internal consistency and a reliability coefficient (Cronbach's alpha) of 0.83. [12,13]

2. Athens Sleep Index- The scale assesses the severity of insomnia using diagnostic criteria set forth by the International Classification of Diseases (ICD-10). The eight-item questionnaire evaluates sleep onset, night and early-morning waking, sleep time, sleep quality, frequency and duration of complaints, distress caused by the experience of insomnia, and interference with daily functioning. The scale has been validated in patients with insomnia and with control participants aged 18–79 years. It has internal consistency ranges from 0.87 to 0.89 and a test-retest reliability of 0.88 – 0.89. Respondents use Likert-type scales to show how several sleep difficulties have affected them during the past month. Scores ranges from 0 (meaning that the item in question has not been a problem) to 3 (indicating more acute sleep difficulties). A cutoff score of 6 or more, is considered as a case of Insomnia. [14,15]

Intervention Tool: The intervention was *Dalk e Layyin Mo'atadil* with "*Roghan Labub e Saba"* done with the quantity sufficient (Q.S.) (Approximately 5ml to 7ml) on forehead and temporal region on the screened patients of Insomnia Disorder.

Duration of Study:

This Pilot study was done in the month of March and April of 2019.

Duration of Intervention:

2 Weeks

Duration of *Dalk* sittings:

15 Minutes

Follow Ups/ Sittings: Total sittings = 14

Follow up – On 15th day

Ethical clearance was obtained from the Jamia Hamdard Institutional Ethics Committee (JHIEC) on dated 14 March 2019. Informed written Consent was taken from the subjects in Hindi / English languages before starting the study.

Statistical Analysis: Comparison of data before and after intervention was done with paired-t test. Graph Pad in Stat software was used for the statistical analysis.

RESULTS:

In total 6 subjects, 4 were males and 2 were females. The Mean age of the subjects was 30.7 years. No adverse effects due to this therapy noted. The effect of massage with *Roghan Labub-e-Saba* when evaluated with Pittsburgh Sleep Quality index and Athens Insomnia scale is as follows.

Effect on the Pittsburgh Sleep Quality Index (PSQI): Significant improvement of sleep was seen when evaluated with the help of Pittsburgh Sleep Quality Index (PSQI) on the 15th day just after the completion of 14 days treatment.

As, it can be seen in Table 1 and Table 2 **,** the mean baseline score for the PSQI was 13.33 with the S. D. of +_4.32. Following the two weeks intervention, the post-treatment mean score for the PSQI was 4.33 with S. D. of +_1.03. The Comparison of data was done with paired-t test and the two

tailed P value equals 0.0040. This difference is very statistically significant. (Table: 1 and Table: 2)

The mean of the difference of the before and after intervention score is 9.00. 95% confidence interval of this difference: from 4.40 to 13.60.

Intermediate values used in calculation: t=5.0312, d.f. = 5, Standard error of difference=1.789.

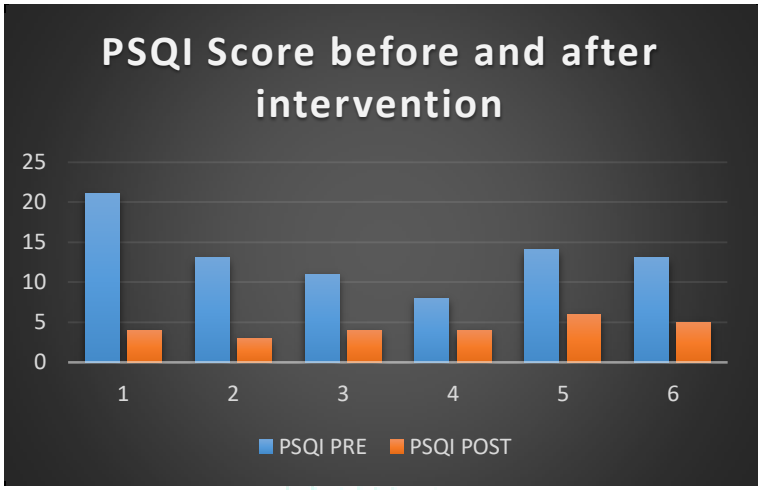

Figure 1: PSQI Score before and after the intervention

Table: 1

n= 6

S. No.	PSQI SCORE(PRE)	PSQI SCORE (POST)
1.	21	4
2.	13	3
3.	11	4
4.	8	4
5.	14	6
6.	13	5
	Mean= 13.33 S. D.= +_4.32	**Mean= 4.33 S. D.= +_1.03**

Table: 2

	PRE	POST	% of Relief	P Value
Mean	13.33	4.33	67.51%	0.0040*
S.D.	+_4.32	+_1.03		*significant

(Table: 1 and Table: 2- Analysis of Effect on PSQI Score before and after the intervention)

Effect on Athens Insomnia Scale (AIS): Significant improvement of sleep was seen when evaluated with the help of Athens Insomnia Scale (AIS) on the 15th day just after the completion of 14 days treatment.

As, it can be seen in Table 3 and Table 4 and, the mean baseline score for the AIS was 10.5 with the S. D. of +_2.16. Following the two-week intervention, the post-treatment, the mean score for the AIS was 5.16 with S. D. of +_0.98. The Comparison of data was done with paired-t test and the two tailed P value equals 0.0003. This difference is extremely statistically significant. (Table: 3 and Table: 4)

The mean of the difference of the before and after intervention score is 5.33. 95% confidence interval of this difference: from 3.75 to 6.91

Intermediate values used in calculation: t=8.6772, d.f .= 5, Standard error of difference=0.615

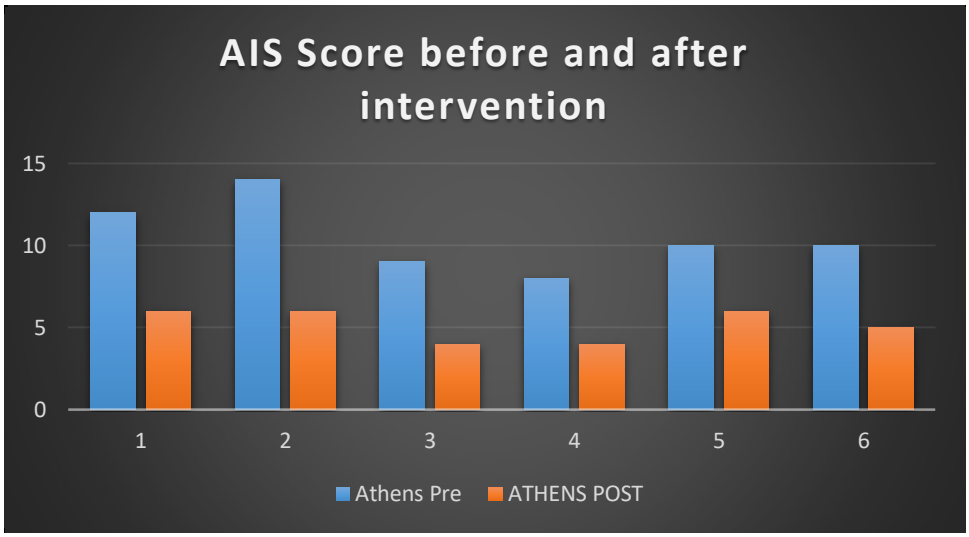

Figure 2: AIS Score before and after intervention

Table: 3
n= 6

S. No.	ATHENS SCORE(PRE)	ATHENS SCORE (POST)
1.	12	6
2.	14	6
3.	9	4
4.	8	4
5.	10	6
6.	10	5
	Mean=10.5 S.D.=+_2.16	**Mean=5.16 S.D.=+_0.98**

Table: 4

	PRE	POST	% of Relief	P Value
Mean	10.5	5.16	50.85%	0.0003*
S. D.	+_2.16	+_0.98		*significant

(Table: 3 and Table: 4 - Analysis of Effect on Athens Score after the intervention)

DISCUSSION:

This pilot study was an intervention type before and after experimental trial. The aim was to evaluate the effectiveness of massage with *Roghan Labub e Saba* in patients with Insomnia Disorder.

The results of the present trial showed that massage is effective compared with pretreatment baseline. Improvements of sleep quality, total sleep time, sleep efficiency, daytime functioning were achieved.

67.51% improvement of sleep was seen when evaluated with the help of Pittsburgh Sleep Quality Index (PSQI) on the 15th day just after the completion of 14 days treatment. Similarly 50.85% of relief was seen when assessment was done with Athens Insomnia Scale on the 15th day just after the completion of 14 days treatment.

In a Multi-central controlled study on three-part massage therapy for treatment of insomnia of deficiency of both the heart and spleen done in the China in 2006.One hundred and sixty-six subjects were randomly divided into a test group (n = 84) and a control group (n = 82). The test group were treated by the three-part massage therapy, and the control group by oral Administration of Guipi Pills, 8 pills each time, thrice daily. The treatment was given for 15 consecutive days and then the therapeutic effects were observed. [16]

Sixty-seven cases were cured, 11 markedly effective, 3 effective, and 3 ineffective in the test group, and the corresponding figures were 10, 21, 29 and 22 in the control group with significant difference between the two groups (P< 0.001). The test group was superior to the control group in improvement when evaluated by Pittsburgh Sleep Quality Index (PSQI), Sleepless Anxiety Scale (SAS) and Sleepless Depression Scale (SDS) (P < 0.001). They concluded that there was a significant improvement in 96% of the cases, similar to the trend observed in this study. [16]

In another pilot study done in Brazil in 2011 to evaluate the effect of massage in postmenopausal women with insomnia. In that study, they selected seven postmenopausal women with insomnia: difficulty in falling sleep or insomnia symptoms for at least three times a week (mean age +_ SD: 56.28 +_ 1.97(SD), range between 50 to 65 years, mean body-mass index (BMI) , 30 kg/m2). These volunteers were submitted to sixteen one-hour sessions of massage twice weekly and evaluated on psychological and physiological parameters. The Sleep Diary showed that all of the participants of the study fell asleep more rapidly, presented a

gradual improvement in quality of sleep and awoke feeling better. This study showed that therapeutic massage decreased the severity of subjective sleep disturbance related to menopause. [17]

CONCLUSION:

Results from this pilot study suggest that *Dalk e Layyin Mo'atadil* with *Roghan Labub e Saba* is a safe and effective regimen in the control of Insomnia Disorder. Two weeks treatment done on small sample size significantly improved the quality and quantity of the sleep of the patients of Insomnia Disorder. Future studies should be conducted in larger samples size, the result will be more promising. *Dalk* (massage) therapy is the safe and good alternative modality of conventional sedative hypnotic medications in the control of Insomnia Disorder. It has also not been noted any adverse and addictive effects, therefore it can be used in long-term therapeutics.

One limitation of the present study is the limited number of subjects as well as the absence of a control group. Nevertheless, these preliminary results indicate that massage can be a safe, effective and non- addictive alternative in treating the patients of Insomnia Disorder.

COMPLIANCE WITH ETHICAL STANDARDS:

Declaration of Interest:

No potential conflicts of interest were reported by the authors.

Funding:

This study received no funding.

Ethical approval:

This article does not contain any studies with animal performed by any of the authors.

This article contains study with human participants.

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Jamia Hamdard Institutional Ethics Committee (JHIEC) (meeting held at 1530 hours, on March 14, 2019) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed written consent in English and Hindi languages was obtained from all individual participants included in the study.

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