

A clinical algorithm for diagnosis and treatment of insomnia in adults: an updated review

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Guidelines

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Abstract

Difficulty falling asleep and/or maintaining sleep are common complaints in patients visiting medical clinics. Insomnia can occur alone or in combination with other medical or psychiatric disorders. Diagnosis and management of insomnia at times are perplexing. This updated study review aimed at a clinical algorithm for diagnosis and treatment of insomnia in adults. We developed an easy-to-apply algorithm to diagnose and manage insomnia that can be used by general practitioners and non-sleep specialists. To this end, our team reviewed the previous studies to determine the prevalence, evaluation, and treatment of insomnia. We used the results to develop a clinical algorithm for diagnosing and managing insomnia. Insomnia occurs in a short (less than 3 months duration) or chronic form (≥ 3 months duration). Insomnia management includes both pharmacological and non-pharmacological interventions. There is ample research evidence for the impact of a variety of non-pharmacological treatments, but both types of treatments can be used for each patient. If there are any contradictions in the diagnosis process, therapists should use objective instruments, such as polysomnography, but they should not be in a hurry to use these instruments.

Introduction

Insomnia is one of the serious concerns related to community health.¹ Difficulty with sleep is also a common complaint in patients visiting medical clinics. These complaints may occur alone or in combination with other medical or psychiatric conditions.² An important issue is that insomnia can impose high direct and indirect economic burden on society.³ The costs of insomnia are high to the extent that some studies have referred to it as a public health crisis.⁴ The World Health Organization (WHO) has also addressed the financial burden and costs of treating insomnia. Thus, researchers have emphasized that insomnia is a financial and costly burden for care systems. These costs can occur directly, for example, through treatment costs, or are imposed indirectly by sick leave or early retirement.⁵ Insomnia also adversely affects the economy by reducing productivity in the workplace.⁶ The available evidence suggests that the financial burden of insomnia is comparable to the financial burden of other psychiatric disorders such as depression, anxiety, and substance use disorders.⁷ Therefore, it is essential to find a suitable model for the diagnosis and treatment of insomnia. Our primary goal is to propose an easy-to-apply clinical algorithm that can be used by nonspecialist practitioners to manage patients with insomnia. Accordingly, this study explores the causes of insomnia, identifies comorbid disorders, and determines the effective diagnosis and treatment methods. We developed an easy-to-apply algorithm to diagnose and manage insomnia that can be used by general practitioners and non-sleep specialists. To this end, our team reviewed previous studies to determine the prevalence, evaluation, and treatment of insomnia. We used the results to develop a clinical algorithm for diagnosing and managing insomnia.

Definition of insomnia and its symptoms

Insomnia is generally defined as the lack of sleep satisfaction, including dissatisfaction with both the quality and quantity of sleep.⁸ The American Academy of Sleep Medicine also defines insomnia as the subjective perception of difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity for sleep, resulting in a complaint of insomnia and/or some form of daytime impairment.⁹ Thus, insomnia is dissatisfaction with the duration and quality of sleep, which can lead to distress and disruption/reduction of a person's quality of life and performance. It should be noted that daytime dysfunction includes a wide range of symptoms, including problems with attention, concentration, and memory impairment, as well as fatigue, weakness, or loss of energy, workplace errors, car accidents, or any other form of social or occupational dysfunction, headache or gastrointestinal symptoms,

daytime drowsiness, and mood dysregulation, including anxiety, depression, and irritability.¹⁰ Some scholars have focused on inadequate sleep and even have claimed that this is a public health concern;¹¹ however, the term insomnia is not only related to sleep duration but also includes dissatisfaction with sleep and daily dysfunction due to insomnia.

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) specifies criteria for insomnia. The first criterion that relates to the patient's main complaint is dissatisfaction with the quantity or quality of sleep, along with symptoms such as difficulty starting sleep, difficulty maintaining sleep (frequent awakenings), and waking up early in the morning. The second criterion refers to daily functioning, showing a significant decline in social, occupational, educational, behavioral, and other functions. The third and fourth criteria deal with the duration of the problem. The problem should persist at least 3 nights a week and last for at least 3 months. The fifth criterion emphasizes that the sleep problem manifests itself despite having enough time to sleep. According to the sixth criterion, sleep problems should not be better explained by the presence of other sleep disorders. The seventh criterion specifies that insomnia is not due to the physiological effect of a substance such as the use of drugs or medication (ie, the acute or withdrawal effects of these substances are not the cause of the problem). The eighth criterion refers to ensuring that other mental and/or medical disorders are ruled out as better

explaining the symptoms of insomnia.¹² The International Classification of Sleep Disorders 3 (ICSD-3) specifies almost the same criteria for diagnosing insomnia.¹³ The symptoms of insomnia are divided into daytime and nighttime symptoms. The nighttime symptoms include sleep disturbances, environmental sensitivity, unsuccessful sleep attempts, presleep arousal, and frequent awakenings. The daytime symptoms include cognitive problems, drowsiness (sleepiness), and fatigue.

Insomnia occurs in a short (<3 months) or chronic form (≥ 3 months).¹⁴ If it lasts less than 3 months, it is called short-term insomnia, and if it lasts for at least 3 months, it is called chronic insomnia.¹⁵ Following existing theories and previous studies in the literature, a diagnostic algorithm was developed for insomnia, as shown in Figure 1. According to this algorithm and its diagnostic criteria presented in Table 1, the clinician must determine if the patient is suffering from primary insomnia or insomnia associated with medical and psychological conditions and substance abuse. In the latter case, the therapist should treat both comorbidity and insomnia. However, if the patient is suffering from primary insomnia, it should be specified if the duration of symptoms is less than 3 months or more. If the symptoms are present for less than 3 months, the patient is diagnosed with short-term insomnia. In such case, the causes of insomnia should be examined and treated accordingly. Moreover, if the symptoms of insomnia have lasted for more than 3 months, the patient is diagnosed with chronic insomnia.

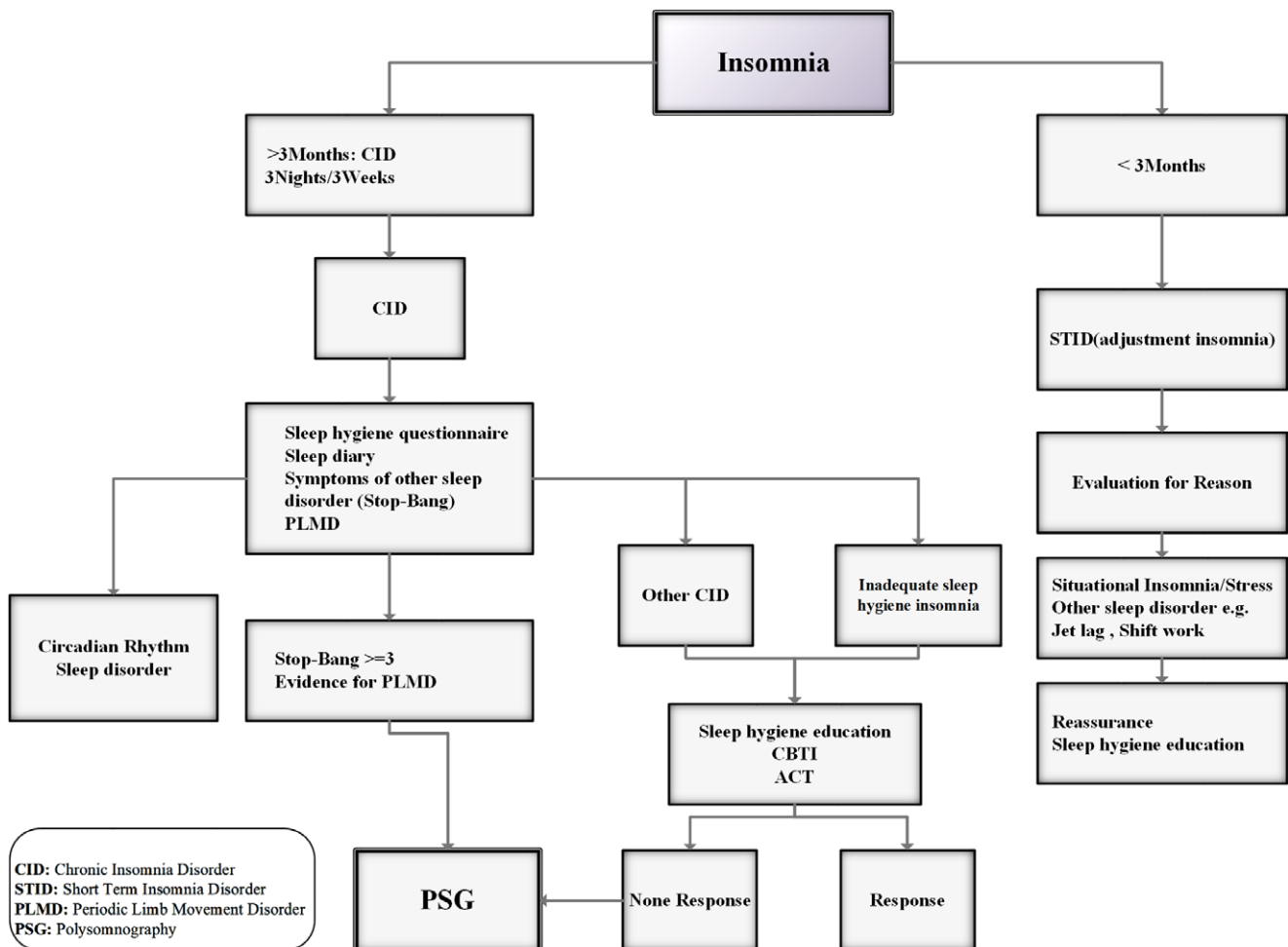


Figure 1. The diagnosis and treatment algorithm for insomnia.

Table 1. Criteria for Diagnosing Insomnia

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| <p>1. The person is mainly complaining about one or more of the following problems:</p> <ul style="list-style-type: none"> A. Difficulty in sleep onset: The person cannot fall asleep easily. B. Difficulty in maintaining sleep: The person may have frequent awakenings. C. The person wakes up earlier in the morning than the desired time. D. The person is not satisfied with the quality of their sleep, and does not feel relaxed and refreshed after waking up. |
| <p>2. Despite the good conditions and opportunities for sleeping, the person cannot fall asleep.</p> |
| <p>3. The person has problems during the day and may complain about one or more of the following problems:</p> <ul style="list-style-type: none"> A. The feeling of lethargy and tiredness B. Lack of concentration and memory impairment C. Occupational, academic, and social dysfunction D. Irritability and mood disorders E. Having drowsiness during the day F. Lack of energy or reduced motivation to do daily activities G. Increased work errors H. Having headaches and gastrointestinal symptoms I. Having ruminations and negative thoughts about sleeping |

It should be noted that there is no clear boundary for the diagnosis and classification of insomnia subtypes, and such subtypes have been not recognized in reliable guidelines, such as the DSM-5 and ICSD-3, but paying attention to them can have some benefits. One subtype of insomnia is termed psychophysiological insomnia and is characterized by presleep arousal, which can be physical, emotional, or cognitive. Before going to sleep while in bed, the affected person may perseverate over concerns about the consequences of not being able to sleep, or be overly sensitive to cues for night/bedtime, which can trigger a “hyperaroused” state upon getting into bed (even if they reported feeling “sleepy” just before).¹⁶ Another type of insomnia, called idiopathic insomnia, affects a person for life. Most patients with this type of insomnia suffer from sleep disorders since childhood, and such disorders do not improve or remit during their lifetime.¹⁷ The third type of insomnia is known as paradoxical insomnia. This type of insomnia is characterized by a discrepancy between subjective and objective evaluation of sleep, rendering diagnosis and treatment more challenging. Typically, polysomnographic (PSG) findings show significantly longer total sleep time than patients’ self-reported sleep (eg, on a sleep diary), and the difference between subjective sleep and PSG is typically greater than that seen in other subtypes of insomnia.¹⁸ Patients with this subtype often complain about insomnia, but objective studies (via PSG or actigraphic monitoring) do not support the patient’s complaint. Another type of insomnia is attributable primarily to engagement in multiple sleep-incompatible hygiene practices and it is commonly referred to as inadequate sleep hygiene. Example behaviors include irregular sleep patterns, use of alcohol, nicotine, caffeine in close proximity to bedtime, or engaging in sleep-irrelevant activities in the bedroom, all of which can negatively affect sleep at night.¹⁶ Inadequate sleep hygiene in majority of cases of insomnia coexist to some degree with the main insomnia diagnosis.

Prevalence of insomnia

Insomnia is a widespread disorder that affects both clinical and general populations. Its epidemiology varies across geographical regions around the world and changes over time. The prevalence of insomnia differs in various communities, ranging between 5% and 40%. An epidemiological review of insomnia shows that its prevalence rate has been reported to range from 5% to 40% in different communities.¹⁹ Another study reported its prevalence in European countries to be between 5.7% and 19%.⁵ The prevalence of

insomnia in adolescence has been reported to range from 4% to 39%.²⁰ This statistic is higher in older adults, with 57% of older adults affected by this disorder.²¹ It has been claimed that women are 1.5 times more likely than men to report insomnia.²² The results of a study showed that symptoms of insomnia are more common in women than men.²³

Furthermore, the reported prevalence has continuously grown over the last 2 decades. A study in 2002 reported a prevalence between 9% and 15%,²⁴ while one study in 2006 reported insomnia varying from 5% to 25%.²⁵ This figure was reported to be between 20% and 40% in 2009.²⁶ A study reported its prevalence in 2015 at 23.8%,²⁷ and a systematic review study in 2020 showed that the prevalence of insomnia is 37.9%.²⁸ However, a study confirmed a growing trend in the prevalence of insomnia.¹¹ In conclusion, insomnia is a common disorder that affects a large number of people in the community. Its prevalence may be even higher than reported due to underreporting. Epidemiological studies on insomnia are essential for understanding the burden of this disorder and developing effective interventions.

Causes of insomnia

Causes of insomnia can be divided into 3 categories: Predisposing factors, including demographic, biological, psychological, and social factors; precipitating factors, such as life stressors and medical conditions; and perpetuating factors, such as behavioral factors and cognitive changes.^{8,29} For example, genetic influences or personality traits such as neuroticism and maladaptive perfectionism are considered predisposing factors,⁵ and maladaptive coping strategies are perpetuating factors.⁵

One study listed the variables that can increase the risk for incident insomnia including having a previous period of insomnia, having a family history of insomnia, susceptibility to irritability, poorer general health, and physical pain.³⁰ The findings of another study highlighted the role of psychological factors, such as emotion regulation, in the development of insomnia.³¹ Furthermore, mental health symptoms, poor sleep quality, and obesity have been identified as risk factors for insomnia.²³ Alcohol consumption is also implicated as a cause of insomnia. Previous studies have confirmed the negative role of alcohol consumption in the development of insomnia.³² The results of another study identified factors such as health anxiety, dysfunctional coping strategies, job and income worries, and old age as risk factors for insomnia.³³ One of the other factors related to insomnia can be personality traits and temperaments.³⁴

A review of the literature shows that there is usually never one primary cause for insomnia, but often multiple physiological, cognitive, and behavioral factors contributing to the development of clinical symptoms. More recently, an increased attention has been paid to psychological and cognitive factors. Cognitive activities can include factors such as worry or anxiety, repetitive thoughts, and a generally “overactive” mind. Most cognitive theories have also emphasized these factors. In the last decade, several cognitive models have been developed to account for cognitive causes of insomnia. These models include Spielman and Glovinsky’s (1991) model,³⁵ Morin’s (1993) integrated model,³⁶ Perlis *et al.*’s (1997) cognitive model,³⁷ Lundh and Broman’s (2000) model,³⁸ Harvey’s (2002) model,³⁹ Espie’s (2007) model,⁴⁰ Vandeckerckhove and Cluydts’s (2010) model,⁴¹ and Ong, Ulmer, and Manber’s (2012) metacognitive model.⁴² A theme in all of these models is how cognitive factors contribute to “arousal” that produces insomnia, but each varies about specific factors or dynamics that can produce arousal. In summary, the factors that are hypothesized to lead to arousal in these cognitive models include maladaptive cognitions, dysfunctional attitudes, and beliefs about sleep, responses to poor sleep that produce irritability, stress, anxiety, emotional conflict, or rumination; and metacognitive beliefs, coping styles, and emotion regulation strategies. No comprehensive model has been yet proposed for the causes and symptoms of insomnia. Besides, there is no consensus among most theorists, researchers, and therapists about the proposed models and theories.

Consequences of insomnia

The negative effects of insomnia are numerous and can vary person-to-person. These negative effects are more significant in vulnerable groups such as those with mental and physical illness, older adults, and women during menopause.¹⁴ Insomnia has been identified as a risk factor for cardiovascular disease,^{10,43} and is generally associated with mental health problems, heart disease, type 2 diabetes, decreased daily functioning, and reduced quality of life.⁴⁴ Insomnia is linked with a number of mental health conditions.⁴⁵ Various studies have shown that insomnia is a risk factor for depression.^{46–49} The results of one meta-analysis reported that insomnia is significantly associated with an increased risk of depression,⁵⁰ although this outcome is not age-specific. Insomnia in children and adolescents is also associated with depression.^{20,51} Insomnia is also associated with anxiety,^{52,53} and may be correlated with increased stress levels.⁵⁴

The results of a study observed that insomnia increases the risk of physical, interpersonal, and psychological problems, and difficulty in daily activities.⁷ Insomnia has also been identified as a risk factor for self-injurious behaviors.⁵⁵ Research has shown that the symptoms of insomnia can predict self-injurious behaviors.^{56,57} In addition, some researchers have identified insomnia as a key risk factor for suicide,⁵⁸ with numerous studies reporting a relationship between insomnia and suicide.^{59–62} Insomnia can also be viewed as a major contributor to road accidents and car crashes.⁶³ Accordingly, the consequences of insomnia can be summarized into 3 categories: health-related consequences, functional consequences, and economic consequences. Health-related consequences include experiencing a wide range of physical, mental, and cognitive problems. Functional consequences include impaired individual and family functioning, while economic consequences include insomnia costs, treatment costs, and reduced productivity.

Evaluating to diagnose insomnia

The most important part of insomnia assessment is a careful analysis of the patient history and a complete physical examination.^{8,64,65} A complete clinical history is often needed to identify the factors influencing insomnia.¹ A general principle in both diagnosis and treatment of insomnia is that the person’s sleep history must be examined as the diagnosis and treatment depend on the person’s sleep history. An analysis of sleep history helps to identify any predisposing factors that increased risk for incident insomnia, precipitating factors that directly contribute to insomnia onset, and perpetuating factors—including maladaptive behaviors—related poor sleep—that maintain the insomnia chronically.⁶⁶ Thus, it has been claimed that insomnia should be diagnosed based on a longitudinal approach.⁶⁷ Useful information to support the diagnosis of insomnia can be obtained through clinical interviews and the completion of sleep diaries. If this information makes the diagnosis possible, there is no need for laboratory diagnostic tests, and these tests may even provide misleading information, since insomnia is diagnosed based on a pattern of sleep over an extended time, and no single night of evaluation. Some patients may insist on having polysomnography (PSG), which should be interpreted based on historical information and questionnaires, and the nature of the disorder must be explained to the patient.

Studies conducted using PSG have shown a large difference between the subjective experience of sleep and the results of PSG in insomnia patients, making the use of PSG a challenging tool for diagnosing insomnia. Hence, insomnia should be assessed and diagnosed based on clinical interviews, sleep questionnaires, and sleep diaries.⁶⁷

Self-report tools collect key and important information to inform the diagnosis and treatment of insomnia. Although other tools developed through scientific advances are used more extensively, self-report tools still play a key role in most studies on insomnia.⁶⁸ Instruments used for measuring insomnia symptoms can be divided into laboratory and non-laboratory instruments. The most important laboratory instrument is PSG. It is the most widely used method in sleep disorders centers. This test is the gold standard for diagnosing many sleep disorders. PSG plays a vital role in diagnosing sleep disorders, including insomnia. Interpreting PSG data are a challenging task that should be performed by professional staff. All the factors involved should be considered when interpreting the data, including the patient’s medical history and medications. Besides, the data from observing the patient’s in the clinic must be taken into account.⁶⁹

Non-laboratory tools can include expert interviews and questionnaires. Questionnaires are useful instruments for assessing insomnia. Questionnaires have several advantages; first, they do not require special facilities and contexts. They can be administered quickly and at a specific time and do not require a person with a specific profession.⁷⁰ There are several valid questionnaires used to measure insomnia. The Pittsburgh Sleep Quality Index is the most common tool for measuring sleep quality worldwide. It is a self-assessment tool that assesses sleep quality and sleep disturbances over the past month.⁷¹ This 19-item tool evaluates 7 components, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction.⁷¹ Another instrument to measure insomnia is the Insomnia Severity Index (ISI), which is a brief self-assessment tool³⁶ that measures the patient’s perception of insomnia. It also measures subjective symptoms and consequences of insomnia (the degree of anxiety or distress caused by its

problems).⁷² The content of the instrument corresponds to some extent with the diagnostic criteria of insomnia.⁷² The ISI assesses the severity of 7 components during the last month. The assessed dimensions are the severity of problems with delayed sleep onset, sleep maintenance, and early morning awakenings, as well as the level of satisfaction with the current sleep pattern, interference with daily functioning, others noticing impairment from the sleep problem, and worry or distress related to the sleep problem.⁷³ The third instrument used to measure insomnia is the Athens Insomnia Scale (AIS). It is a self-assessment tool designed to measure sleep problems according to the ICD-10 criteria. The instrument measures 8 sleep characteristics: sleep induction, awakenings at night, final awakening, sleep duration, sleep quality, and daytime symptoms: well-being, functioning, and sleepiness.⁷⁴ The first part of this scale assesses the quality of night sleep, and the second part evaluates daytime functioning.⁷⁰ Previously, ISI and AIS have been proposed as a part of comprehensive sleep assessment to evaluate patients with suspected insomnia disorder.⁶⁴

Another instrument that measures insomnia is the Bergen Insomnia Scale. This scale was developed based on existing clinical diagnosis criteria for insomnia. This 16-item instrument measures sleep initiation, sleep maintenance, early morning awakening, nonrestorative sleep, and experiencing dysfunction (loss of function) during the day.⁷⁵ This scale is a self-report tool that is completed in a short time.⁷⁵ The items are answered based on the number of nights that the person has experienced insomnia syndrome. Thus, the respondent is asked to rate their sleep quality on a scale of 0–7 based on their experience during the past month.

Another important tool to measure insomnia is the Sleep Diary. This 11-item instrument determines the respondent's sleep pattern during each night in a week. It measures bedtime and/or lights-out time, sleep latency, nighttime awakening time, final wake-up time, and rise time. The instrument also provides information about the quality of sleep and the feeling of relaxation after sleep. This diary is a useful tool for measuring and assessing the symptoms of insomnia. The instrument contains 11 items that are completed daily by the patient. It measures components such as sleep duration, sleep onset delay, number of night awakenings, sleep efficiency, and subjective quality of sleep.^{19,76} It is worth mentioning that sleep assessment tools are not perfect, flawless instruments, but they can provide some helpful information for therapists that help them diagnose and treat insomnia.⁶⁸ Two important things should be considered when diagnosing insomnia. The patient is dissatisfied with the quantity and quality of their sleep, and this dissatisfaction has caused suffering. The patient reports daytime dysfunction and

their performance has declined psychologically, emotionally, occupationally, socially, and physically. Table 2 provides a short description of the most important instruments used to diagnose insomnia:

By considering diagnostic criteria, objective evaluations, and the patient's reports according to the model presented in Figure 2, the therapist can take diagnostic and therapeutic measures to treat insomnia.

Co-occurrence of other diseases with insomnia

Depression is a disorder that usually occurs simultaneously as insomnia. Thus, the question is which disorder needs to be treated first. A recent study claimed that conceptualizing insomnia as a secondary symptom of depression should be avoided⁷⁷ for some reasons: First, insomnia symptoms often appear before mood swings and are independently associated with an increased risk of depression in the future. Second, insomnia symptoms persist after treatment for depression; and third, if depression is treated alone and insomnia is not treated, depression will recur⁷⁷.

In addition to depression, other mental health problems such as anxiety may be observed in patients with insomnia.⁷⁸ Other sleep disorders, such as sleep apnea, may also co-occur with insomnia.^{79,80} The results of a study showed that diseases such as hypertension, diabetes, heart disease, migraine, gastric ulcer, asthma, osteoarthritis, and menstrual problems are also found in patients with insomnia.⁸¹ Insomnia may also occur at the same time as other sleep disorders such as obstructive sleep apnea (OSA).⁸² It is argued that the association between insomnia and OSA is an important yet unknown area of research that requires in-depth investigations.⁸² Furthermore, therapists should consider evaluating the possibility of other sleep disorders. Given the possibility of insomnia co-occurring with other mental disorders and physical illnesses, therapists should be careful in their assessment and diagnosis and need to evaluate the co-occurrence of other mental disorders such as depression, anxiety, post-traumatic stress disorder, and bipolar disorder. It is important to note that treating insomnia should not be delayed in the presence of comorbid disorders and the therapist should treat insomnia at the same time.

Treatments for insomnia

Following the literature, insomnia therapies can be divided into non-pharmacological treatments and pharmacological treatments:

Table 2. The Most Important Instruments used to Diagnose Insomnia

| Instrument | Year of construction | Number of items | Content (subscales) |
|---------------------------------------|----------------------|-----------------|--|
| Pittsburgh Sleep Quality Index (PSQI) | 1989 | 19 | Subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction |
| Insomnia Severity Index (ISI) | 1993 | 7 | The severity of problems with delayed sleep onset, sleep maintenance, early morning awakenings, satisfaction with current sleep pattern, interference with daily functioning, and so forth |
| Athens Insomnia Scale (AIS) | 2000 | 8 | Measuring sleep problems based on the ICD-10 criteria |
| Bergen Insomnia Scale (BIS) | 2008 | 6 | Measuring the symptoms of insomnia and diagnosis criteria |
| Sleep Diary | - | 11 | Bedtime and/or lights-out time, sleep latency, nighttime awakening time, final wake-up time, rise time, and sleep quality |

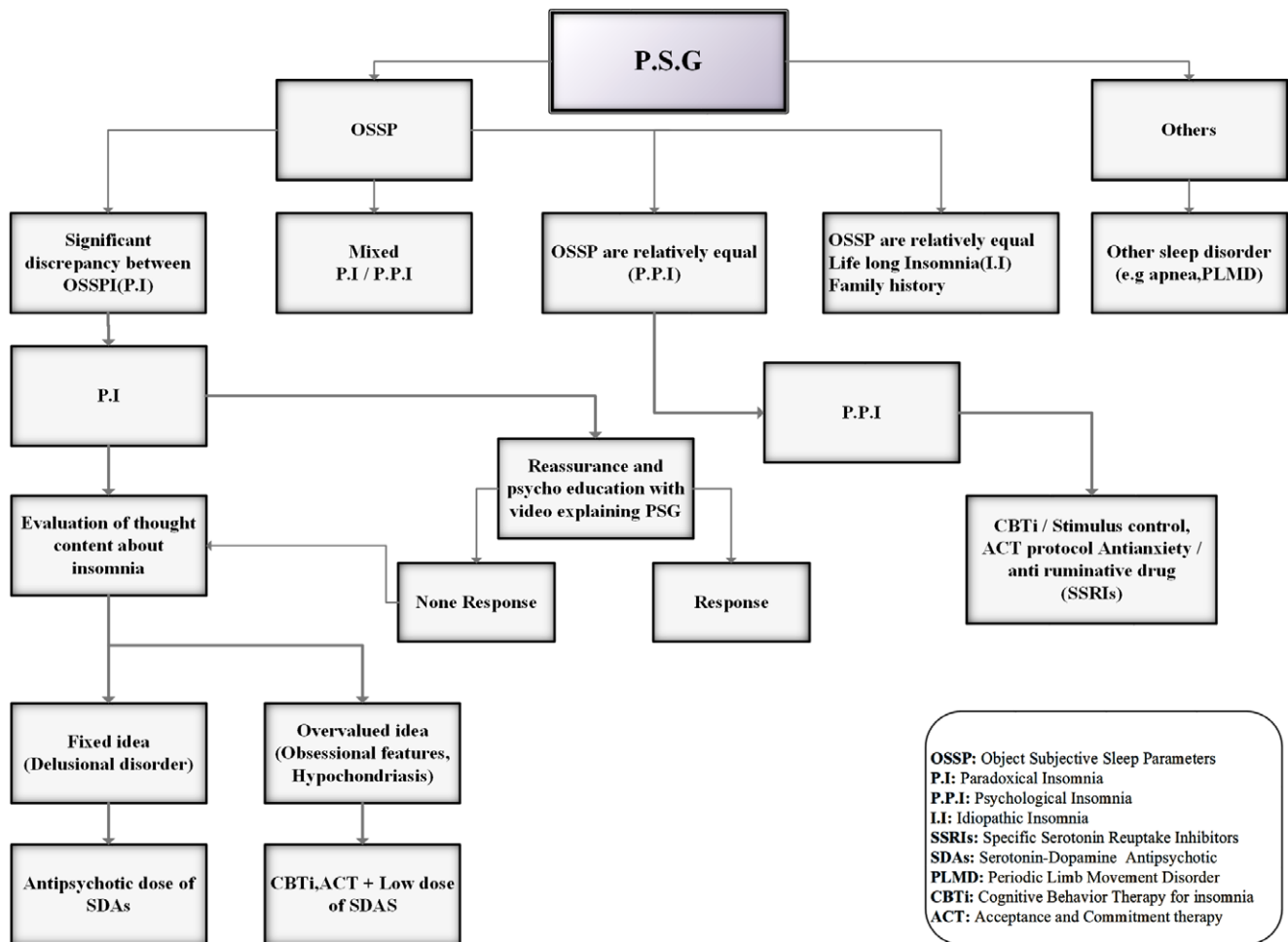


Figure 2. The diagnosis and treatment algorithm of insomnia based on polysomnography data.

Non-pharmacological treatments

Given the side effects of medications prescribed for the treatment of insomnia, as well as uncertainties about the effectiveness of these medications, therapists are recommended to use non-pharmacological treatments. In fact, in the treatment of insomnia, priority is given to non-pharmacological treatments. Following a review of the literature, the most important and effective non-pharmacological treatments are introduced as follows:

1. **Cognitive-behavioral therapy for insomnia (CBT-I):** CBT-I is an evidence-based psychotherapy that uses a range of treatments such as behavioral interventions to regulate sleep cycles, cognitive interventions to address maladaptive thoughts, and the reduction of over-reliance on sleeping medication.⁸³ The components of CBT-I usually include stimulus control, sleep restriction, cognitive therapy, and relaxation training.⁸⁴ Studies have shown that CBT-I is effective in reducing sleep onset latency (SOL) and wake time after sleep onset and improving sleep efficiency.^{85,86} The results of a meta-analysis study showed that CBT-I is an effective treatment to improve insomnia that causes significant changes in the indices of the daily insomnia diary. The results of this study also indicated that the effects of CBT-I on SOL, wake-up after sleep, and sleep efficiency are stable over time.⁸⁷ It should be noted that CBT-I can be effective

for patients with disorders occurring with insomnia and can improve sleep parameters.⁸⁸ This treatment can also be done electronically and has effective outcomes for patients.⁸⁹

2. **Sleep hygiene education (SHE):** SHE is commonly used as a practical treatment for insomnia.⁹⁰ SHE focuses on things like not consuming caffeine, cigarettes, and alcohol, developing a sleep-wake schedule, and some nutrition tips. SHE can improve sleep, improve sleep quality, facilitate sleep, rest, and job performance, and also reduce daily sleepiness.⁹¹ Need to emphasize that effects in chronic insomnia disorder are minimal (SHE is often a control arm in RCTs for CBT-I).
3. **Mindfulness-based therapy for insomnia (MBT-I):** Mindfulness has emerged as a new approach to regulating emotions and reducing stress, and it has several health benefits. Recently, MBT-I has been proposed⁹² to help the patient increase their awareness of the mental and physical conditions associated with insomnia, as well as experience ways to adapt to these conditions, which are usually undesirable. It also helps the patient monitor their daily activities and sleep schedule by paying attention to insomnia-induced fatigue during the day and applying strategies for regulating insomnia-related emotions.⁹² This therapy focuses on mindfulness and sleep, mindfulness of stress, mindfulness for breathing, mindfulness for thoughts and emotions, meditation, and the role of mindfulness in dealing with future challenges.⁹³

4. **Mindfulness-based cognitive behavioral therapy:** The combination of 2 methods of mindfulness and CBTI can be used in the treatment of insomnia. This new treatment technique integrates CBTI components and mindfulness exercises to reduce sleep-related arousal and improve sleep.⁹⁴ The results of a study showed that this integrative approach can be an effective treatment for insomnia, reduce the symptoms of insomnia, and produce stable outcomes over time.⁹⁵
5. **Acceptance and Commitment Therapy (ACT):** One of the therapies that can be considered for treating insomnia is ACT. ACT focuses on 6 processes or skills: Acceptance, cognitive defusion, being at present, self as context, values, and committed action.¹⁹ In the ACT, the main emphasis is on the individual's desire for inner experiences. Thus, it can help patients with chronic insomnia to consider dysfunctional beliefs and sleep-related thoughts as just thoughts.¹⁹ This treatment not only focuses on sleep problems and symptom control but also emphasizes the patient as a whole. This focus is vital for increasing the patient's quality of life and psychological resilience, reducing the severity of insomnia.⁹⁶ The results of a study showed that ACT can improve sleep quality and sleep patterns in patients with insomnia, and also this treatment reduces dysfunctional sleep beliefs and attitudes in patients.¹⁹ Furthermore, a meta-analysis study showed that ACT is an effective treatment for insomnia, reduces the severity of insomnia, and is effective in improving sleep patterns.⁹⁶ The results of another study indicated that ACT reduces the symptoms of insomnia.⁹⁷

An overview of non-pharmacological therapies shows that these therapies focus on presleep thoughts and emotions that cause the person to become aroused and have difficulty starting to sleep. As noted earlier, arousal has been addressed as a keyword and effective factor in treatment in cognitive models and theories.

Given that daytime symptoms are the main problems associated with insomnia, an effective treatment should reduce the incidence of these symptoms. Thus, an effective treatment technique for insomnia improves constructs such as functional health, psychological well-being, and quality of life. Accordingly, paying attention to these constructs can be a very important part of satisfactory insomnia treatment.⁴⁴ The most important and

effective non-pharmacological treatments for insomnia are introduced in Table 3.

Pharmacological treatments

A wide range of drugs are prescribed for the treatment of insomnia. These drugs can be divided into 7 categories as follows:

1. **Benzodiazepines (BZD):** These drugs are commonly used to treat insomnia and can be effective.⁹⁸ A meta-analysis study showed that the use of BZD for treating insomnia is associated with an increase in sleep duration, but no significant effect was on sleep latency.⁹⁹ However, there are problems with BZD. Thus, researchers recommend that due to the high risk of abuse and dependence on these drugs, they should be administered with great caution, and if BZD are prescribed, they should be taken in the shortest possible time and with the lowest possible dose.¹⁰⁰
2. **ANTIDEPRESSANTS:** Antidepressants used to treat insomnia include amitriptyline, doxepin, and trazodone. The results of one study showed that trazodone is a safe and effective drug for the treatment of insomnia.¹⁰¹ However, another study suggested that there may be a slight improvement in sleep quality with short-term use of doxepin and low-dose trazodone compared to the placebo.¹⁰² There are some uncertainties about the use of antidepressants in the treatment of insomnia, and studies have not definitively indicated their effectiveness.^{102,103} However, some researchers recommend the use of these drugs for the treatment of insomnia should be prescribed only to patients who, along with insomnia, are also suffering from depression.¹⁰⁴
3. **ANTICONVULSANTS:** The results of studies have shown that taking tiagabine can increase the duration of sleep. Besides, increased deep sleep has been observed with the use of this drug, but it does not have a significant effect on subjective sleep quality.¹⁰⁵ Other studies have also confirmed the effect of gabapentin and pregabalin on improving sleep quality.^{106,107} In general, it has been claimed that the use of these drugs increases sleep duration and sleep quality, but they should not be taken frequently.¹⁰⁰

Table 3. Non-pharmacological Treatments for Insomnia

| Therapy | Content | Goal(s) | Treatment duration |
|---|---|--|------------------------|
| Cognitive-behavioral therapy for insomnia (CBT-I) | Sleep hygiene, sleep restriction, stimulus control, cognitive therapy, thought challenging, and relaxation training | Improving sleep efficiency, increasing sleep duration, regulating the sleep-wake cycle, and changing the nature of sleep-related dysfunctional thoughts | Four to eight sessions |
| Sleep hygiene education (SHE) | Teaching proper sleeping habits, dietary and nutritional recommendations, teaching healthy sleep-related lifestyles | Improving sleep quality, increasing sleep duration, regulating the sleep-wake cycle | 4 sessions |
| Mindfulness | Mindfulness exercises | Increasing awareness of the mental and physical states associated with insomnia Adaptation to adverse conditions caused by insomnia Monitoring activities and sleep schedule | Six to eight sessions |
| Mindfulness-based cognitive behavioral therapy | Mindfulness meditation, sleep restriction, stimulus control, sleep education, and sleep hygiene | Decreasing presleep arousal Reducing nighttime symptoms of insomnia Reducing dysfunctional sleep cognitions | Six to eight sessions |
| Acceptance and Commitment Therapy (ACT) | Acceptance, cognitive defusion, being at present, self as context, values, and committed action | Accepting dysfunctional beliefs and thoughts related to sleep Accepting emotions before going to sleep Improving sleep quality and regulating sleep patterns | Six to eight sessions |

4. **ANTIPSYCHOTICS:** Drugs such as quetiapine, olanzapine, and risperidone are some antipsychotics that have been used for treating insomnia. Studies have shown that these drugs can improve sleep quality.¹⁰⁸ Furthermore, research on the effectiveness of these drugs for sleep has confirmed their relative effectiveness.^{109,110} Another study showed that olanzapine and risperidone have a significant effect on improving sleep quality.¹¹¹ One advantage of these drugs is that they are not addictive and can be used by people who are concerned about substance abuse.⁷⁶ The effects of these drugs on sleep are due to the blocking of neurotransmitter receptors such as dopamine and serotonin.¹¹² Nevertheless, there is insufficient research evidence to confirm the effectiveness of these drugs on insomnia.
5. **Z-drugs:** This group of drugs includes eszopiclone, zaleplon, and zolpidem. They have been approved for treating insomnia.¹¹³ Eszopiclone is an effective and safe drug with a low risk of dependence. Research has shown that this drug can be effective in sleep latency and maintenance.¹¹⁴ These drugs can generally be useful in the short term for people with insomnia.¹¹⁵ However, there are some concerns about the side effects of this group of drugs, because they also have side effects similar to BZD, and can cause anterograde amnesia, sedation, impaired balance, and complex sleep-related behavior.¹¹⁶
6. **Melatonin agonists:** One of the drugs used to treat insomnia is ramelteon. It has minimal side effects and is effective in improving SOL and increasing sleep duration, making it a valuable first-line option. It also improves sleep maintenance and has mild side effects including drowsiness.¹⁰⁴ It is said to be a safe drug that can be used in old age.¹⁰⁵ These medications can reduce SOL.
7. **Antihistamines:** Antihistamines are commonly used for people with allergic rhinitis,¹¹⁷ but some, such as diphenhydramine, doxylamine, and hydroxyzine, are used to treat insomnia.¹¹² A study showed that diphenhydramine can improve sleep quality.¹¹⁸ However, there is no strong empirical evidence to confirm the effectiveness of these drugs in the treatment of insomnia.¹¹² Since antihistamines do not have significant potential for abuse, they can be used in patients with insomnia prone to substance abuse. Antihistamines are also suitable for people with insomnia who have allergy symptoms or upper respiratory tract infections.^{100,112}
8. **Dual orexin receptor antagonists:** Suvorexant and lemborexant have recently been considered dual orexin receptor antagonists for treating insomnia. Studies have shown that these 2 drugs have a significant effect on the treatment of insomnia.^{119–121} Research data have confirmed that suvorexant has significant effects on sleep onset time, sleep duration, and sleep quality,¹²² but it has side effects such as drowsiness, fatigue, and abnormal dreams.¹²² The results of a study on lemborexant showed that this drug can have significant effects on sleep onset time and sleep maintenance.¹²³ Another study suggested that lemborexant (2.5–10 mg) was effective in treating insomnia while minimizing residual drowsiness the next morning.¹²⁴

Overall, it has been claimed that pharmacological treatments have immediate relief effects, but the therapeutic outcomes do not last over time, and the effects are temporary.¹²⁵ On the other hand, long-term use of sleep medication carries the risk of dependence, and people often have difficulty quitting.¹²⁵ Another issue in prescribing sleep medication is the problem of drug interactions that may cause problems for patients, so these issues should be considered when prescribing such medication. Furthermore, in

people with a history of BZD, other classes of drugs may not be responsive, so the process of taking other drugs should not be stopped. However, if medication is to be prescribed for the first time, it is best to start treatment with other drugs. Another point to note is that pharmacological treatments are not recommended for patients who report symptoms of insomnia for less than 3 months (short-term) unless the medication can correct the defective subjective cycle. Finally, the use of antianxiety drugs and SSRIs can be helpful for patients with psychophysiological insomnia due to repetitive thoughts and anxiety. In addition, if preoccupation in patients with paradoxical insomnia is obsessive, SSRIs and low doses of antipsychotics can be effective. However, antipsychotics can be used in cases where mental preoccupation has become a fixed idea that evokes delusions.¹⁸

Suggestions and future directions

In this study, we tried to adhere to the 2 principles of resource validity and summarization. Thus, we were very careful in reporting previous studies in the literature. There were a large number of studies, and we had to select the most important studies and report the most practical results. Following the observations made in this study, sleep therapists must be careful in the diagnosis process. Patients may seek prompt treatment and insist on treatment in a short time. Thus, therapists should not neglect a thorough examination of the history of the disease and patients' conditions. If there are any contradictions in the diagnosis process, therapists should use objective instruments such as PSG, but they should not be in a hurry to use these instruments. Figures 1 and 2 provide a simple and practical model of diagnosis and treatment. Besides, given the high probability of co-occurring insomnia with other mental disorders and physical illnesses, therapists should be careful in diagnosing comorbid disorders.

Future research can focus on both diagnosis and treatment. Certainly, comparing the diagnostic power of objective and subjective tools can be useful in the development of this discipline. Future studies also need to focus on the parameters of insomnia when seeking effective treatments, and to determine which treatment is more effective for a given symptom. Sleep therapists are also recommended to pay attention to third-wave behavioral therapies, such as ACT. Moreover, analysis of co-occurrence of insomnia with other disorders is an important and practical research area. Thus, future studies should focus on the nature and the reasons for this problem.

Data availability statement. The datasets used during the current study are available from the corresponding author on reasonable request.

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Ethics approval and consent to participate. The protocol for this study was registered in the Sleep Disorders Research Center of Kermanshah University of Medical Sciences in Iran and was approved by the ethics committee of the university. This study was performed under the ethical principles laid down in the seventh and current edition (2013) of the Declaration of Helsinki. Written informed consent was obtained from all subjects and/or their legal guardian(s).

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