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UTILIZATION OF UNANI REGIMENAL THERAPY FOR THE MANAGEMENT OF INSOMNIA: A RAPID SCOPING REVIEW

Meraj Meraj ^{1*}, Abdul Rehman M.I ², Naseem Ahmad Khan ³, Sadique Husain ⁴ & Noushiba Khan ⁵

¹ PG Scholar, Dept. of 'Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital AYUSH Campus, Nehru Nagar Kolar Bypass Road, Behind MANIT, Bhopal - 462003 (M.P.) India.

² Assistant Professor, Dept. of 'Ilāj bi'l Tadbīr (Regimenal Therapy), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital Bhopal, India.

³ Assistant Professor, Dept. of Munafeul Aza (Physiology), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital Bhopal, India.

⁴ Assistant Professor, Dept. of Ilmul Advia (Unani Pharmacology), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital Bhopal, India.

⁵ PG Scholar, Dept. of Tahaffuzi Wa Samaji Tibb (Preventive & Social Medicine), Hakim Syed Ziaul Hasan Government (Autonomous) Unani Medical College & Hospital Bhopal, India.

Article History	Abstract
<p>Received on: 20-05-2024 Revised on: 28-05-2024 Accepted on: 04-06-2024</p>	<p>Objective: To review existing clinical trials in humans having <i>Unani Regimenal Therapy</i> for the management of insomnia.</p> <p>Data sources: A systematic review was conducted using PubMed, Google Scholar, and Google from January 2010 to March 2024.</p> <p>Study selection: Keywords like "Insomnia, <i>Sehar</i>, <i>Sahar</i>, <i>Bekhawbi</i>" and "<i>Ilaj Bil Tadbeer</i>, Unani Medicine, Greco-Arab Medicine" were used in the search strategy. Only studies in English were selected. Two reviewers independently screened the studies, and conflicts were resolved by consensus. Studies that do not list the <i>Unani Regimenal Therapy</i> were excluded.</p> <p>Data extraction: A total of 22 articles were identified, and 7 were included in the final analysis. The following data were extracted: author, year of publication, intervention, outcome measures, and result.</p> <p>Data synthesis: The results of the present review indicate that the implication of <i>Unani Regimenal Therapy</i> is beneficial in the management of insomnia.</p> <p>Conclusion: Insomnia, resembling <i>Sahar</i> in <i>Unani Medicine</i>, is typically treated with drugs in conventional medicine, often with adverse effects. However, the reviewed studies reveal the efficacy and safety of <i>Unani Regimenal Therapy</i> in alleviating insomnia symptoms without adverse effects. Early intervention with this therapy yields better outcomes, but more clinical trials are needed due to limited research. While some <i>Regimenal Therapy</i> modalities like <i>Naṭūl</i> (Irrigation Therapy), <i>Tadhīn</i> (Oiling), and <i>Dalk</i> (Therapeutic Massage) are explored, others remain unexplored. Overall, combining medicine with <i>Unani Regimenal Therapy</i> offers a promising approach to managing insomnia.</p> <p>Keywords: Insomnia; Unani System of Medicine; Sahar; Regimenal Therapy; Natul; Insomnia.</p>



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*Corresponding Author

Meraj Meraj

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currently a prevalent disease with the incidence varying globally between 10% and 60% [2,3,4,5]. Insomnia is described as *Sahar* or *Bekhawbi* in the Unani System of Medicine [6,7,8,9,10,11,12,13]. According to the Unani System of Medicine, health is attributed to the equilibrium of *Akhlāt* (body fluid) and *Asbāb Sitta Ḍarūriyya* (Six Essential Factors) such as *Hawā'* (Air), *Ma'kulāt-o-Mashrūbāt* (Foods and drinks), *Al-Ḥaraka wa'l Sukūn al-Badanī* (Bodily movement and Repose), *Al-Ḥaraka wa'l Sukūn al-Nafsānī* (Psychic movement and Repose), *Al-Nawm Wa'l Yaqza* (Sleep and Wakefulness) and *Al-Ihtibās wa'l Istifrāgh* (Retention and Evacuation)[14,15]. Among these six essential factors, sleep and wakefulness are

Introduction

Sleep, a vital element of human health and wellness, encompasses a multifaceted biological process. Insomnia, characterized by ongoing challenges in initiating, maintaining, or experiencing quality sleep despite adequate opportunity and circumstances to sleep, leads to daytime dysfunction [1]. It is

the fifth factor and the imbalance between them causes a disease which is known as *Sahar*. Insomnia is considered multifactorial in aetiology but primarily manifests as a result of the imbalance in the temperament of the brain (due to *Hārrarat* (Hotness) and *Yubūsat* (Dryness) temperament) and secondarily due to some other medical or mental illness [6]. There are three types of causes broadly classified: a). *Ikhtiyāri Asbāb* (voluntary causes)- These are voluntary and under our control [7,8,9]. b). *Asbāb 'Arḍiyya* (dependent causes)- These are temporary in origin and when removed or decreased sleep is restored [7,8,9]. c). *Asbāb Maraḍiyya* (disease causes)- These are caused because of diseases [7,8,9,10]. In Conventional Medicine, insomnia is treated with hypnotic and antidepressant drugs that have many side effects [16,17,18], while the Unani System of Medicine has a multidirectional approach to its management. Despite a long history of *Regimenaal Therapy (Ilāj bi'l Tadbīr)* use for the management of insomnia, only a few studies have been conducted.

The objective of this scoping review was to carry out a review seeking overall influential factors of using *Unani Regimenaal Therapy* for insomnia. This scoping review was conducted to quickly investigate any potential therapeutic benefits for insomnia when using *Unani Regimenaal Therapy* to inform the research and medical community.

Methods

Ethics and dissemination

The study reviewed published literature, and as no patient recruitment or personal data collection has occurred, no ethical approval is required.

Eligibility criteria

Types of participants

Trials in humans involving a treatment component of *Unani Regimenaal Therapy* as a remedy for insomnia were included.

Types of intervention and control

The reviewed studies included patients treated with *Unani Regimenaal Therapy* alone and also those treated with *Unani Regimenaal Therapy* with a combination of fewer Unani drugs.

For control groups, active control, placebo, or any type of studies comparing *Unani Regimenaal Therapy* were eligible. Studies that do not list the *Unani Regimenaal Therapy* were excluded.

Types of studies

Case studies, case series, pilot studies, and original clinical studies including randomized controlled clinical trials (RCTs), and nonrandomized controlled clinical trials (CCTs) were included.

Main Outcomes

For inclusion, studies had to assess at least one important outcome measure of insomnia i.e. Insomnia Severity Index (ISI), Insomnia Severity Questionnaire Index (ISQ Index), Pittsburgh Sleep Quality Index (PSQI), Athens Sleep Index (ASI), and Structured Insomnia Schedule (SIS).

Data sources and search strategy

The review data was gathered from several online resources, PubMed, Google Scholar, and Google. Keywords including "Insomnia, Sehar, Sahar, Bekhawbi" and "Ilaj bil tadbier, Unani Medicine, Greco-arab Medicine" were part of the online search strategy. Articles dated between January 2010 and March 2024 were chosen. Only studies in English were selected.

Data extraction and management

Two authors (N.A and N.K) independently extracted data on study design, intervention, outcome, and results using a previously developed data extraction form. After study selection, we extracted the following data: author, year of publication, intervention, outcome measures, and result.

Result

A total of 20 articles were screened and identified through a search of the database i.e. PubMed, Google Scholar, and Google. In addition, two articles were identified through sources other than core search, through references to the relevant article. A total of eight full-text articles were screened for eligibility. One full-text article was excluded because of not use a measure scale. A total of seven full-text articles were screened that met inclusion standards and have been decided for review. The final 7 articles were composed of 3 RCTs, 2 single-arm clinical studies, 1 case study, and 1 pilot study. Figure 1 further depicts the selection procedures of the studies. Author, year of publication, Internal medication, *Regimenaal Therapy*, scale used, and outcomes of studies are depicted in Table 1.

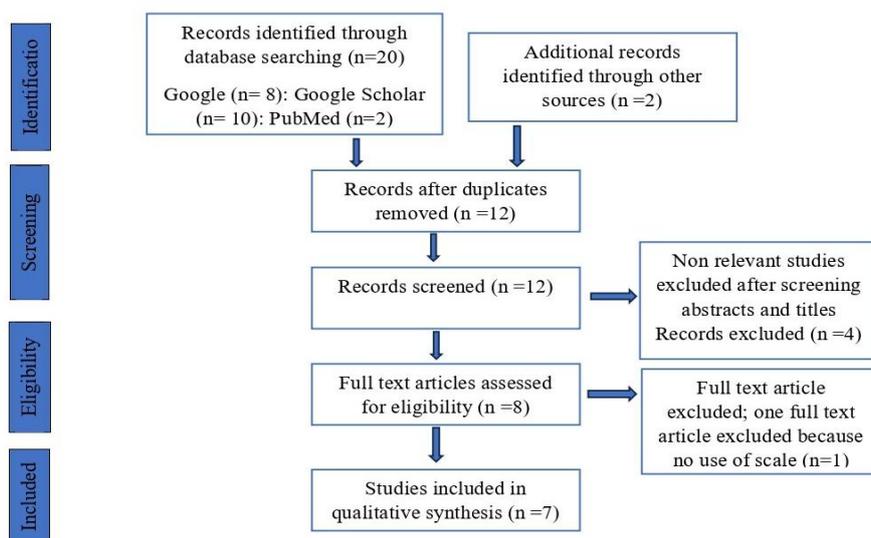


Figure 1: Flow diagram of the literature screening and selection process

Table 1: Screened Articles

Author	Year of publication	Internal Medication	Regimenal Therapy	Scale Used	Outcome
Muhib et al. [19]	2013		<i>Nutool</i> with <i>Roghan e Banafsha</i> and <i>Roghan e Gul</i>	Insomnia Severity Index (ISI)	<i>Nutool</i> therapy showed statistically significant improvement $p < 0.001$
Jahan et al. [24]	2014		<i>Nutool</i> with <i>Roghan e Banafsha</i> and <i>Roghan e Gul</i>	Structured Insomnia schedule (SIS)	<i>Nutool</i> therapy showed statistically significant improvement in all the parameters of SIS $p < 0.001$
Mohd Shamim Akhtar et al. [21]	2017	<i>Sofoof Kahu</i>	<i>Tadhin</i> (Oiling) with <i>Roghan Kaddu</i> over the scalp	Pittsburgh Sleep Quality Index (PSQI)	Oiling showed statistically significant ($p < 0.01$)
Mohammed Sheeraz et al. [25]	2018		<i>Nutool</i> with <i>Roghane Babuna</i>	Insomnia Severity Questionnaire Index (ISQ Index)	<i>Nutool</i> showed a significant improvement in objective parameters i.e. 60%
Samreen Khan et al. [22]	2019		<i>Nutool</i> with <i>Roghan-e-Banafsha</i>	Pittsburgh Sleep Quality Index (PSQI)	<i>Nutool</i> showed statistically significant ($p < 0.001$)
Saba Fatma et al. [23]	2019		<i>Dalk</i> (Massage) with <i>Roghan Labub- e- Saba</i>	Athens Insomnia Scale and Pittsburgh Sleep Quality Index (PSQI)	Massage with <i>Roghan Labub- e- Saba</i> was found effective in reducing insomnia and it was found statistically significant (0.0040 and 0.0003)
Parvez Khan et al. [20]	2023		<i>Tadhin</i> (Oiling) with <i>Raughan Kahu</i>	Insomnia Severity Index (ISI)	Oiling showed a significant reduction of 27.11% ($p < 0.0001$)

Discussion

Studies were reviewed, and statistically significant improvement in ISI score by $p < 0.001$ [19], 27.11% ($p < 0.0001$) [20], in PSQI $p < 0.01$ [21], $p < 0.001$ [22], $p < 0.0003$ [23], in SIS $p < 0.001$ [24], reduction in ISQ Index 60% [25] and statistically significant improvement in Athens Insomnia Scale $p < 0.0040$ [23] were observed. One study was identified as a case study [25], two as a single-arm clinical study [20,21], three as Randomized Controlled Clinical Trials (RCTs) [19,22,24], and one as a pilot study with 6 patients [23]. Placebo control was used in three RCTs [19,22,24]. One pilot Study used the Athens Insomnia Scale and Pittsburgh Sleep Quality Index (PSQI) both for outcome measures [23]. In one study internal medication was used [21] and Table 2 depicts the actions of drugs. All studies used *Regimenal Therapy (Ilāj bi'l Tadbīr)* in the management of insomnia. *Ilāj bi'l Tadbīr* or *Regimenal Therapy* is the modification in *Asbāb Sitta Ḍarūriyya* (Six Essential Factors). Almost all studies followed the treatment principle of *Sahar*. According to the line of management of *Sahar* patients suffering from it should be administered *Sa'ūt* (Nasal Drops), *Ḥammām* (Therapeutic bath/Turkish bath), *Riyāḍat* (Exercise), *'Tilā'* (Liniments), *Ḍimād* (Poultice), *Lakhlakha* (Inhalation of vapour arising from fragrant drugs), *Shamūm* (Inhalation), *Qaṭūr* (Drops), *Nashūq* (Liquid Snuf), and *Pāshoya* (Foot bath). *Naṭūl* (Irrigation Therapy), *Tadhīn* (Oiling), and *Dalk* (Therapeutic Massage) should also be used [26]. Here, various studies have included *Naṭūl* [19,22,24,25] as a therapeutic procedure for insomnia. *Naṭūl* is a classical and active therapy in Unani Regimens which is described as the pouring or dripping of medicated decoction or warm water on desired organs [27,28]. *Naṭūl* is effective in relieving chronic disease, pain, and various types of stiffness [29]. *Naṭūl* is useful as *mussakine alam* (analgesic), *mukhadir* (sedative), *muratib* (emollient), *mubarid* (cold), *munawim* (hypnotic), *muqawwie dimag* (brain tonic properties) [30], it is helpful in insomnia. Two studies were conducted on *Tadhīn* (Oiling) [20,21] (Applying oil over the part of the body) and found helpful in insomnia. Oiling therapy has certain limitations mainly that it is little known, and is not widely available. Oiling therapy can be used more widely and to greater effectiveness in the clinical to reduce various types, severities, and manifestations of insomnia without side effects that are associated with other pharmacological treatments. More research is needed to evaluate the clinical and economic implications of Oiling therapy and to determine the true potential of this reliable old *Regimenal Therapy* of the Unani system of medicine. *Dalk* (Therapeutic Massage) is defined as the affected region of the body that is rubbed with hands using medicated oil with a variety of techniques that result in physiological and psychological therapeutic effects on the body and in disease conditions [26,31]. Here, one pilot study used *Dalk* in the management of insomnia and showed significant improvement in Insomnia [23].

All studies showed statistically significant improvement in the management of insomnia. There are only a few published studies available in *Unani Regimenal Therapy* for the management of insomnia, there are no active control RCTs available on insomnia in Unani. There is a need to conduct

more clinical trials in *Unani Regimenal Therapy* for the management of insomnia.

Table 2: Mechanism of action of drugs used in studies

Drugs	Mechanism of action
<i>Roghan e Banafsha</i> [19,22,24]	<i>Musakkin</i> (Sedative) [32,33], <i>Murattib</i> (Humectant) [30]
<i>Roghan e Gul</i> [19,24]	<i>Mubarid</i> (Frigorific) [32]
<i>Roghan Kaddu</i> [21]	<i>Murattib</i> (Humectant), <i>Munawwim</i> (Hypnotic) [32]
<i>Roghane Babuna</i> [25]	<i>Musakkin-e-Alam</i> (Analgesic) [33]
<i>Roghan Labub-e-Saba</i> [23]	<i>Murattib</i> (Humectant) [32,33]
<i>Raughan Kahu</i> [20]	<i>Musakkin</i> (Sedative), <i>Murattib</i> (Humectant), <i>Munawwim</i> (Hypnotic) [32]
<i>Safoof Kahu</i> [21]	<i>Musakkin</i> (Sedative), <i>Murattib</i> (Humectant), <i>Munawwim</i> (Hypnotic) [21]

Limitation

This scoping review has several limitations. First, including studies in only English may have excluded articles published in other languages. Second, although the assessment included three databases, it is possible that some gray literature in other databases has not been included.

Conclusion

The disease of insomnia described in the conventional system of medicine resembles *Sahar* in Unani classical literature. In Conventional Medicine, insomnia is treated with hypnotic and antidepressant drugs that have many side effects. All the above studies have shown the effectiveness of Unani Regimenal management in relieving the signs and symptoms of insomnia. There is no adverse effect of internal medication as well as *Unani Regimenal Therapy* is reported in the above studies which depict the safety of management. Early intervention with *Unani Regimenal* management of insomnia can produce better outcomes. There are very less studies reported on insomnia available, so there is a need to conduct more clinical trials on insomnia. *Naṭūl* (Irrigation Therapy), *Tadhīn* (Oiling), and *Dalk* (Therapeutic Massage) *Unani Regimenal Therapy* are well explored in Insomnia, whereas *Sa'ūt* (Nasal Drops), *Ḥammām* (Therapeutic bath / Turkish bath), *Riyāḍat* (Exercise), *'Tilā'* (Liniments), *Ḍimād* (Poultice), *Lakhlakha* (Inhalation of vapour arising from fragrant drugs), *Shamūm* (Inhalation), *Qaṭūr* (Drops), *Nashūq* (Liquid Snuf), and *Pāshoya* (Foot bath) are still unexplored. It can be concluded that medicine along with the *Unani Regimenal Therapy* has a better effect on insomnia.

Author contributions

M. M and A. R.: Conceptualization, Validation, Visualization, Writing of original draft, Methodology; N. A and N. K: Resources, software, and data extraction; S. H: Supervision, writing- review, and final editing.

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Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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