Clinical Practice Guidelines for the Management of Patients with Insomnia in Primary Care

NOTE:

It has been 5 years since the publication of this Clinical Practice Guideline and it is subject to updating.

The recommendations included should be considered with caution taking into account that it is pending evaluate its validity.

CLINICAL PRACTICE GUIDELINES IN THE SPANISH NHS
MINISTRY OF HEALTH AND SOCIAL POLICY

MINISTERIO DE CIENCIA E INNOVACIÓN
MINISTERIO DE SANIDAD Y POLITICA SOCIAL
Plan de Calidad para el Sistema Nacional de Salud
SaludMadrid
Agencia Lain Entralgo para la Formación, Investigación y Estudios Sanitarios
Comunidad de Madrid

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The GPC is an aid to decision making in health care. Compliance with it is not compulsory nor does it replace the clinical judgment of health care professionals.

Edition: 2009
Published by: Ministry of Science and Innovation
NIPO: 477-09-051-2
Legal Deposit: M-52948 -2009
Printer: ESTILO ESTUGRAF IMPRESORES, S.L.
Pol. Ind. Los Huertecillos, nave 13 - 28350 CIEMPOZUELOS (Madrid)

This GPC has been financed via the agreement signed by the Carlos III Health Institute, an independent body of the Ministry of Science and Innovation, and the Health Technology Assessment Unit of the Laín Entralgo Agency (Community of Madrid), within the collaboration framework of the National Health Service Quality Plan of the Ministry of Health and Social Policy.

This guideline must be cited:

Guideline Development Group for the Management of Patients with Insomnia in Primary Care; Clinical Practice Guidelines for the Management of Patients with Insomnia in Primary Care; National Health System Quality Plan, Ministry of Health and Social Policy; Health technology Assessment Unit. Laín Entralgo Agency. Community of Madrid; 2009. Clinical Practice Guidelines in the NHS: UETS No. 2007/5-1.

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Background

Care practice is increasingly complex for a number of reasons, among which is the increase of scientific information available. Science is constantly changing and knowledge needs to be updated to effectively and safely meet the needs of health and disease care.

In 2003, the National Health System (SNS) Interterritorial Council created the Health Guide project whose ultimate aim was the improvement of quality in clinical decision making. In pursuit of this, a SNS Clinical Practice Guidelines (CPG) register was prepared according to explicit criteria from its scientific committee.

In early 2006, the SNS Quality Agency Directorate General prepared the Quality Plan for the National Health System deployed in 12 strategies. The purpose of this Plan was to increase the cohesion of the system and help ensure the highest quality healthcare for all citizens regardless of their place of residence. This Plan includes the preparation of the CPG by different agencies and expert groups in prevalent pathologies related to health strategies.

This guide was produced within this framework for the management of patients with Insomnia in Primary Care.

Sleep is a part of everyone's daily life, and is a biological necessity restoring basic physical and psychological functions to achieve satisfactory performance. Its disorders are among the most important health problems that go unreported, with consequences that involve individual, work, economic and social development. One of these disorders, insomnia, is notable because of its widespread nature, and must be treated early and appropriately to prevent adverse effects on the health and quality of life of the sufferer.

It is important to have common guidelines for both the diagnosis and treatment, which build on the best scientific knowledge available. This is the reasoning behind this Clinical Practice Guide, designed and developed specifically for use in Primary Care.

Pablo Rivero Corte
General Director of the Quality Agency of the NHS

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Spanish Association of Neuropsychiatry, **AEN**

Spanish Patients Association for Sleep Disorders, **ASENARCO**

Spanish Society of Geriatrics and Gerontology, **SEGG**

Spanish Society of Primary Care Physicians, **SEMERGEN**

Spanish Society of Family and Community Medicine, **SEMFYC**

Spanish Society of Clinical Neurophysiology, **SENFC**

Spanish Society of Psychiatry, **SEP**

Spanish Sleep Society, **SES**

Spanish Union of Scientific Nursing Societies, **UESCE**

Members of these societies have taken part in the development and external review of this Clinical Practice Guideline.

Declaration of interests: All members of the Development Group have made a declaration of interest as reflected in Appendix 13.

Questions to answer

Concepts, definition, clinical features and classification

- What are the general concepts involved in sleep?
- What is the definition of insomnia as a complaint?
- What is the definition of specific clinical insomnia?
- How can insomnia be classified?

Diagnosis of insomnia

- What are the diagnostic criteria for insomnia?
- What are the differential diagnoses to consider?
- Are there any key questions that can help primary care (PC) professionals detect insomnia in an interview with the patient?
- What tests or tools can be used for the diagnosis of insomnia in PC?

Treatment of insomnia

- What constitutes effective insomnia treatment?
- What are the most effective psychological therapies for insomnia?
- What are the most effective drugs for treating insomnia?
- Are there effective measures to prevent this disorder from becoming chronic?

Patient information and adherence to treatment

- What is the basic information to be provided for patients with insomnia?
- How can compliance/adherence in the treatment of insomnia be improved?

Diagnostic and therapeutic strategies

- What are the steps to follow with primary insomnia patients?

Recommendations

Assessment of insomnia

√	In *acute insomnia*, an interview to assess the clinical onset and course of insomnia and its relationship with potential trigger situations is recommended. In addition, possible precursor factors of chronic insomnia (vulnerability and poor sleep habits) must be identified.
√	In *chronic insomnia*, the interview should include sociodemographic factors and detailed characteristics of the complaint, as well as the psychiatric, sleep and substance use history. Information provided by the family and anyone who sleeps with the patient must also be taken into account.
√	Key questions are recommended to help detect insomnia, and to rule out other sleep problems or other disorders (Appendices 3 and 4).
D	It is recommended to use a 2-week sleep diary to get to know the sleeping and waking times of the patient to differentiate primary chronic insomnia from other conditions. It can also be used to assess the treatment and monitor the patient's progress if kept for at least two months.
C	To assess the severity of insomnia, it is recommended to use the self-administered questionnaire *Insomnia Severity Index* (ISI), see Appendix 6.
C	The self-administered questionnaire Pittsburgh Sleep Quality Index (PSQI) is recommended to assess the quality of sleep in insomnia or the presence of other sleep disorders, as it includes information from the person with whom the patient sleeps (Appendix 6).

Therapeutic Interventions

Health education for insomnia

Q	The ideas, concerns and expectations of the patient regarding sleep complaints should be discussed with the patient, in order to be able give further informartion and correct any misconceptions.
D	Health education for insomnia should be based on the structure of sleep, influence of age, the number of hours required and individual variations, prevalence of insomnia, sleep as a reflection on daytime functioning and vice versa, the importance of conditioning and mental processes that lead to a vicious circle, the place of medication in treatment, the effect of certain substances and the clarification of treatment goals to adjust to expectations.

Sleep hygiene education for insomnia

A	Sleep hygiene education is recommended in the treatment of chronic insomnia as an adjunct to other psychological and pharmacological therapeutic interventions.
A	To achieve greater sleep efficiency, a combination therapy is recommended, that includes one of the following techniques in addition to sleep hygiene education: stimulus control, relaxation therapy or sleep restriction.

Psychological interventions

Behavioural therapy and cognitive behavioural therapy (CBT) for insomnia, aimed at Primary Care

B	In Primary Care (PC, general practitioners, nurses and social workers can perform both individual and group approaches for patients with insomnia, using techniques based on the principles of behaviour therapy and cognitive behavioural therapy (CBT), provided that they have received adequate training.
B	Behavioural interventions for insomnia should include at least stimulus control and/or sleep restriction . Other CBT interventions that may be recommended are breathing and relaxation therapies, paradoxical intention and cognitive restructuring.
√	*First choice* psychological techniques in PC* to reduce the symptoms of insomnia are: relaxation therapies, stimulus control and sleep restriction.

√	*Second choice* psychological techniques in PC to reduce the symptoms of insomnia are: paradoxical intention techniques and cognitive restructuring.
√	Psychological interventions in PC should be performed by trained professionals and have the following common features in their application: to be structured, simple and easy to implement, short, with set times, well targeted and with described effectiveness.

* Appendix 9 provides information for the PC professional and patient on the main interventions: relaxation therapies, stimulus control and sleep restriction.

Pharmacological interventions

Benzodiazepine and non-benzodiazepine hypnotics for insomnia

B	If hypnotics are to be used for treating insomnia, it is recommended that treatment is short-term (not more than four weeks) and at the lowest possible dose.
C	Long-term use of hypnotics is not recommended. If doing so, it should always be monitored, with a diagnosis and for a specific regimen.
B	To prevent dependence on BZDs, it is recommended that use be restricted to acute insomnia, at the lowest dose possible and for no longer than 2-4 weeks.
B	As first choice hypnotics for insomnia, either a benzodiazepine or non-benzodiazepine can be chosen, as no significant differences in clinical or adverse effects have been demonstrated between the two types.
B	If a patient does not respond to treatment with a hypnotic, it is not recommended to change to another, unless there are side effects directly related to a specific hypnotic drug.
B	It is recommended to use the hypnotic which is most efficient and responsive for the patient, unless side effects directly related to the chosen hypnotic are observed.
B	If a BZD is needed during pregnancy, it should be used at the lowest effective dose and for the shortest time possible to avoid the risk of birth defects.
B	The new discontinuous zolpidem treatment regimens, either intermittent or on demand according to the patient's needs, supported by stimulus control techniques, can be used in the short term as an alternative to continuous dosing.
√	When prescribing hypnotics, patients should be informed of the therapeutic objectives, the duration of treatment and possible side effects, including tolerance and dependence problems associated with their use, as well as the lack of studies reporting long-term efficacy.
√	When prescribing hypnotics, the following parameters must be considered: age, previous treatment, tolerance, potential pregnancy, side effects, patient preferences and costs of equally effective choices.

Other drugs for insomnia

Antidepressants	
B	There is enough evidence to recommend the use of antidepressants for insomnia associated with depressive disorder, but not for primary insomnia.
B	There is insufficient evidence to recommend the use of trazodone and doxepin until results from long term studies are obtained.
B	There is insufficient evidence to recommend the use of the antidepressants amitriptyline and mirtazapine in the treatment of insomnia.
Ramelteon	
B	More long-term comparative studies are needed to recommend the use of ramelteon in the treatment of insomnia.
Not recommended	
B	The use of chloral hydrate, meprobamate or barbiturates are not recommended for the treatment of insomnia.

Other Treatments

Melatonin for insomnia

B	There is insufficient evidence to recommend the use of melatonin in the treatment of insomnia until good quality methodological trials demonstrate its effectiveness.
B	There is not enough evidence to recommend the use of melatonin for the interruption of prolonged use of BZDs.

Acupuncture for insomnia

B	There are no studies of enough methodological quality to recommend the use of acupuncture in the treatment of primary insomnia.

Herbal medicines for insomnia

B	There is not enough evidence to recommend the use of valerian alone or in combination with hops for the treatment of insomnia.
√	Professionals should ask patients about any herbal product they are taking or have taken.

Self-help for insomnia

B	The application of bibliotherapy based on CBT principles via self-help manuals and guided by professionals is recommended in health centres.

Treatment of insomnia in the elderly

√	Any concurrent conditions, the possibility of modification of lifestyle factors affecting sleep quality and the contribution that some drugs can have on insomnia must first be taken into account.
B	Either behaviour therapy or cognitive behavioural therapy (CBT) is recommended in older people with insomnia; especially stimulus control and sleep restriction, supported with sleep hygiene education.
√	The use of hypnotics in older people is generally not recommended, due to the unfavourable risk/benefit ratio.
B	There is enough evidence to recommend the use of antidepressants for insomnia associated with depressive disorder, but not for primary insomnia.
√	There is insufficient evidence to recommend the use of clomethiazole in the treatment of insomnia in older people.
B	The use of barbiturates, antipsychotics or antihistamines, such as diphenhydramine, hydroxyzine, and doxylamine, is not recommended for older people with insomnia.
√	When prescribing any hypnotic in the elderly, it is recommended to start with half the usual adult dose.
B	For elderly long-term users of hypnotics, a gradual reduction of the drug combined with CBT is recommended, to help slow or stop the consumption of BZDs.
B	Slow-release melatonin* may be used in patients aged 55 or over with primary insomnia, as it improves sleep quality and daytime sleepiness.
B	More long-term comparative studies are needed to generalise the use of exercise in the treatment of elderly patients with insomnia.

* In Spain, melatonin has been adopted for use in people over 55 years with insomnia, however, it is not commercially available.

Patient information and adherence to treatment for insomnia

D, √	It is recommended to provide information for patients with insomnia, including general information about the problem and effective interventions (see Appendix 11 - patient Information).
D, √	To improve treatment adherence and facilitate shared decision-making, patient experiences, expectations and preferences regarding treatment decisions must be taken into account.
D, √	It is recommended to encourage the patient to acquire a certain degree of motivation to carry out the clinical recommendations of health professionals regarding sleep hygiene education, stimulus control, sleep restriction and relaxation therapies.
D, √	Patients must be informed of the barriers they need to overcome and the effort involved in compliance with certain psychological interventions, in connection with the adoption of new patterns of behaviour, (eg, keeping to the same sleep timetable every day, getting out of bed until feeling sleepy again and stopping certain habits-tobacco and alcohol).

1. Introduction

Sleep disorders and especially insomnia are matters of common consultation in primary care (PC) and a number of such clinical complaints can be and are resolved at this level of care. PC practitioners are usually the first within the health system consulted by patients for advice and treatment, and therefore play a key role in the detection and management of insomnia. For a proper therapeutic approach, it is fundamental to conduct a correct diagnosis, etiology and treatment when a patient complains of insomnia.

Multiple classifications and definitions of insomnia hinder its management in primary care. It is essential to provide tools that allow professionals practical and useful classifications to address these disorders by reducing both diagnostic and therapeutic variability. Therefore, a current and evidence-based CPG is a PC tool to help in healthcare for sleepless patients.

This document is the *full* version of the CPG on insomnia in Primary Care. The CPG is organized by chapters that provide answers to questions appearing at their beginning. The summary of the evidence and recommendations are given at the end of each chapter. Throughout the text, the right margin indicates the type of study and the possibility of bias in the literature reviewed.

The material which presents a detailed description of the information with the methodological process of the CPG (description of the techniques used in qualitative research, search strategy for each clinical question, evidence tables) is available on the websites of both the *GuíaSalud* and the *UETS*, the Health Technology Assessment Unit of the Lain Entralgo Agency. These sites also have the *CPG Methodological Handbook* that consists of the general methodology employed. There is also a *short version* of the CPG, significantly reduced and with the main appendices from the *full version*, as well as a *quick version* with the recommendations and main algorithms, both in printed form and on the aforementioned websites. In addition, there is a *patient information* section (on the aforementioned websites).

2. Scope and objectives

The main purpose of this guide is to help professionals working in *Primary Care (PC)*, firstly in the *diagnosis of insomnia* in *adults* (over 18 years), and secondly, in the *choice of recommendations*, based on available scientific evidence on *treatment and care interventions* for the management of these patients with either acute or chronic primary insomnia in a PC environment. This is intended to improve the quality of care for patients with insomnia and thereby increase their quality of life.

The guide is therefore aimed at health professionals working in primary care (physicians, nurses, social workers), and all patients who suffer from these problems requesting attention at this first level of care. This will enable patients to learn the strategies and therapeutic possibilities of their problem, so that they can avoid treatments that are not supported by scientific evidence.

The guide presents various treatment options (pharmacological and non-pharmacological) that can be used in PC according to available resources. In fact, existing resources at this level of care are taken into account in the final recommendations.

Since this guideline is focused nationally, it does not cover organizational questions, but rather tries to establish a basic circuit for patients between the two levels of healthcare – Primary Care and Specialized Care – so it will also be distributed among the other professionals involved in providing patient care in an effort to provide integrated care of patients.

3. Methodology

The methodology used is given in the *CPG Handbook* of the Ministry of Health[1].

The steps followed are:

- Forming the guide development group, composed of professionals in: Primary Care (general practice, nursing, social work), Specialist Care (psychiatry, neurophysiology, geriatrics, psychology and nursing) and researchers in the Health Technology Assessment Unit (UETS). In addition, and within the development group itself, a patient with insomnia has been involved in preparing this guide from the early stages.
- Forming a subgroup, with members of the guide group and another patient, for the production of patient information.
- Establishing the scope and objectives of the guide, including the social vision of the disease with the use of qualitative research techniques.

  Firstly, contact was made with health care professionals (physicians in Primary and Specialist Care) and the resources of participant observation and in-depth interviews via a questionnaire were used. Thus, social, demographic, health, treatment and care information was collected on patients with insomnia after being cared for by these professionals.

  Subsequently, patients with insomnia were involved in a discussion group to freely discuss their experiences, interests and concerns in the management of their condition.
- Formulation of clinical questions using the Patient/Intervention/Comparison/Outcome (PICO) format.
- Literature search in Medline, Embase, PsycINFO, CINAHL, Cochrane Plus, DARE, HTA, Clinical Evidence, INAHTA, NHS EED, CINDOC in Spanish, English and French. Studies in adults over 18 years. Publication year limitation: only for primary studies (those that use original data).

  Firstly, a search was performed to find clinical practice guidelines (CPG), and their quality assessed using the AGREE instrument. Four CPGs are included as a secondary source of evidence to answer specific sections of the guide (diagnostic and therapeutic strategies, patient information/communication). The guides included are: "Prise en charge du patient adulte se plaignant d'insomnie en médecine générale. Recommandations pour la pratique clinique. Argumentaire", 2006, Haute Autorité de Santé (HAS); "Insomnie: Recommandation en première ligne de soins". Recommandations de Bonne Pratique, 2005, Société Scientifique de Médecine Générale (SSMG); "Clinical guideline for the evaluation and management of chronic insomnia in adults", 2008, American Academy of Sleep Medicine (AASM); "Clinical Practice Guidelines Adult Insomnia: Diagnosis to management", 2007, Alberta Medical Association.

  The second phase was to carry out a search for systematic reviews, meta-analyses and evaluation reports in the aforementioned databases. Thirdly, an extended search was made of primary studies (clinical trials, observational studies, diagnostic and prognostic test studies).
- Assessment of the quality of the studies and summary of evidence for each question following the Scottish Intercollegiate Guidelines Network (SIGN) recommendations (Appendix 1).

- Formulation of recommendations based on "considered judgment" by SIGN. Any controversial recommendations or those lacking evidence were resolved by consensus of the development group (Appendix 1).
- An external review of the guide was performed by a group of professionals selected for their knowledge of the methodology of Guidelines development, the pathology addressed and its scope.
- Various scientific societies collaborated in preparing the guide to address this health problem in different areas: the Spanish Society of Family and Community Medicine (SEMFYC), Spanish Society of Primary Care Physicians (SEMERGEN), Spanish Psychiatry Society (SEP), Spanish Association of Neuropsychiatry (NEA), Spanish Union of Scientific Nursing Societies (UESCE), Spanish Society of Sleep (SES), Spanish Society of Geriatrics and Gerontology (SEGG), Spanish Society of Clinical Neurophysiology (STDE) and the Spanish Patients Association for Sleeping Disorders (ASENARCO). All societies are represented by a member of the development group or external reviewers.
- Detailed information with the CPG methodological process (description of the techniques used in qualitative research, search strategy for each clinical question, evidence tables) are available at www.guiasalud.es.

Updating the GUIDE:

The UETS is responsible for both the publication of the Guide and its update within a period of 3 to 5 years, or earlier, depending on new evidence. This update will include information from updated literature searches, with particular focus on those aspects where the recommendations could be substantially modified. The methodology described in the updating guidelines handbook, prepared within the framework of the Clinical Practice Guidelines in the SNS2, will be used for updating the guidelines.

4. Epidemiology of insomnia

Insomnia is the most common sleep disorder and one of those with the greatest health and social significance. The patient with insomnia complains primarily of dissatisfaction with the quality and/or quantity of sleep. This dissatisfaction may stem from the difficulty in falling or staying asleep throughout the night, or the number of times patients wake up during the night.

To understand the epidemiology of insomnia it helps to understand the clinical relevance of this disorder. There are few studies in Spain that have examined the prevalence of insomnia, and there is none that has analysed its incidence. However, data on the prevalence of insomnia in Spain is similar to other western countries.

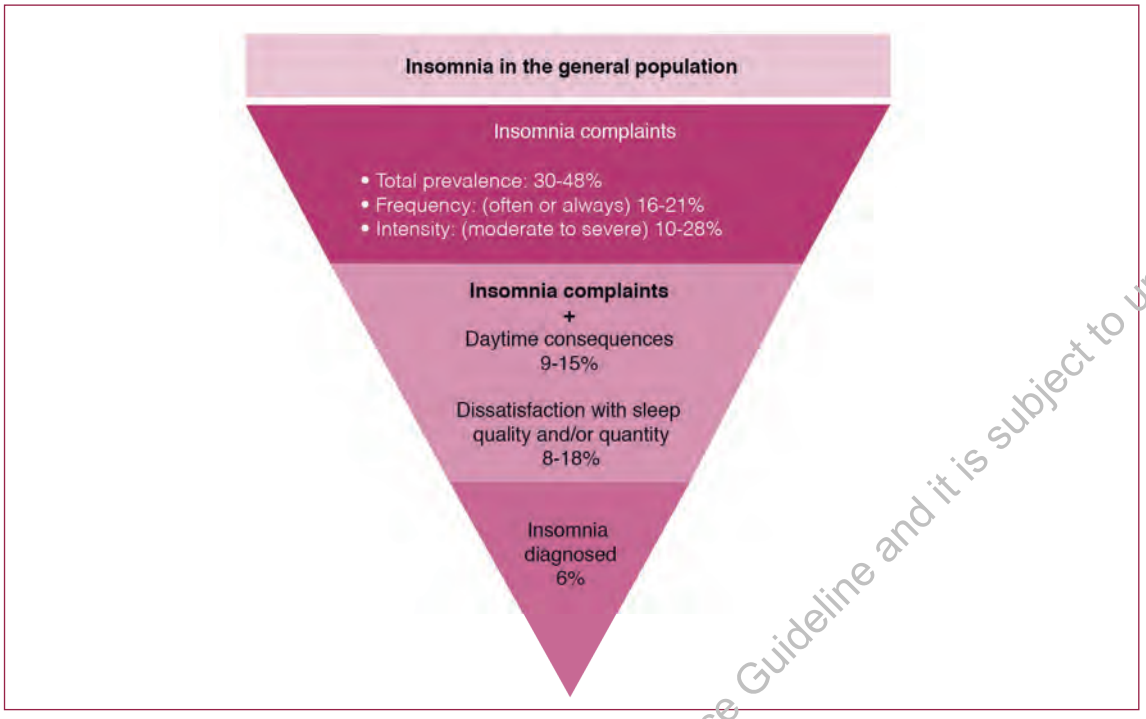
4.1 Prevalence of insomnia

The prevalence of insomnia in the general population varies widely, depending on the samples taken across studies. This can be explained by methodological differences, mainly related to the definition used of insomnia.

Epidemiological studies have grouped people in three categories, as proposed in the literature. The first is the one that includes data for the clinical manifestations of insomnia, such as difficulty in falling and/or maintaining sleep or of non-restorative sleep, irrespective of its duration or consequences. The second group consists of those who take into account consequences during daytime and dissatisfaction with the quantity or quality of sleep, in addition to their declarations on night sleep. The third group meet the diagnostic criteria of insomnia, according to classifications such as the Diagnostic and Statistical Manual of Mental Disorders (the revised third edition, DSM-III-R, the fourth edition, DSM-IV or the revised fourth edition, DSM -IV-TR) and the International Classification of Sleep Disorders (ICSD). See section 5.4.

When the definition also includes the daytime clinical consequences of insomnia and dissatisfaction with the quantity/quality of sleep, the prevalence rate is between 9% -15% and 8% -18%. Finally, if the definition is also based on the classification of DSM-IV, the prevalence of people diagnosed with insomnia reduces to 6%[3]. These data are presented in graphical form below.

Figure 1. Insomnia in the general population



Modified Ohayon, Sleep med Rev, 2002[3]

A meta-analysis performed in the US showed that of patients attending PC, more than 50% complained of insomnia only if specifically asked about sleeping, 30% visit their GP on their own initiative, and only 5% go to consultation with the main objective of receiving treatment to solve this problem[4]. A recent study, also in the US, estimates that only 15% of people with sleep problems were diagnosed with *sleep disorders*. 4% of these patients were diagnosed with *Insomnia* and only half of them received further treatment for this condition[5].

It was also noted that patients with long-term insomnia, according to DSM III-R and DSM IV criteria were between 19% (in 1999) and 26.5% (in 2001), respectively[6].

In Spain, sleep disorder prevalence studies in the general population are very limited and show that approximately 23% have some trouble sleeping with 11% reporting having insomnia[7]. These figures are seen in young adults[8] and appear to increase with age[7,9]. Insomnia is the sleep disorder that PC practitioners find more frequently in daily clinical practice[10]. A PC prevalence study showed 17.4% insomnia according to DSM-III-R, about 27% for complaints of poor sleep and 55.5% had no sleep problems[11].

The definition of insomnia used in studies influences the prevalence figures obtained and the sociodemographic features of the insomniac patient. Regardless of the definition used, women are more likely than men to suffer from insomnia. Age seems to increase only "complaints" about sleeping (or insomnia)[12], as with marital status. People who are separated, divorced or widowed (again, more likely in women) described a higher prevalence[13].

Insomnia is more common among people who do not work for pay than among those who do, although this association appears to be an effect of age and sex. There are some studies that associate the prevalence of insomnia with lower income and education levels, but further studies suggest that this may be explained by confusing these categories with others, such as age[3].

4.2 Impact of insomnia: associated burden of disease

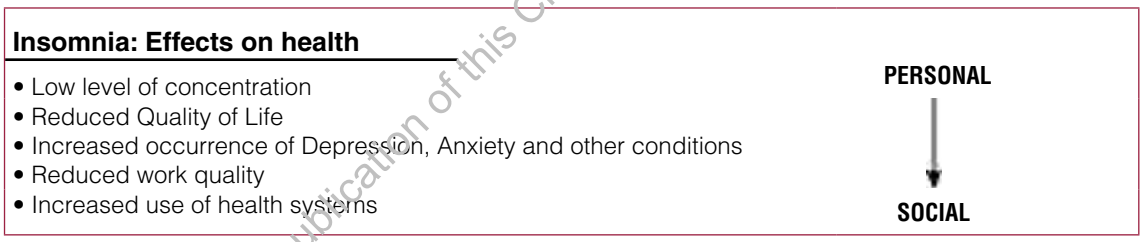
The impact of insomnia on health has been studied from the epidemiological point of view, except for its relationship to psychopathology. However, several studies have shown an association of insomnia with a worse overall health status and a self-perception of poor health[14,15].

Insomnia is usually associated with daytime fatigue and mood disorders such as irritability, dysphoria, tension, helplessness and depression[14,16,17], with one study suggesting that untreated chronic insomnia may be a risk factor in developing major depression[18]. In addition, patients with insomnia often have somatic complaints, typically gastrointestinal and respiratory, or headaches and non-specific pains[14,19].

During the day, patients with chronic insomnia may have problems that affect both their health and social and occupational functioning[6,20]. They may complain of symptoms on the emotional, behavioural and cognitive level and of an impairment in their social and working lives, with an increase in absenteeism[21]. Moreover, they are more likely to have accidents. In a survey conducted recently in the United States, 26% of people with insomnia reported that on some occasions they felt drowsy while driving or during working hours. This results in a poorer quality of life: they are impatient, have difficulty concentrating, organising their work or are warned that their productivity is lower than expected[5].

Other studies, also conducted in the US, show that patients with insomnia generally have more frequent health service consultations, which represent an increase in both direct and indirect health costs[22,23]. Diagram 1 shows some of the health effects caused by insomnia, with both personal and social consequences.

Diagram 1. Effects of insomnia on health



When insomnia becomes chronic, it is associated with increased morbidity[19]. Insomnia or typical manifestations have been associated in epidemiological studies with respiratory disease (chronic obstructive pulmonary disease-COPD, asthma, chronic bronchitis), rheumatic diseases, cardiovascular diseases (coronary heart disease, hypertension), cerebrovascular conditions (stroke), diabetes and painful diseases, among others[19,20].

The effects of tobacco and alcohol are also clear. Smoking is associated with more difficulties in falling and staying asleep and more daytime sleepiness, while alcohol is often used as a self-medication by people with insomnia[14,16]. About 10% of patients with insomnia consume alcohol several nights a week[5].

A relationship that has been repeatedly demonstrated in studies of the general population is that between psychopathological factors and insomnia. It shows that patients with chronic or persistent insomnia are at increased risk of developing other psychiatric disorders, especially depression, anxiety or alcoholism, when compared with patients without insomnia or those who

have recovered from this disorder[6]. The relationship with depression is particularly clear. Firstly, the typical difficulties of insomnia are present in four out of five people with major depressive disorder; while secondly, the persistence of the manifestations of insomnia markedly increase the likelihood of suffering a major depression in a period of one year[13,24].

It is unclear whether the fact of having insomnia is associated with increased mortality. According to some authors, sleep problems in the elderly, in particular, are linked to an increased risk of mortality[25].

Regarding the impact of insomnia on the Spanish population, it is estimated that in 2006 the Spanish population bore a *burden of disease*[26] equivalent to losing 37,628 years of disability-adjusted life years (DALY). Since no recorded deaths are caused by this condition, the entire burden is attributable to associated morbidity and disability. This figure accounts for 2.6% of the total disease burden of neuropsychiatric diseases, 0.8% of total non-communicable diseases and 0.7% of the total DALYs lost in Spain. The disease burden of (primary) insomnia is higher in women than men (56% of DALYs for that reason), and is concentrated between those of 15 and 59 years of age (see Table 1 and Figure 2). The overall figures for Spain are similar to those of other neighbouring European countries (Table 2).

Table 1. Burden of disease of (primary) insomnia*, Spain, 2006

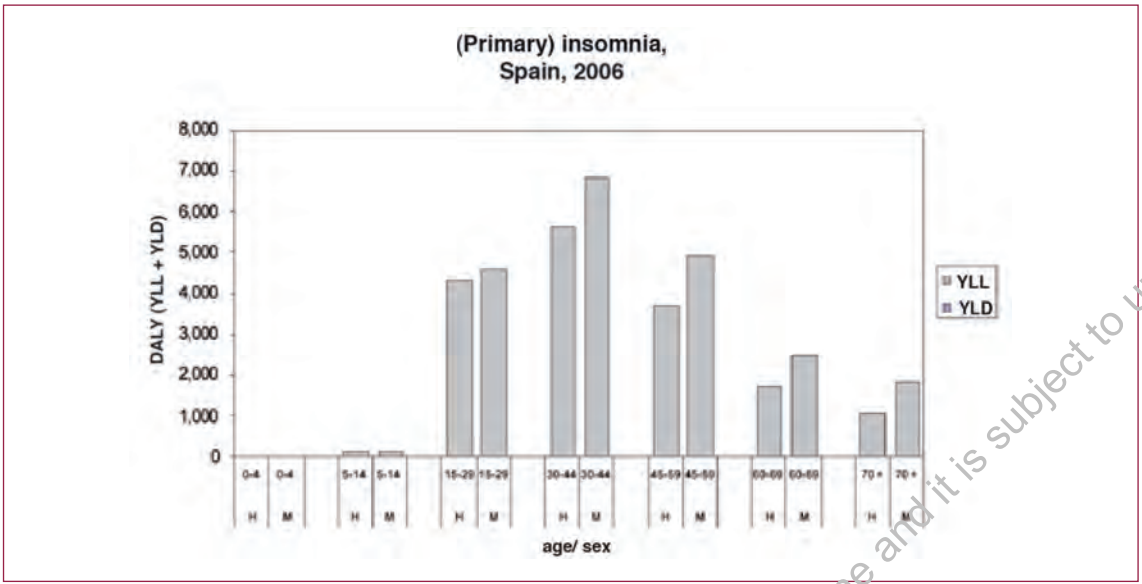
	Men	Women	Total
DALY	16,669	20,959	37,628
By sex			
DALY	44.3 %	55.7 %	100 %
As a percentage of neuropsychiatric conditions			
DALY	2.5 %	2.6 %	2.6 %
As a percentage of non-communicable diseases			
DALY	0.7 %	1.0 %	0.8 %
As a percentage of all causes			
DALY	0.6 %	0.9 %	0.7 %

(*) Code F51 in the CIE-10

DALY: Disability-adjusted life years lost.

Source: Information prepared and provided by the Department of Health Reports and Studies, Ministry of Health, Community of Madrid.

Figure 2. Burden of disease of (primary) insomnia by age group*, Spain, 2006



(*) Code F51 in the CIE-10

DALY: Disability-adjusted life years lost.

YLD: Years of life lost due to disability or poor health.

YLL: Years of life lost due to premature death.

Source: Information prepared and provided by the Department of Health Reports and Studies, Ministry of Health, Community of Madrid.

Table 2. Disease burden of (primary) insomnia*, Europe-A subregion (WHO), 2004

	Men	Women	Total
DALY	155,085	198,419	353,504
By sex			
DALY	43.9 %	56.1 %	100 %
As a total of neuropsychiatric conditions			
DALY	2.6 %	2.8 %	2.7 %
As the total of non-communicable diseases			
DALY	0.7 %	0.9 %	0.8 %
As a percentage of all causes			
DALY	0.6 %	0.9 %	0.7 %

(*) Code F51 in the CIE-10

DALY: Disability-adjusted life years lost.

Source: WHO. The global burden of disease: 2004 update (2008). Information prepared and provided by the Department of Health Reports and Studies, Ministry of Health, Community of Madrid

The elderly

There are few studies on the prevalence of insomnia in people over 65 years. In international studies, the figures vary between 12% and 40%[27]. In Spain, studies show that although about 32% of elderly people suffer sleep disturbances, the figures are around 12% when applied to the classification of insomnia. The most frequent complaints are related to "waking up early" and "waking up tired"[7,9].

Although not all sleep disorders are pathological for these age groups, severe sleep disturbances can contribute to depression and cognitive impairment[18]. Some studies report that chronically disturbed sleep affects daytime functioning (eg mood, energy, performance) and quality of life, and there is evidence that these sleep disturbances contribute significantly to increased health-care costs[27].

The prevalence rates of insomnia are even higher when taking into account the coexistence of other clinical or psychiatric conditions. Lifestyle changes associated with retirement, the higher incidence of health problems and an increased use of medication put older people at greater risk of sleep disturbances[27].

The consequences of chronic insomnia in the elderly result in slower reaction times and greater difficulty in maintaining balance, which brings an increased risk of falls. These falls are directly related to an increased risk of mortality. People also have attention and memory deficits as a result of poor or little sleep, which are symptoms that could be misinterpreted as those of mild cognitive impairment or dementia[25,28].

5. Concepts, definitions, clinical features and classifications

Questions to answer:

- What are the general concepts involved in sleep?
- What is the definition of insomnia as a complaint?
- What is the definition of specific clinical insomnia?
- How can insomnia be classified?

5.1 General concepts: sleep stages

Sleep is a state (or complex behaviour), different from wakefulness, with which it is closely related, with both expressing different types of brain activity. The two states are integrated into a functional unit known as the *sleep-wake cycle*, whose periodic onset is circadian and a result of the interaction of different areas at the brainstem, diencephalon and cerebral cortex.

Humans spend approximately one third of their lives sleeping. It has been shown that sleep is an absolutely essential activity, because physiological functions carried out during it are essential for the physical and psychological balance of individuals. It restores the homeostasis of the central nervous system and other tissues, restoring cellular energy levels and reinforcing the memory[29,30].

The duration of sleep at night varies among individuals and is between 4 and 12 hours, with the most frequent duration being 7-8 hours. However, even in the same person, the need for sleep varies according to age, health status, emotional state and other factors. The ideal time for sleeping is one that allows us to perform daily activities normally.

There are two distinct types of sleep: REM (Rapid Eye Movement) or paradoxical sleep and slow wave sleep, known as non-REM sleep (Non-Rapid Eye Movement). REM or paradoxical sleep is associated with high neuronal activity and dreams[31,32]. Non-REM sleep can be subdivided into four stages: Stage 1 is the shortest and corresponds to the lightest sleep stage; Stage 2 consists of more than 50% of the total time asleep; Stages 3 and 4 correspond to so-called delta sleep, which is the deepest and most restorative sleep [31,32].

Night time sleep alternates between non-REM and REM sleep in cycles (4-6 times). At the beginning of the night, delta sleep predominates, and occupies less time as sleep progresses, while the duration of REM sleep periods increase in subsequent cycles. Appendix 2 has a more detailed outline of the physiology of sleep.

When there are problems with sleep, and these exceed a certain intensity or the adaptive capacity of the person, they become pathological, and cause significant discomfort with symptoms that affect both the physical realm, as well as the psychological and behavioural.

The elderly

In general, the elderly do not sleep less than the rest of the population, but differently. The characteristics of sleep in older people differ in some respects with regard to other adults. This is important to realise, for both professionals and patients, as this can prevent inappropriate diagnosis and the patient will realise that what he perceives as pathological may be perfectly normal for his age.

With age, sleep becomes more distributed over a 24-hour period, caused both by the temporary disruption of physiological functions as well as the reduction and/or absence of external synchronisers. This results in a shorter nocturnal sleep and an increased tendency to sleep during the day.

REM sleep hardly changes at all with age, and the proportion remains stable in healthy subjects until very old age. The only change we find is in its distribution throughout the night: the first REM appears much earlier in older rather than younger subjects, and this increase disappears during the night. Thus, the first REM sleep is more longer-lasting than in younger people, without any significant differences in subsequent cycles.

From the standpoint of polysomnography, there is an increased number of arousals (see glossary) and a shorter duration of deep delta sleep.

A summary of the features of sleep in older people is shown in the following table.

Table 3. General clinical features of sleep in the elderly[33]

- The duration of nocturnal sleep decreases
- Tendency to take several naps or snoozes during the day
- More fragmented sleep
- Increased number of night time awakenings, which may last longer
- Decreased ability to recover after periods of sleep deprivation
- Reduced amount of sleep, with respect to time in bed
- Progressive reduction in the waking threshold with auditory stimuli (lighter sleep)
- Apparent tendency to earlier night time sleep and earlier wakening
- Increased perception of poor sleep quality, especially among women

5.2 Definitions, ethiopathogenia and pathophysiology of insomnia

• ***Insomnia:*** literally means "lack of sleep at bedtime" (from the Latin, *Insomnium*)[34]. However, in practice this term is used with very different meanings, which explains the great disparity in the prevalence results of epidemiological studies, as well as introducing some confusion in the clinical setting. In fact, insomnia as used in this guide should not be confused with voluntary or imposed deprivation or lack of sleep, nor with the "complaining of poor sleep", in which there is no impact on functioning the next day.

The most characteristic manifestations of insomnia are difficulty falling and staying asleep and waking up early. However, as shown by some epidemiological studies, people who suffer from these difficulties do not necessarily recognise they are suffering from insomnia[3]. Patients complaining of insomnia also complain of other symptoms during the day, such as mood disorders (eg, apathy), fatigue, difficulty performing daily tasks, cognitive impairment, drowsiness and others. Despite occasionally complaining of drowsiness, people with insomnia cannot sleep during the day, which is demonstrated by daytime polygraph records - as the multiple sleep onset latency test - and is recognised by patients when asked directly about it[35-38]. In fact, many authors believe insomnia to be a state of *hyperarousal* or a "waking disorder that lasts 24 hours a day". This becomes a problem affecting the person, both at night and by day[39]. Although there is no reference in current diagnostic manuals to difficulty sleeping during the day, it should be included in the definitions for insomnia. This would distinguish insomnia from other situations commonly encountered in the clinic, where night time sleeping may be disturbed and the patient is sleepy during the daytime and manages to sleep. This may be the case for a variety of diseases of different systems. However, some people can have this type of condition and develop a state of excessive activation lasting 24 hours, as occurs with insomnia.

Insomnia is considered to be a state of hyperarousal or a "waking disorder that lasts 24 hours a day", and therefore difficulty in sleeping during the day is characteristic.

• ***Sleepiness and fatigue:*** It should be emphasised that while patients with chronic insomnia may complain of drowsiness during the day, they actually find it difficult to sleep any time of day (including a nap, for example) and display high levels of tiredness (ie, fatigue). It is important that the practitioner differentiates between the two concepts, *sleepiness and fatigue*; not only to identify them in insomnia but also to rule out other problems linked to excessive daytime sleepiness.

– *Sleepiness* is the subjective feeling of physical and mental tiredness associated with an increased propensity to sleep. It is the typical consequence of sleep deprivation/poor sleep and is characterised by occasional sleeping during the day.

– *Fatigue* is a subjective sense of physical and mental tiredness that is not associated with an increase in sleep propensity. It is the state characteristic of disturbed sleep (insomnia) and is characterised by difficulty sleeping at any time of day, despite the physical and mental tiredness[40].

• ***Ethiopathogenia of insomnia:*** Factors contributing to the emergence, development and maintenance of insomnia are grouped into: predisposing, precipitating and perpetuating[14,41]. This division, based on the clinical course of the disorder in which various factors act, is indicative only, since in some aspects they may overlap.

➢ ***Predisposing factors:***

– *Sex, age, socioeconomic status and health status* are predisposing factors for insomnia[42].

– *Genetic*. There are few studies in this area, probably because of the difficulty in defining the phenotype. Some studies in twins and families suggest the inheritability of insomnia[42]. Although specific studies are needed, it seems that certain temperamental traits are inherited, such as a tendency to be emotional[43], which, for the purposes of insomnia, may result in a facility for alertness when in a stressful situation[44].

– *Psychological*. Traits found are, above all, *negative feelings* and a *tendency to brood*[14,45], which are difficult to distinguish from a *tendency to internalise emotions (inhibition of emotional expression)*, and have been associated with somatic hyperarousal states since the last century[46]. Nevertheless, some "models" artificially separate the emotional and cognitive in the genesis and development of insomnia. In addition, natural psychopathological predisposing factors have been widely documented in studies that have used operational criteria like those of DSM[47]. These have shown that almost all patients with chronic insomnia have symptoms and/or personality disorders/traits. The most common of these are dysthymic disorder, anxiety disorders and obsessive personality disorders/traits[47]. In addition, patients with chronic insomnia use stress coping strategies focused on emotion, which are less effective in problem solving and typically increase emotional arousal[48].

➢ ***Precipitating factors:***

The most common for chronic insomnia are those associated with *stressful situations*. Controlled studies have shown that the onset of chronic insomnia is preceded by an increase in stressful events[49].

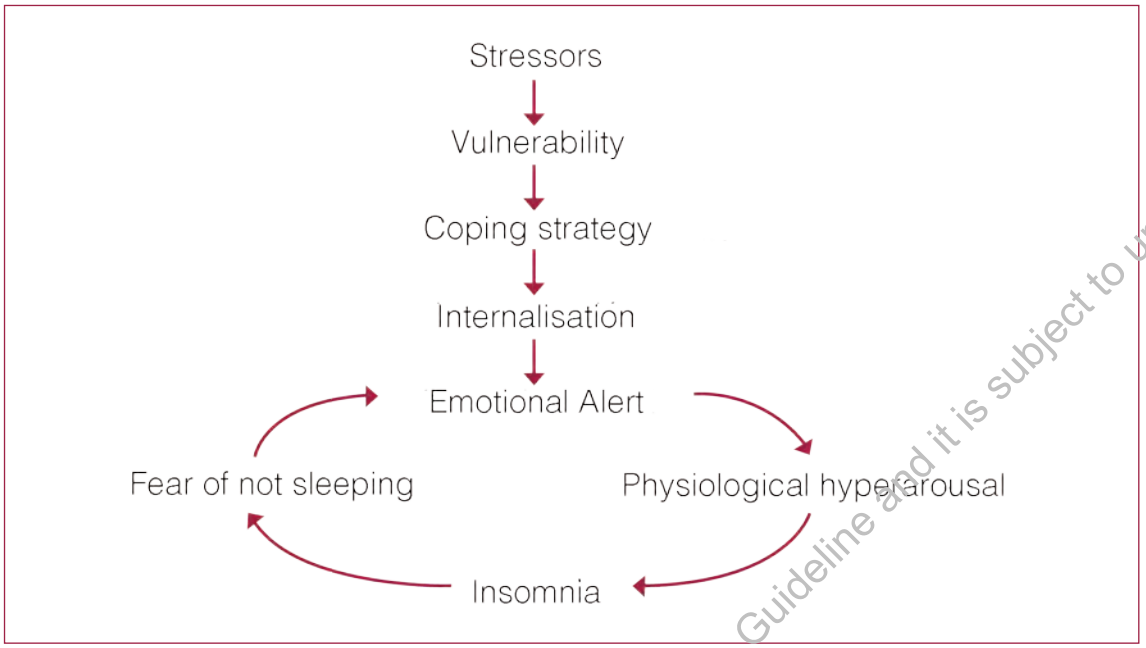
➢ ***Perpetuating factors:***

These are mainly related to the fear *of not sleeping and with non-adaptive beliefs and behaviours* (with the consequent development of incorrect habits) *in connection with sleep*[14,42,50].

• ***Pathophysiology of insomnia*** can be summarised as a *psychophysiological state of hyperarousal*. This has been demonstrated objectively in the areas of brain, vegetative and endocrine activity[51-53]. Overall, these studies have demonstrated hyperactivity of the two branches (CRH-ACTH-cortisol and sympathetic) of the response system to stress and alterations in the rate of secretion of proinflammatory cytokines (IL-6 and TNFá). This seems to be the physiological basis of common clinical complaints from people with chronic insomnia who cannot sleep during the day (or, to put it another way, not to display sleepiness during daytime), and instead are fatigued[53]. Several theoretical "models" have been proposed in recent years in this direction, which offer partial views to support the non-pharmacological techniques for treating insomnia[50].

An integrated view of the ethiopathogenic and pathophysiological factors of chronic insomnia is provided by the *hypothesis of internalisation (inhibition of emotional expression)*[14], see Figure 3.

Figure 3. Explanatory model of the components and mechanisms of chronic insomnia: the internalisation hypothesis



As shown in Figure 3, the interaction between stressful life events and the vulnerability of individuals is the source of insomnia. In particular, patients with insomnia set in motion stress coping strategies focused on emotion, typically the tendency to inhibit emotional expression (internalisation of emotion), to cope with these stressors. This results in a state of *excessive emotional arousal*, which causes *excessive physiological arousal* before and during sleep that prevents sleep, leading to *insomnia*. Once insomnia appears, a conditioning process is established that contributes to insomnia becoming chronic. This happens as follows: once a person has experienced insomnia, he develops a fear of *again sleeping badly and its consequences*, and therefore develops apprehension. After this, his attention focuses too much on insomnia. The *fear of insomnia* then itself produces an *emotional and physiological activation*, *which aggravates the existing excessive physiological arousal and leads to farther insomnia in a circular and escalating fashion*, which provides a conditional form of chronic insomnia. This hypothesis, in addition to an overall sense of the relationship between etiological factors (stress and coping) and pathophysiological (excessive emotional and physiological arousal and conditioned fear) has a clinical value, as it can be used to formulate a multidimensional treatment plan for a multifactorial problem such as chronic insomnia.

5.3 Clinical features of insomnia

Although patients with chronic insomnia mainly complain about the amount and/or quality of nocturnal sleep, insomnia as a disorder is clinically characterised by both daytime and night time events[39]. Therefore:

Essential features of chronic insomnia include a subjective complaint of insomnia (regarding the amount and/or quality of sleep) and daytime problems of a physiological, emotional and cognitive nature.

The clinical features of insomnia are shown in the following table:

Table 4. Features of insomnia by night and day

- Nocturnal sleep:
  - Difficulty in sleeping (+++)
  - Difficulties in maintaining sleep (+++)
  - Waking up early (+++)
  - Sleep not restorative (+++)
- Daytime functioning:
  - Fatigue (+++)
  - Symptoms of anxiety and depression (+++)
  - Dysphoria (+++)
  - Mild attention/concentration deficit (++)
  - Poor memory (+)
  - Deficits in executive functions (+)
  - Excessive sleepiness (+)
- Other associated features:
  - Personality disposed to worrying (+++)

Note: (+++) Features almost always present, (++) sometimes present, (+) not usually present.
Modified by Morin and Espie[16].

5.4 Classifications

There are many ways to classify insomnia, but for practical purposes they can be classified according to *etiology, time of night when it occurs* or *duration*.

- ***According to etiology***:
  - *Primary Insomnia*: which does not have a clearly identifiable etiological factor or is not associated with any other medical condition. It may be related to certain personality traits and coping styles.
  - *Secondary or comorbid insomnia**: appears as a consequence, or in the context of other medical condition(s) or adaptive situation.

*The term "secondary" has been recently replaced by "*comorbid*". The reasons given by the authors for this are: a) the limited understanding of the mechanisms in chronic insomnia which, according to these authors, prevents clear conclusions being drawn on the nature of the association between insomnia and other medical conditions, and therefore the causal relationship, b) the use of the term "secondary" may result in insomnia being considered as less important and therefore not adequately treated[20,54].

The practical implication of all this is that, although the patient may have insomnia as a new problem, the practitioner must consider whether it is primary insomnia or not.

Therefore, he must examine the consumption of substances that may interfere with sleep and the psychopathological traits of the patient, even if these are clinically subthreshold, whether in branch I or II of DSM-IV TR.

• ***According to time of night when it occurs***[55]:

– *Falling asleep*: the patient's complaints refer to difficulties in starting sleep. This usually occurs in the young, and is the most common form of insomnia linked to medical problems, drug abuse or certain psychiatric disorders, such as anxiety disorders.

– *Staying asleep*: The patient has trouble maintaining sleep, with frequent interruptions appearing and/or periods of wakefulness during the night. It is common in cases of psychological and medical problems associated with ageing[56].

– *Waking up early*: When waking occurs at least two hours earlier than normal for the patient.

• ***According to duration*** [30,57]*:*

– *Transient insomnia*: Lasting less than a week. This is the most common and widespread form among the population. In a period of one year, about one-third of the adult population have a problem with insomnia and, of those, about half have what is known as transient insomnia. It is often associated with precipitating stressors (eg, environmental causes, sudden changes in sleeping times, occasional physical stress, emotional crisis), and when they disappear, sleep returns to normal.

– *Short-term or acute insomnia*: Lasting between one and four weeks. It is related to stress factors, but more longer-lasting than for transitory insomnia.

– *Chronic insomnia*: Lasts for four or more weeks and may be due to intrinsecal causes in the organism, eg a long-term physical or psychiatric illness or it may have no apparent underlying cause.

DSM-IV TR defines *primary insomnia* as a sleep disorder characterised by difficulty in falling or staying asleep, or in not having restorative sleep, for at least 1 month. This causes significant discomfort or clinically significant impairment of the activity of the individual, and is not associated with other disorders (see Table 7). This definition seeks to encompass both the *primary* and chronic (duration) nature as the etiology. On the other hand, and as discussed in the next section, the International Classification of Sleep Disorders: Diagnostic and Coding Manual, 2nd edition (ICSD-2) uses the term *psychophysiological insomnia*, which focuses on the etiology and pathophysiology of primary insomnia. *Psychophysiological insomnia* is defined as the difficulty in sleeping and/or extreme ease in waking from sleep lasting for longer than a month, which is expressed by at least one of the following conditions: anxiety or excessive concern with sleep; difficulty falling asleep at bedtime or at other planned times, but not at other times of the day, while carrying out monotonous tasks when there is no intention to sleep; mental hyperactivity; intrusive thoughts or an inability to stop mental activity, which keeps the subject awake; improved sleep outside the bedroom or normal environment; excessive somatic tension in bed, making it difficult to relax and preventing sleep[58].

Diagnostic classification

There are universal criteria for diagnosing whether a person has a sleep disorder and, more specifically, insomnia. The diagnostic criteria vary according to the different classifications used.

The classifications used in Primary Care are:

– International Classification of Primary Care (ICPC-2)

– Classification of Diagnostic and Statistical Manual of Mental Disorders, 4th edition.(text Revision). Primary Care (Dsm-IV-Tr-Pc)

– International Statistical Classification of Diseases and related Health Problems (ICD-10)

– International Classification of Sleep Disorders: Diagnostic and Coding Manual, 2nd edition (ICSD-2)

– International Classification of the North American Nursing Diagnosis Association (NANDA-I)

– **International Classification of Primary Care (ICPC-2)**, World Organisation of National Colleges, Academies and Academic Associations of General Practitioners and Family Physicians (WONCA)[59]:

  The ICPC-2 is currently the most widely used classification in Spanish PC, and is installed in most electronic primary care medical records. The code, **PO6 sleep disorders**, includes insomnia and other disorders, such as nightmares, sleep apnea, sleepwalking and drowsiness. It does not include problems caused by changing time zone, eg, jet lag (A38).

  An inclusion criterion for insomnia is a significant sleep disorder in which the patient and general practitioner agree is not caused by another illness, but is an entity in itself. It is a qualitative or quantitative sleep disorder which is uncomfortable for the patient and lasts a considerable time. Equivalent codes in the *ICD-10 are F51 (non-organic sleep disorders) and G47 (sleep disorders)*.

– **Classification of Diagnostic and Statistical Manual of Mental Disorders, 4th revised edition. Primary Care (DSM-IV-TR-PC),** from the American Psychiatric Association (APA)[60]:

  A manual produced between PC and Psychiatry to diagnose mental disorders in Primary Care. All codes are from the DSM-IV-TR.

– **International Statistical Classification of Diseases and other Health Problems (ICD-10)**, World Health Organisation (WHO)[61]:

  The list of ICD-10 codes is the tenth version of the International Statistical Classification of Diseases and other Health Problems. It provides codes to classify diseases and a wide variety of signs, symptoms, abnormal findings, social circumstances and external causes of injury and/or disease. ICD-9-CM is an acronym for International Classification of Diseases, Ninth Revision, Clinical Modification, which is an earlier version of the current code, ICD-10.

– **International Classification of Sleep Disorders: Diagnostic and Coding Manual, 2nd edition (ICSD-2),** American Sleep Disorders Association (ASDA)[62]:

  The International Classification of Sleep Disorders is quite different in structure to the DSM-IV. This manual is focused solely on the diagnosis of sleep disorders. It features more than 80 discrete disorders, organised in eight categories and does not use an axial system, like the DSM. The ICSD-2 represents the consensus opinion of more than 100 sleep specialists from around the world. (http://www.aasmnet.org/).

  Table 5 below shows the classifications most used in our context for sleep disorders, and shows equivalences between them: the DSM-IV, TR-PC, ICD-9-CM and ICD-10 manuals (with their official codes).

Table 5. Classification of sleep disorders and equivalences between the DSM-IV-TR-PC, ICD-9-CM and ICD-10

ICD-9-CM	NON-ORGANIC SLEEP DISORDERS (ICD-10)	PRIMARY SLEEP DISORDERS (DSM-IV-TR-PC)
[327]	G47.x ORGANIC SLEEP DISORDERS	SLEEP DISORDER DUE TO … (indicates CONDITION)
[780.59]	G47.3 SLEEP APNEA	SLEEP DISORDER RELATED TO BREATHING
[291.82]	F10.8 SLEEP DISORDER DUE TO ALCOHOL	SLEEP DISORDER INDUCED BY ALCOHOL
[292.85]	F19.8 SLEEP DISORDER DUE TO MULTIPLE PSYCHOTROPIC DRUGS OR OTHER SUBSTANCES	SLEEP DISORDER INDUCED BY SUBSTANCES
[307.42]	F51.0 NON-ORGANIC INSOMNIA	INSOMNIA RELATED TO … (indicates BRANCH I or II DISORDER)
[307.44]	F51.1 NON-ORGANIC HYPERSOMNIA	HYPERSOMNIA RELATED TO … (indicates BRANCH I or II DISORDER)
[307.45]	F51.2 SLEEP-WAKE CYCLE NON-ORGANIC DISORDER	CIRCADIAN RHYTHM DISORDER (formerly sleep-wake schedule disorder)
[307.47]	F51.5 NIGHTMARES	NIGHTMARES (formerly dream anxiety disorder)
[307.46]	F51.4 NIGHT TERRORS (night terrors)	NIGHT TERRORS
[307.46]	F51.3 SLEEPWALKING	SLEEPWALKING
[307.47]	F51.8 OTHER NON-ORGANIC SLEEP DISORDERS	NON-SPECIFIC PARASOMNIA
[307.42]	F51.0 NON-ORGANIC INSOMNIA	PRIMARY INSOMNIA
[307.47]	F51.9 NON-SPECIFIC NON-ORGANIC SLEEP DISORDERS	NON-SPECIFIC DYSSOMNIA
[347]	G47.4 NARCOLEPSY	NARCOLEPSY
[307.44]	F51.1 NON-ORGANIC HYPERSOMNIA	PRIMARY HYPERSOMNIA

Finally, the International Classification of the North American Nursing Diagnosis Association (NANDA) is presented below:

– **International Classification of the North American Nursing Diagnosis Association (NANDA)[63]:**

NANDA (North American Nursing Diagnosis Association) is a scientific nursing society whose purpose is to standardise nursing diagnosis, while developing the nomenclature, criteria and taxonomy of such diagnoses. In 2002, NANDA became NANDA International. In 2006, the North American Nursing Diagnosis Association included the diagnosis of insomnia in its classification, defined as a "disorder of the quantity and quality of sleep impairing functioning". Table 6 lists the defining characteristics and factors associated with insomnia, according to the nursing criteria. Each related diagnosis includes an "expressed by" section (defining characteristics of individuals, families and communities who are observable and verifiable) and other "related with" (which are related factors providing the context for the defining characteristics).

Table 6. NANDA characteristics and factors related to insomnia

00095. INSOMNIA
Defining characteristics
– Observation of changes in emotional states. – Observation of low energy. – Increased absenteeism from work or school. – The person reports mood swings. – The person reports a decline in health status. – The person reports difficulty in concentrating. – The person reports difficulty in sleeping. – The person reports difficulty in staying asleep. – The person reports dissatisfaction with their sleep (currently). – The person reports an increase in accidents. – The person reports lack of energy. – The person reports sleep as nonrestorative. – The person reports sleep disorders with consequences the following day. – The person reports waking up too early. – The person reports a reduction in their quality of life.
Related factors
– Pattern of activity (eg, time, quantity). – Anxiety. – Depression. – Environmental factors (eg, noise, exposure to daylight/darkness, temperature/humidity, unfamiliar environment). – Fear. – Hormonal changes related to sex. – Bereavement. – Inadequate sleep hygiene (current). – Taking stimulants. – Taking alcohol. – Impairment of normal sleep pattern (eg, due to travel, change of work, parental responsibilities, interruptions due to interventions). – Drugs. – Physical discomfort (eg, body temperature, pain, shortness of breath, coughing, gastroesophageal reflux, nausea, incontinence/urgency). – Stress (eg, ruminative pre-sleep pattern).

6. Diagnosis of insomnia

Questions to answer:

- What are the diagnostic criteria for insomnia?
- What are the differential diagnoses to consider?
- Are there any key questions that can help primary care (PC) professionals detect insomnia in an interview with the patient?
- What tests or tools can be used for the diagnosis of insomnia in PC?

As an aid in diagnosis, the following should be taken into account: the night time and daytime clinical characteristics of insomnia mentioned in the previous chapter (see Table 4), the diagnostic criteria (presented here in stepwise fashion) and a diagnostic algorithm prepared from these steps.

6.1 Diagnostic criteria

The scheme established in the DSM-IV-TR-PC manual[60] is proposed in the form of modified steps. The sleep disorder symptoms must comply with the diagnostic criteria established for the diagnosis of *primary insomnia*.

Step 1

Consider the role of a medical condition or substance use and take into account whether the sleep disturbance can be better explained by another mental disorder:

1A. Consider the role of medical conditions.

Sleep disorder due to... (indicate medical condition, other than breathing-related sleep disorder).

1B. If the subject is indulging in substance abuse or taking medication, consider:

Sleep disorder induced by substances (including medication).

1C. Consider the role of other mental disorders.

Insomnia related to another mental disorder.

Hypersomnia related to another mental disorder.

Step 2

Consider if the sleep disturbance is related to frequent changes in time zones or shift work:

Circadian rhythm disorder (formerly, sleep-wake schedule disorder).

This disorder includes *delayed sleep* (when the sleep-wake cycle is delayed in relation to society demands), *jet lag* (related with frequent travel to different time zones), *shift work changes* or *non-specific*.

Additional information: Complaints must be distinguished and attributed to either external, intrinsic or circadian rhythm factors. For many PC patients, the causes of insomnia are related to their environment, especially the effects of light, temperature or noise; sleeping in different environmental conditions than usual; or changes in people's schedules caused by work shift rotations.

Step 3

Consider if the symptoms are basically events that occur during sleep:

3A. If there are repeated awakenings with memories of terrifying dreams, consider:

Nightmares (formerly, dream anxiety disorders).

3B. If there are repeated awakenings without remembering them or the content of dreams, consider:

Night terrors.

3C. If the individual gets up and walks during sleep without waking, consider:

Sleepwalking.

3D. If clinically significant events occur during sleep, but none meets the criteria for any of the above parasomnias, consider:

Non-specific parasomnia.

Step 4

Consider breathing-related sleep disorders:

If the sleep disorder is associated with a history of snoring or obesity, consider:

Breathing-related sleep disorder.

Step 5

Consider if the primary symptom is insomnia (ie, difficulty in falling or staying asleep):

5A. If there is difficulty in falling or staying asleep lasting for more than 1 month, consider:

Primary insomnia

Difficulty in falling or maintaining sleep, or the feeling of not having had a good sleep for at least 1 month (criterion A). Sleep disturbance is related with daytime fatigue, causing clinically significant distress or impairment in social, occupational or other important area of functioning (criterion B).

Additional clinical information: The diagnosis of Primary Insomnia can only be established once other possible causes of insomnia have been ruled out. It is therefore essential to carry out an appropriate history to consider all possible secondary causes of insomnia (see Table 7).

Table 7. Diagnostic criteria for Primary Insomnia, according to the DSM-IV-TR[64]

- Diagnostic criteria for Primary Insomnia

A. The predominant complaint is difficulty initiating or maintaining sleep, or nonrestorative sleep, for at least 1 month.

B. The sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

C. The sleep disturbance does not occur exclusively during the course of Narcolepsy, Breathing-Related Sleep Disorder, Circadian Rhythm Sleep Disorder, or a Parasomnia.

D. The disturbance does not occur exclusively during the courseof another mental disorder (e.g., Major Depressive Disorder, Generalized Anxiety Disorder, a delirium).

E. The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

To assess the severity of chronic primary insomnia, there are several items that operationally define and evaluate the clinical significance of it (see Table 8).

Table 8. Criteria for defining the severity of insomnia.

- Impaired night time sleep:
  - Sleep onset latency or Wake time after sleep onset, greater than 30 minutes.
  - The last awakening occurs more than 30 minutes before the desired time and before the total sleep time reaches 6½ hours.
  - Percentage of sleep obtained with respect to time in bed (sleep efficiency) is less than 85%.
- Frequency:
  - Difficulties in sleeping happen three or more nights a week.
- Duration:
  - Difficulties with sleep and/or the complaint of insomnia last for more than 1 month (DSM-IV criteria).
- Impaired daytime functioning:
  - The patient scored 3 or 4 in items 3 and 5 of the Insomnia Severity Index (ISI; Appendix 6)*.

Modified from Morin and Espie[16] and Lineberger[65].
*Although it is advisable to supply the entire ISI, these items can be used in the form of structured questions for a more rapid assessment.

5B. If there is clinically significant difficulty in falling or staying sleep which persists for at least 1 month, consider:

Non-specific dyssomnia (see Step 7).

Step 6

Consider if the primary symptom is excessive sleepiness:

6A. If there is a pattern of excessive sleepiness accompanied by sleep attacks and episodes of loss of muscle tone, consider:

Narcolepsy.

6B. If excessive sleepiness causes distress or significant disturbances, consider:

Breathing-related sleep disorder.

6C. If excessive sleepiness occurs as prolonged episodes of sleep or regular naps for at least 1 month, consider:

Primary hypersomnia.

6D. If excessive sleepiness causes distress or impairment but lasts less than 1 month, consider:

Non-specific dyssomnia (see Step 7).

Step 7

Consider if there are clinically significant sleep disturbances, but they do not meet the criteria for any of the disorders described above:

Non-specific dyssomnia

In this category are the clinical symptoms of insomnia, hypersomnia or circadian rhythm disturbances that do not meet criteria for a specific dyssomnia. The clinician can determine the presence of a sleep disorder, but is unable to determine whether it is primary, due to a medical condition or related to substance use.

Step 8

If the clinician has determined that there is no disorder but wants to indicate the presence of symptoms, consider:

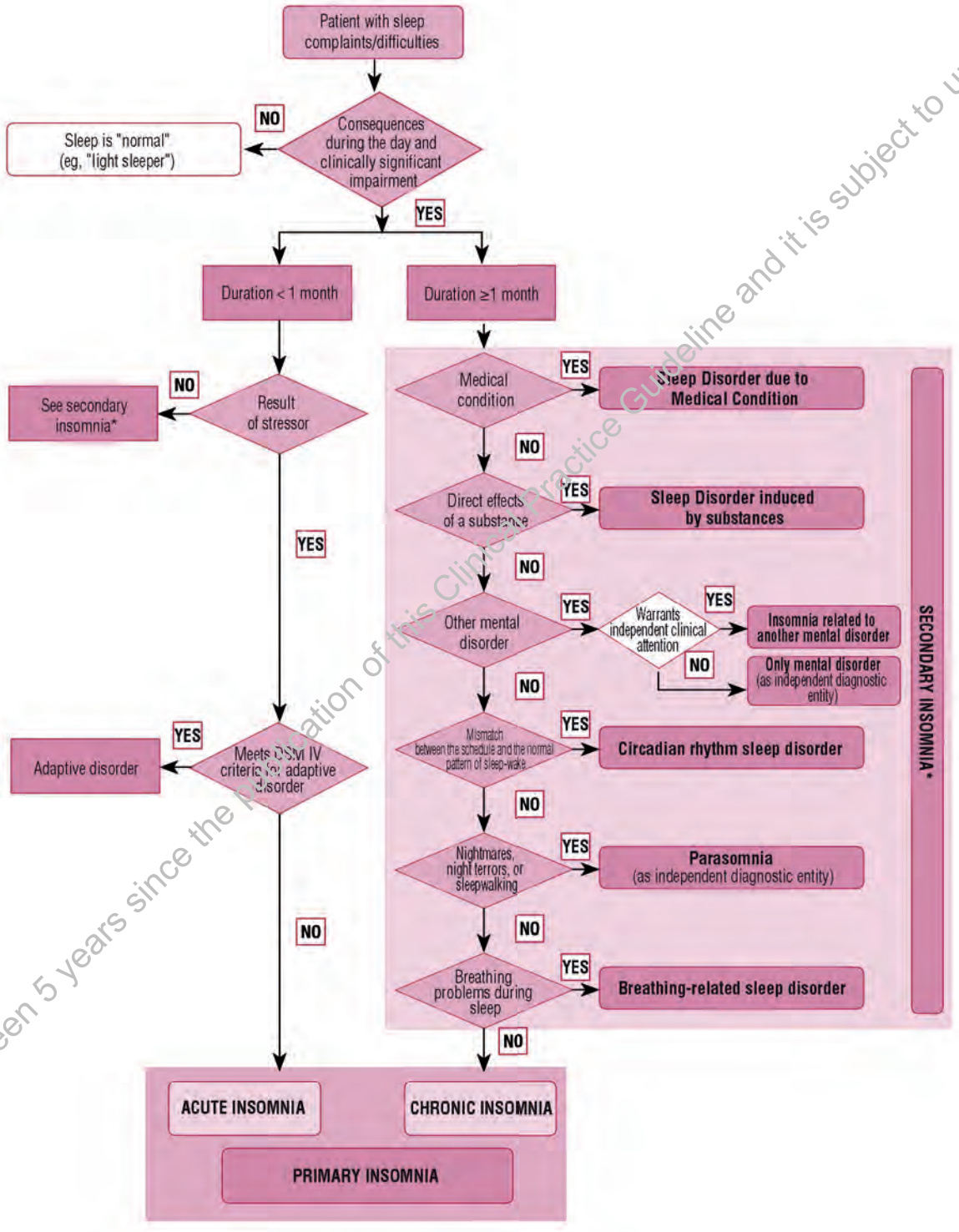
Sleep disturbances, anxiety dreams

Insomnia

Excessive sleepiness

6.2 Diagnostic algorithm

The following diagnostic algorithm is given as an initial guide for a patient with sleep complaints/ difficulties:



6.3 Assessment of insomnia

6.3.1 Clinical interview

The diagnosis of insomnia is mainly clinical and the instrument of choice is the clinical interview.

The semi-structured interview (combining the two types of interview: the free interview and the structured interview) is modified according to the practitioner-patient encounter occurring in the PC field. This interview takes a biological, psychological and social approach (taking in the "whole person"), focuses on the patient as an expert in himself, seeks agreements with the patient and integrates time management in the consultation.

The interview starts with open questions (with content partially predetermined by the practitioner), supports the response of the patient and is then directed towards specific or closed questions essential for identifying and managing the problem. The different parts of the semi-structured interview are described in the following table[66-69].

Table 9. Semi-structured interview phases

Semi-structured interview phases[70-72]			
Preliminary	Exploratory	Decisive	Final
• Warm welcome • Establish the reason for visit • Prevention of additional requests: Avoid "now that I'm here", etc and identify the reasons for consultation	• Get basic specific information – Symptoms – Location – Intensity – Chronology and evolution • Collect additional specific information – Presence of pathology: organic or iatrogenic – Triggers: changes, pain... – Social and family environment – Personal history: manic episodes, previous depression • Psychological and social exploration – Beliefs and expectations – Thought content – Affectivity – Personality	• Synthesis and enumeration of problem(s) • Patient information on the nature of the problem • Check understanding of explanations • Involving the patient in preparing a diagnostic and therapeutic plan – Agreements – Negotiation – Commitment	• Taking precautions • Final agreement • Farewell

The information is completed in the exploratory phase. As usual at this stage, the PC practitioner and the rest of the team will already have collected much of the psychological, social and additional information of the patient, which facilitates the process. The decisive step is to redirect the beliefs about insomnia through health information and education. The final phase of the interview is where the final agreement must be emphasised, such as changing ideas and reaching understandings[70-72].

6.3.2 Anamnesis: Key questions

As described above, insomnia is a complex clinical problem, with many factors involved in its origin, development and maintenance. It is therefore advisable to make a full assessment in this regard.

For *acute insomnia*, assessment is usually easier and, if associated with a stressful situation, the procedures are similar to those used in crisis intervention. They are based on the interview, through which information is obtained about the person and the situation. Questions are asked about the beginning and the clinical course of insomnia and its relationship with the trigger situation. Possible precursors in the development of chronic insomnia should also be identified, such as ways of coping based on internalisation, vulnerability factors in childhood and poor sleeping habits.

For *chronic insomnia*, as well as general aspects of the whole clinical history (social and demographic factors, details of the complaint), the assessment should include a sleep history, general medical history, psychiatric history, medication history and substance use.

A series of guide questions are included in Appendix 3 to help in preparing the *sleep history*. For the patient interview where insomnia is suspected, there are also some *key questions* in Appendix 4, which follow the diagnostic criteria of the DSM-IV-TR, with some additional questions.

These questions can be used as a guideline to help health professionals detect primary insomnia and perform a differential diagnosis with other sleeping problems or disorders[73-75].

In some cases, information from the person who sleeps with a patient is also crucial, because they can report any signs of abnormal movements during sleep or if apnea syndrome, among other complaints, are present. If this is not possible, it is important to ask the patient if anyone they share a bed or room with has commented on these aspects. In addition, the family, together with the patient, can also provide crucial information for monitoring the impact of insomnia in different areas of the life of the sufferer.

Furthermore, knowledge of the sleep-wake schedule for 24 hours a day is essential for differentiating insomnia disorders from circadian sleep-wake rhythm, so a *sleep diary* is a useful tool in PC. If the cause of insomnia is not clear, the health practitioner may suggest the patient keeps track of the time he goes to bed, stays awake in bed before falling asleep, how often he wakes during the night, what time he gets up in the morning and how he feels in the morning (sleep quality).

A sleep diary can help identify patterns and conditions that may be affecting the sleep of a person. It also helps in monitoring the patient's progress, providing a self-assessment of their problem[73,75]. The sleep diary does not have to alter the evaluation or the patient's sleep, but does require some time to get used to, so it is recommended to do it for at least 2 weeks. This time

period allows a more reliable baseline and will therefore be more representative of the patient's sleep patterns. It also serves as a tool for evaluating treatment, when it should be used for at least two months[16]. Appendix 5 contains an example of a **sleep diary**, which can be adapted to personal needs and characteristics if the clinician or patient deem it appropriate. As well as an assessment tool, it can also act as a springboard for dialogue between both parties[76].

6.3.3 Using insomnia questionnaires

Scales are measuring instruments to help complete a proper assessment of the patient's problem, as they reinforce the initial diagnosis made after the clinical interview and mental status examination. Scales by themselves do not provide a diagnosis, but allow people with high marks in the suspected pathology to be selected, thus justifying further study[77].

Scales in insomnia do not lead to mass screening. It is therefore not feasible or desirable to use scales routinely for clinical purposes in PC, and they must never replace the clinical interview. However, they are useful to guide the interview and to support clinical judgment. They have also become essential tools in the field of clinical research, as well as checking the effect of different therapeutic interventions on the evolution of the condition[72-75,77-80].

Some of the scales that may be useful for insomnia in PC are:

1) Insomnia Severity Index (ISI). A simple, short, self-administered questionnaire. It consists of seven sections: The first assesses the severity of insomnia (divided into three items), while the rest are used to measure the satisfaction of sleep, interference in daytime functioning, the perception of the sleep problem by others and the patient's level of concern[81]. Diagnostic Studies III

2) Pittsburgh Sleep Quality Index (PSQI) A self-administered questionnaire of 19 sections that analyse different determining factors of sleep quality, grouped into seven components: quality, sleep onset latency, duration, efficiency, sleep disturbances, use of sleep medication and daytime dysfunction. It can guide the clinician on the most affected parts of sleep. At a cut-off point of 5, it had a sensitivity of 88.63%, a specificity of 74.99% and a PPV of 80.66%[82]. Diagnostic Studies III

3) Pre-Sleep Arousal Scale (PSAS). A self-administered scale of 16 sections divided into two subscales: somatic and cognitive. It is considered useful to identify cognitive features associated with sleep and it may help in screening for or detecting persons with disturbed sleep[83]. Diagnostic Studies III

4) Epworth Sleepiness Scale (ESS). Self-administered questionnaire of 9 sections, which provides information about the patient's sleepiness during the day[84]. Diagnostic Studies III

Two of these scales are included in Appendix 6, the **Insomnia Severity Index (ISI)** and the **Pittsburgh scale (PSQI)**, as the guide working group felt that these were easy to handle and interpret in the field of PC.

Evidence on the assessment of insomnia

4	There are key questions for use in Primary Care to help detect primary insomnia and to rule out other sleep problems or other disorders[73-75].
4	A sleep diary, kept for at least a fortnight, is useful in Primary Care to find out about sleeping and waking times 24 hours a day, and to differentiate insomnia disorders from circadian sleep-wake rhythm. Also, if used for used at least two months, it can help in monitoring the progress of the patient, by providing a self-assessment of the problem[73,75].
III	The Insomnia Severity Index (ISI) is an internationally validated self-administered questionnaire for assessing the severity of insomnia. It also measures sleep satisfaction, interference with daytime functioning, perception of the sleep problem by others and the level of concern[81].
III	The Pittsburgh Sleep Quality Index (PSQI) is a self-administered questionnaire that analyses different determinants of sleep quality, giving guidance on the most damaged parts of sleep. At a cut-off point of 5, its sensitivity was 88.63%, its specificity 74.99% and PPV 80.66%[82].

Recommendations on the evaluation of insomnia

√	In *acute insomnia*, an interview to assess the clinical onset and course of insomnia and its relationship with potential trigger situations is recommended. In addition, possible precursor factors of chronic insomnia (vulnerability and poor sleep habits) must be identified.
√	In *chronic insomnia*, the interview should include sociodemographic factors and detailed characteristics of the complaint, as well as the psychiatric, sleep and substance use history. Information provided by the family and anyone who sleeps with the patient must also be taken into account.
√	Key questions are recommended to help detect insomnia, and to rule out other sleep problems or other disorders (Appendices 3 and 4).
D	It is recommended to use a 2-week sleep diary to get to know the sleeping and waking times of the patient to differentiate primary chronic insomnia from other conditions. It can also be used to assess the treatment and monitor the patient's progress if kept for at least two months.
C	To assess the severity of insomnia, it is recommended to use the self-administered questionnaire *Insomnia Severity Index* (ISI), see Appendix 6.
C	The self-administered questionnaire Pittsburgh Sleep Quality Index (PSQI) is recommended to assess the quality of sleep in insomnia or the presence of other sleep disorders, as it includes information from the person with whom the patient sleeps (Appendix 6).

7. Treatment of insomnia

Questions to answer:

- What constitutes effective insomnia treatment?
- What are the most effective psychological therapies for insomnia?
- What are the most effective drugs for treating insomnia?
- Are there effective measures to prevent this disorder from becoming chronic?

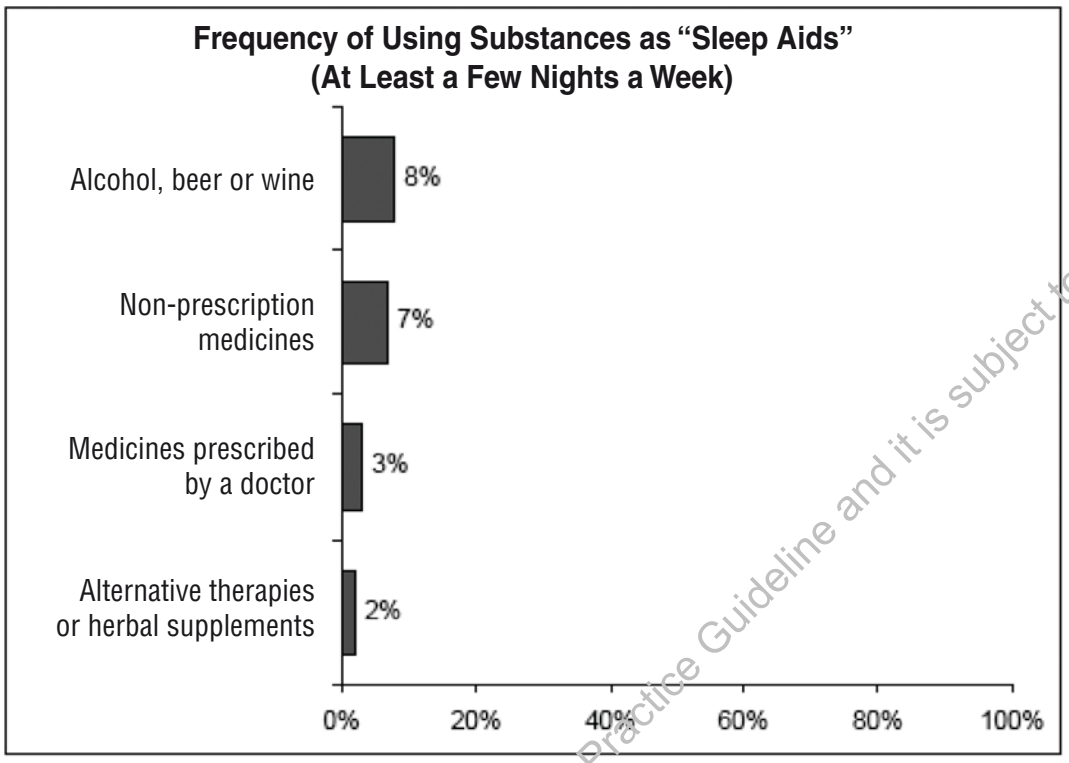
The diversity of hypotheses about the origin, development and maintenance of insomnia mean a global view of it is required. So, before resorting to any treatment, it is essential to identify the type of insomnia and its causes, as sometimes it may be symptomatic of other disorders.

The main objective of Primary Care insomnia treatment is to improve the level of satisfaction with sleep, by focusing on interventions that promote it positively. It has to be an integrated therapeutic approach, which takes into account all contributing factors. This will lead to improving sleep quality and quantity, reducing sleep onset latency and nocturnal awakenings, increasing the total time asleep and improving day-time functioning.

A survey of general practitioners conducted in France (n = 6,043) stated that 60% of physicians do not prescribe medication at the start and, when prescribing hypnotics, 81.3% do so by suggesting sleep hygiene measures as well as the medication[85].

In a US survey, the general population was asked about the different options used to help sleep and how often they are used. 8% of people said they drank alcohol at least two nights a week, 7% used pharmaceutical products from chemists, 3% took medication prescribed by their doctor and 2% preferred alternative therapies, such as acupuncture, melatonin, or other herbal preparations, such as valerian. These data are shown in Figure 4[5].

Figure 4. Frequency of Using Substances as "Sleep Aids"[5]



Total sample of general population, n = 1,000

THERAPEUTIC INTERVENTIONS:

Insomnia treatment interventions can be classified as follows:

– Health education

– Sleep hygiene education

– Psychological therapies

– Pharmacological therapy

– Other treatments

The types of outcome measures used to evaluate the efficacy and/or effectiveness of these interventions are summarised in Appendix 7.

7.1 Health education

As well as healing sick patients, Primary Care is also concerned with the health promotion of individuals and the community. One method used to achieve this goal is health education for both individuals and the whole population[86].

For patients with insomnia, this means providing information about both understanding the source of the problem (etiology, epidemiology) and learning the measures to be taken to resolve it (treatment and relapse prevention)[76]. It is an intervention that professionals usually put in place before starting any insomnia treatment, regardless of the therapeutic action chosen.

CPG (SR and RCT) 1+

Patients need to receive adequate information about their health problems, so that they can also be involved in the decision-making process (shared decision-making). Studies have been unable to unequivocally confirm, however, the effectiveness of this intervention for the treatment of insomnia[76,87].

CPG (SR and RCT) 1+
4, Qualitative Research

The practitioner seeks to correct misconceptions about the sleep cycle, its problems and therapeutic measures, which in some areas is known as "psychological education" (see Appendix 8). By taking into account the views of the patient regarding his sleep problem, the practitioner can make better use of the information obtained when implementing therapeutic interventions for insomnia[76,88].

CPG (SR and RCT) 1+
4, Qualitative Research

The essential points on which to base the intervention are the following[76]:

Expert opinion 4

1. Sleep structure.
2. Influence of age on sleep structure.
3. The number of hours of sleep needed and individual variations.
4. The prevalence of insomnia.
5. Sleep as a reflection of daytime functioning and vice-versa.
6. The importance of conditioning.
7. The mental processes that cause a vicious circle to start.
8. The role and purpose of medication in the treatment of insomnia, and the effect of substances such as alcohol.
9. Clarification of the goals and objectives of the treatment to suit expectations.

Appendix 9 includes information about the therapeutic objectives of this intervention for both practitioners and patients.

Evidence on health education for insomnia

1+,4, I.Qualit. R	Studies have been unable to unequivocally confirm the efficacy of this intervention for the treatment of insomnia[76,87].
4, I. Qualit. R	Adequate information for patients about their health problems helps them get involved in the decision-making process (shared decision-making)[76,87].
4, I. Qualit. R	The practitioner can help correct misconceptions about the patient's sleep cycle, its problems and therapeutic measures[76,88].
4, I. Qualit. R	Knowing the patient's conceptions of their sleep problems can help health practitioners optimise the therapeutic proposal to be followed[76,88].
4	Appropriate interventions in health education for insomnia should be based on: sleep structure, influence of age on sleep structure, number of hours of sleep needed and individual variations, the prevalence of insomnia, sleep as a reflection on daytime functioning and vice versa, the importance of conditioning, the mental processes causing a vicious circle to start, the role and purpose of medication in treatment, the effect of substances such as alcohol and clarifying the goals and objectives of the treatment to suit expectations[76].

Recommendations on health education for insomnia

Q	The ideas, concerns and expectations of the patient regarding sleep complaints should be discussed with the patient, in order to be able give further information and correct any misconceptions.
D	Health education for insomnia should be based on: the structure of sleep, influence of age, the number of hours required and individual variations, prevalence of insomnia, sleep as a reflection on daytime functioning and vice versa, the importance of conditioning and mental processes that lead to a vicious circle, the place of medication in treatment, the effect of certain substances and the clarification of treatment goals to adjust to expectations.

7.2 Sleep hygiene education

Sleep hygiene measures include a series of behavioural habits that facilitate falling and staying asleep and are the common denominator in all therapeutic interventions used for sleep disorders.

Sleep hygiene measures includes a series of recommendations that people with sleep problems can adopt to minimise the impact of their problem and promote normal sleep. The process consists of acquiring habits which are suitable for a general lifestyle (eg, physical activity) or of changing those that are known to interfere with sleep, such as using drugs or substances that make it harder to sleep.

Key sleep hygiene measures for insomnia are based on the following[73,74,76,89]: **CPG (SR and RCT) 1++,1+**

1. Going to bed only when sleepy.
2. Getting up every day at the same time, including weekends.
3. Avoiding staying in bed awake longer than necessary.
4. Avoiding daytime naps.
5. Reducing or stopping consumption of alcohol, caffeine, hypnotics.
6. Not eating heavy meals before bedtime.
7. Maintaining appropriate environmental conditions for sleep (regarding temperature, ventilation, noise, light).

8. Avoiding stressful activities in the hours before bedtime.

9. Doing some moderate physical exercise at the end of the evening.

10. Practising relaxation exercises before bedtime.

11. Having a bath with the water at body temperature for its relaxing effect.

Appendix 9 expands on the information on these measures.

CPG (SR and RCT) 1++,1+ SR of RCT 1++,1+

Studies published on the efficacy of sleep hygiene measures agree that by themselves these measures are unable to resolve chronic insomnia. There is also no information on their effectiveness in the treatment of acute insomnia. In fact, most of the time these measures were used in studies as an adjunct to other therapeutic interventions[73,74,76,90,91]. They are included in the majority of treatments, despite their impact on sleep being minimum when used as the only intervention[90,91].

CPG (SR and RCT) 1+ SR 1+

In terms of sleep efficiency, there are studies that compare sleep hygiene as monotherapy compared with a combination therapy (sleep hygiene plus stimulus control or plus more relaxation or more sleep restriction). In general, the study results show the combination therapy to be more efficient[76,92].

Evidence of sleep hygiene education for insomnia

1++,1+	Sleep hygiene measures alone are not able to resolve chronic insomnia[73,74,76,91].
1++/1+	There is no data on the efficacy of sleep hygiene measures for the treatment of acute insomnia[73,74,76,91].
1++,1+	Sleep hygiene measures are often used as an adjunct to other therapeutic interventions[73,74,76,91].
1+	A combination therapy of sleep hygiene plus stimulus control, more relaxation or more sleep restriction has better results in terms of sleep efficiency than sleep hygiene as monotherapy[76,92].

Recommendations on sleep hygiene education for insomnia

A	Sleep hygiene education is recommended in the treatment of chronic insomnia as an adjunct to other psychological and pharmacological therapeutic interventions.
A	To achieve greater sleep efficiency, a combination therapy is recommended, that includes one of the following techniques in addition to sleep hygiene education: stimulus control, relaxation therapy or sleep restriction.

7.3 Psychological therapies

Psychotherapy is an interpersonal communication process between an experienced practitioner (therapist) and a subject in need of help for health problems (patient). The aim is to make changes to improve the health of the patient by removing or modifying existing symptoms, modifying or changing behaviour and/or promoting the growth and development of a positive personality[93,94]. The psychotherapeutic approach of insomnia arises mainly from the viewpoint of behavioural interventions and cognitive behaviour. This guide focuses primarily on the models of behavioural interventions and cognitive behaviour as most applicable research concerns these fields.

Behaviour therapy and cognitive behavioural therapy (CBT)[95,96]

Behaviour therapy considers the symptoms as a learning of maladaptive behaviour patterns and aims at correcting these through different intervention techniques.

Cognitive behavioural therapy (CBT) includes a set of techniques that incorporates elements of both behaviour therapy and cognitive therapy. It takes into account affective and cognitive processes (expectations, beliefs, thoughts), whose distortion leads to symptoms; and its objective is the identification and analysis of these dysfunctional thoughts and beliefs, their relationship with the symptoms, and the construction of more adaptive and functional behaviour patterns.

Cognitive behavioural therapy (CBT) is characterised by an active and direct method, with patient and therapist working together in a structured fashion, with tasks outside the meeting.

In the treatment of insomnia, both behavioural techniques - relaxation and breathing, stimulus control, sleep restriction and paradoxical intention - as well as cognitive behavioural therapy that combines cognitive restructuring as a cognitive element are used, with one or more behavioural interventions.

The main purpose of *behavioural techniques*, applied to the treatment of insomnia, is to change behaviours and cognitions learned with regard to sleep, which are factors that perpetuate or exacerbate sleep disturbances. These factors may be due to poor sleeping habits (such as staying too long in bed), irregular sleep-wake patterns (waking up at different times) or psychophysiological hyperactivation. *Cognitive techniques* are aimed at identifying and analysing thoughts and dysfunctional beliefs in relation to sleep or the consequences of insomnia. It also aims to reduce anticipatory anxiety (fear of not sleeping) that occurs before going to bed which prevents sleep from coming. Once the therapy is finished, the person may occasionally have some difficulty sleeping. The CBT then has another implicit goal which is to teach patients effective skills to cope with such problems after therapy.

Over the past decade, advances in the treatment of insomnia from the cognitive and behavioural perspectives have been significant and therapeutic interventions well accepted by patients. However, despite these advantages, this type of treatment is still largely unknown. Moreover, behavioural therapies and CBT for insomnia are used little in PC, and can be said to be under-used[97].

At the level of treatment of insomnia, psychological interventions have focused on such behavioural techniques alone, or in combination with each other, and on cognitive behavioural therapy interventions.

CBT is a psychotherapy model that works with the ideas the patient has about sleep, its problems at bedtime and ideas about managing these problems[76]. In the treatment of insomnia, CBT combines cognitive techniques - cognitive restructuring, paradoxical intention - with one or more behavioural techniques.

The following additional guidance is presented as a table describing CBT interventions that are often used in the treatment of insomnia.

Table 10. Description of behavioural and cognitive techniques used for the treatment of insomnia[69,72,95,96,98-100]

Intervention	Description
Stimulus Control	– Based on the principles of classical conditioning: it associates the use of the bed with sleep. – The main objective is to re-associate the bedroom with a rapid onset of sleep. – Establishing a set wake-up time stabilises the sleep-wake rhythm. – Activities acting as cues for staying awake are gradually restricted.
Sleep restriction	– Intervention to consolidate sleep, shortening the time spent in bed to increase the sleep efficiency of sleep. – It involves restricting the allowed time in bed to match the average time people spend sleeping.
Relaxation therapies and breathing	– To reach a state of hypoactivation to counteract and help control anticipatory anxiety. It is presented and practised to reduce the somatic arousal levels of the person rather than as a method to induce sleep. • Training in progressive relaxation. • Training in breathing control. – The main techniques include progressive muscle relaxation, diaphragmatic or abdominal breathing, relaxation in directed imagination and biofeedback.
Cognitive restructuring techniques	– To replace irrational or distorted thoughts with more rational ones. The work is structured in a skills training model to help patients develop the ability to identify maladaptive cognitions, to compare them with reality and defuse them by generating their own rational thoughts. – Used to identify dysfunctional beliefs, attitudes, expectations and attributions a person may have about sleep, and to restructure them by replacing them with others of more adaptive value. – In the long term, they can be used to overcome all the concerns relating to sleep and to eliminate the anxiety associated with poor quality and quantity of sleep or inability to sleep.
Paradoxical intention	– This assumes that an important part of the sleep problem are the attempts to try to resolve it and the anxiety produced by failure to control sleep. – The patient is asked to do the opposite, ie to strive not to sleep.

Studies in the field of Specialised Care

The Clinical Practice Guidelines revised for the preparation of this guide consider behavioural interventions and CBT as a treatment for primary chronic insomnia[73-75].

CPG (SR and RCT) 1++,1+

The meta-analyses, systematic reviews and randomised clinical trials (RCTs) included in the HAS guide[73] evaluate the efficacy and/or length of the effects of behavioural interventions, for the following types: stimuli control, sleep restriction, relaxation and biofeedback compared to a control group. The parameters studied were sleep onset latency, nocturnal sleep maintenance, total sleep time and in some cases the quality of sleep, daytime functioning and quality of life. The results were analysed separately, depending on whether they were obtained by subjective or objective methods. The conclusion was that behavioural intervention and CBT demonstrated their effectiveness in reducing sleep onset latency and maintenance of sleep at night, but not with total sleep time[73].

CPG (meta-analysis) 1++

When comparing CBT treatment with either a control group or an alternative drug treatment, the conclusion was that psychological intervention showed superior effectiveness in reducing sleep onset latency and the number of nocturnal awakenings as well as in improvement in daytime functioning and quality of life. But no significant change was found in total sleep time. The long term duration of the effects ranged between 6 months, 12 months and 2 years after treatment[73].

CPG (SR and RCT) 1++,1+

CBT also helps in reducing the consumption of drugs and psychotropic substances, especially for older patients, and appears to contribute to more cost-effective, long-term drug treatment.

Among the various behavioural interventions, stimulus control is the most effective, followed by sleep restriction. There is controversy over the effectiveness of relaxation and the combination of behavioural interventions was no more effective than stimulus control and sleep restriction alone[73].

CPG (SR and RCT) 1++,1+

For Canadian and American guidelines, the initial focus of insomnia treatment should include at least the following: a behavioural intervention such as stimulus control or relaxation therapy, or a combination of cognitive therapy, stimulus control, sleep restriction and/or relaxation: this is known as cognitive-behavioural therapy (CBT) for insomnia. These guidelines recommend that when the initial psychological intervention proves ineffective, it be replaced with a different one or by a combination of psychological techniques, and that pharmacological interventions are used as adjuvants for non-pharmacological treatment[74,75].

CPG (different types of studies 2++, expert opinion 4)

There are other systematic reviews that provide additional information to support the use of stimulus control interventions, relaxation therapies, paradoxical intention, sleep restriction, cognitive restructuring and cognitive behavioural therapy. The outcome parameters were again sleep onset latency, the number of nocturnal awakenings, total sleep time, wake time after sleep onset, sleep efficiency and the quality of sleep. All treatment was performed using scales, questionnaires, sleep diaries and in some cases polysomnography and actigraphy (see glossary). The effectiveness of CBT was demonstrated both for patients with primary insomnia and for insomnia associated with other diseases[90,91].

SR of RCT 1++,1+

It was found that the highly effective psychological interventions were latency and sleep quality, while they were moderately effective for the other parameters. Between 70% and 80% of patients with insomnia benefit from CBT treatment, although only between 20% and 30% achieved complete remission. A significant proportion of patients reached an inflexion point (plateau) in their recovery and continued having sleep difficulties after the therapy, which carries a risk of relapse.

SR of RCT 1++,1+

This shows the limitation that exists with the outcome parameters used, because they focus on the symptoms of insomnia and do not assess, for example, other effects such as reduction of morbidity or other, more qualitative, ones, such as improving the quality of life of the patients[90,91].

There was another meta-analysis evaluating the effectiveness of some of the cognitive and behavioural techniques, such as progressive relaxation, sleep restriction, stimulus control, paradoxical intention and biofeedback against a control group. For latency parameters and sleep quality, all techniques showed similar effects. The effectiveness of relaxation was lower, but not significantly, in the wake time after sleep onset. However relaxation was significantly less sleep "efficient" when compared to other interventions. It can be concluded therefore that relaxation may be the least effective behavioural intervention for the treatment of insomnia. However, the authors of the study show that the sleep efficiency results should be interpreted with caution given the small number of studies assessed in each behavioural group intervention, and that future RCTs should use sleep efficiency as an outcome variable, as this would clarify the results[101].

Meta-analysis (RCT 1++)

In addition to studying the efficacy of stimulus control and relaxation for the treatment of insomnia, recent studies demonstrated the efficacy of the sleep restriction and CBT (behavioural techniques with cognitive therapy). Although it is unusual to provide a patient with insomnia with a single cognitive or behavioural technique, to be able to measure the relative effectiveness of each component, the comparisons made indicate that the sleep restriction, alone or in combination with stimulus control therapy, is more effective than relaxation alone. This in turn is more effective than sleep hygiene alone[90,91].

SR of RCT 1++,1+

Although there are various psychological interventions that have proven effective in the treatment of insomnia, there is a clear tendency on the part of researchers to conduct studies that use a combination of two or more techniques. A systematic review evaluating the efficacy of a CBT programme (which includes stimulus control, sleep restriction of time, cognitive restructuring and relaxation and sleep hygiene) compared well with the following: a control group (placebo or waiting list); those undergoing a single intervention, cognitive or behavioural; and a pharmacological treatment. Sleep hygiene was also included in all RCTs, except one. The outcome variables were sleep onset latency, wake time after sleep onset, sleep efficiency, total sleep time, total wake time and sleep quality. An at-home sleep log was used for assessment, questionnaires and scales. The interventions were administered by psychologists, except in one RCT review where nurses were used. The included studies showed that CBT combined with different behavioural techniques produced statistically significant changes in all outcome variables, in comparisons with simple interventions such as relaxation, sleep hygiene, medication and with a waiting list control group[92]. **SR of RCT 1++,1+**

When the effectiveness of CBT was evaluated against combined CBT treatments and medication or medication alone, there was evidence of the superiority of CBT and combination therapy compared to drug treatment alone. It also concluded there was a reduction of medication used in combination therapies, without which a deterioration in sleep, anxiety or depression would have been found, as these results were also statistically significant[92,102]. **SR of RCT 1++, 1+ RCT 1++**

Although the reason for the change in trend of researchers towards the use of multicomponent intervention programmes is not sufficiently clear, according to some studies it could be related to the idea of better treatment of chronic insomnia factors[90,91]. **SR of RCT 1++,1+**

There is little evidence on the optimal duration of psychological treatment. The reviews found suggest between 6, 8 and 10 weeks[91,92]. However, a subsequent RCT achieved different results[103]. For 8 weeks, the patients included in the study were assigned treatment of behavioural techniques lasting 1, 2, 4 or 8 sessions, or put on a waiting list. Interventions included sleep hygiene, stimulus control and sleep restriction. Evaluation was done by sleep diaries, questionnaires, and actigraphy. The outcome parameters were sleep onset latency, total sleep time, wake time after sleep onset, total wake time and sleep efficiency. There were also additional quality of life indicators obtained from questionnaires. A follow-up was also carried out at 6 months. It was assumed that the treatment given with 8 week sessions would be most effective, but the results showed that the 4 biweekly sessions given was the optimal treatment. The authors conclude therefore that the optimal duration of treatment with these techniques is 4 sessions fortnightly. The fortnightly frequency favours adherence to therapy, because it allows the patient to implement the guidelines learned and come across difficulties, which can be solved in future sessions[103]. **SR of RCT 1++,1+**

More RCTs are needed to determine the optimal duration of therapy, and to see if the maintenance of long-term therapy improves the efficacy results for insomnia.

SR of RCT 1++, 1+

As insomnia may be a recurring problem, it is important to assess the result of the interventions after the initial treatment. There are not many studies that have monitored the effectiveness of this type of long-term treatment. However, those that exist show good results with short-term behavioural interventions and CBT, which are maintained over a longer time period. These can reach up to 24 months after completion of therapy in studies which were monitored up to that point[91,92,104,105].

SR of RCT 1++, 1+
Expert opinion 4

There are reviews that assess the long-term effectiveness of behavioural and CBT interventions (with or without relaxation or sleep hygiene) in comparison with drug treatments (temazepam and zolpidem). The benefits obtained in results such as sleep onset latency and sleep efficiency for patients treated only with psychological interventions are maintained between 3 and 12 months afterwards. In those using medication only, effectiveness was only short-term (lasting no more than 3 months)[20,91,92].

As there is a significant proportion of patients with chronic insomnia who still benefit from short-term therapy, they are vulnerable to recurrent episodes. Further studies are needed to assess both the long-term efficacy of this type of treatment and the maintenance techniques to prevent or minimise the recurrence of insomnia.

SR of RCT 1++,1+

Most of the studies cited so far have considered behavioural and CBT interventions done individually. In cases assessing the effectiveness of CBT applied individually and in a group, they concluded that the two methods yield similar results regarding significant improvement of sleep and secondary parameters, with no differences in effectiveness between the two types[76,91]. However, there are trials that suggest that group therapy can be a cost-effective alternative compared to individual therapy, and that it provides an incentive for greater patient motivation in difficult techniques, such as sleep restriction and withdrawal of the medication[91,106-108].

Studios in the field of Primary Care

With only one exception, as outlined in previous studies[92], all interventions were carried out in Specialised Care by psychologists and psychiatrists, who implemented the CBT for insomnia, following the Morin intervention model. According to this model, the therapeutic goals are: reducing hyperarousal (somatic, cognitive and emotional), modifying poor sleeping habits and changing dysfunctional beliefs about sleep and insomnia[50].

CPG (SR and RCT)
1+ RCT 1-

Studies on the use of psychological interventions and their effectiveness for insomnia in Primary Care are scarce and have methodological weaknesses. There is one study of the effectiveness of interventions with combined behavioural techniques compared to the total absence of treatment, over a programme of six group sessions conducted by trained nurses.

A significant decrease in sleep onset latency and wake time after sleep onset were observed in the psychological intervention group versus the control group. A follow-up one year later showed the effects of psychological therapy persisted, although no comparison was made with the control Group[76,109].

CPG (SR and RCT) 1+ RCT 1-

There was another comparison of effectiveness between a short form of CBT (2 sessions) with sleep hygiene advice among patients with chronic primary insomnia. CBT was significantly better than sleep hygiene in the follow-up three months after treatment. Nearly half of the patients who received CBT experienced at least a 50% decrease in wake time after sleep onset [76,110].

According to some authors, CBT interventions for insomnia that include stimulus control, sleep restriction, relaxation training, and paradoxical intention are still underused in PC. This is probably because they are slow and require medical staff training to be effective[111,112].

SR of RCT 1++,1+ RCT 1+ 1-

The proper implementation of psychological therapies usually requires more time than prescribing a hypnotic drug, which may represent a significant barrier to the use of such interventions in clinical practice. However, some interventions such as restricting time in bed and stimulus control require less time and can be implemented by PC practitioners. Some studies have reported benefits in terms of cost-effectiveness of implementing interventions carried out by trained nurses, in group therapy or with self-help materials to supplement intervention directed by a therapist (psychologist or psychiatrist). However, additional studies of the cost-effectiveness of different psychological interventions for insomnia are needed[91,106-108,113].

Expert opinion 4

The treatment of insomnia with psychological interventions is based mainly on international studies, although some of these techniques can be performed in Spanish Primary Care. General Practitioners, nurses and social workers play an important role in the therapeutic management of insomnia in this first level of care. They can perform both individual and group approaches, using techniques that can be implemented provided that the practitioners have received the necessary training.

The general principles of psychological interventions have already been expressed as well as the importance of a professional attitude from the first interview. These PC interventions must be applied with some common features[95], differing from the usual support relationship found in PC, which can be summarised as follows:

- Structured: simple to learn and easy to apply
- Brief and with times established in the initial manual
- With specific goals, set after the evaluation
- Having a description of their effectiveness for treating the condition

Evidence on the treatment with behavioural therapy and cognitive behavioural therapy (CBT) for insomnia

Specialised Care	
1++,1+	Behavioural techniques and CBT are effective in the treatment of primary chronic and secondary insomnia because they reduce the latency of sleep onset, and improve and maintain sleep throughout the night[73].
1++,1+	Behavioural techniques and CBT are also effective for patients with insomnia associated with other diseases (medical conditions or mental disorders[91].
1++,1+	The most effective techniques for reducing sleep onset latency and the number of night time awakenings are stimulus control and sleep restriction [73,91].
1++,1+	Relaxation seems to be the least effective intervention for the treatment of insomnia [73].
1++,1+	The combination of several behavioural techniques has not proved more effective than stimulus control and sleep restriction alone[73,91].
1++,1+	The revised CBT includes stimulus control, sleep restriction, relaxation and breathing, paradoxical intention and/or cognitive restructuring[73,91].
1++,1+	Duration of the CBT in the studies varies between 4, 6 and 8 weeks. However, there is no evidence for the optimal duration of therapy nor for whether the maintenance of long-term therapy would improve effectiveness results for insomnia[91,103].
1++,1+	The short-term efficacy achieved with behavioural interventions and CBT remains up to 24 months after completion of the therapy[91,92,104,105].
1++,1+	With behavioural interventions and CBT alone, the benefits obtained in sleep onset latency and sleep efficiency are maintained from 3 to 12 months afterwards. However, the effectiveness achieved from medication (temazepam or zolpidem) lasts no more than 3 months[91,92].
1++,1+	Behavioural and CBT interventions applied individually have a similar effect to group treatment for significant improvement in sleep and secondary parameters. However, it is suggested that group therapy can be more cost-effective, and may motivate patients more[91,106-108].
Primary Care	
1++,1+	There is evidence of the effectiveness of the implementation of behavioural interventions in PC, such as sleep restriction, stimulus control and relaxation[91].
1+/1-	Psychological interventions in a programme of six group sessions conducted by trained nurses compared with no treatment showed a significant decrease in sleep onset latency and wake time after sleep onset [76,109].
1++,1+	Interventions carried out by trained nurses, group therapy or self-help materials to supplement intervention led by a therapist (psychologist or psychiatrist) have shown their benefit in terms of cost effectiveness. The sleep restriction and stimulus control can be implemented by professionals in PC[91,106-108,113].
4	The following techniques could be used in PC to reduce symptoms associated with insomnia: – Relaxation therapies: progressive relaxation training or breathing control – Stimulus control techniques – Sleep restriction – Paradoxical intention – Cognitive restructuring: replacing irrational or distorted thoughts with rational ones
4	The following common features were found in brief psychological interventions made in PC, individually or in groups, that achieved greater effectiveness[95] • Carried out by trained practitioners • Structured: simple to learn and easy to apply • Brief and with times set in the initial manual • With specific goals, set after the evaluation • Describing their effectiveness in treating the clinical condition

Recommendations on treatment with Behavioural Therapy and Cognitive Behavioural Therapy (CBT) for insomnia, aimed at Primary Care

B	In Primary Care (PC, general practitioners, nurses and social workers can perform both individual and group approaches for patients with insomnia, using techniques based on the principles of behaviour therapy and cognitive behavioural therapy (CBT), provided that they have received adequate training.
B	Behavioural interventions for insomnia should include at least stimulus control and/or sleep restriction. Other CBT interventions that may be recommended are breathing and relaxation therapies, paradoxical intention and cognitive restructuring.
√	*First choice* psychological techniques in PC* to reduce the symptoms of insomnia are: relaxation therapies, stimulus control and sleep restriction.
√	*Second choice* psychological techniques in PC to reduce the symptoms of insomnia are: paradoxical intention techniques and cognitive restructuring.
√	Psychological interventions in PC should be performed by trained professionals and have the following common features in their application: to be structured, simple and easy to implement, short, with set times, well targeted and with described effectiveness.

* Appendix 9 has information for the PC practitioner and patient on the main interventions: relaxation therapies, stimulus control and sleep restriction.

7.4 Pharmacological interventions

Pharmacological treatment is an adjunctive measure in the comprehensive treatment model for insomnia. Before establishing drug therapy, the duration of the problem and the type of insomnia have to be taken into account[73,76].

The selection of a drug for the treatment of insomnia is influenced by several factors: symptoms, treatment goals, responses to past treatment, patient preference, cost of the drug, availability of other treatments, comorbidity conditions, contraindications and interactions with other drugs and side effects[74].

One goal of pharmacotherapy is to achieve a favourable balance between the potential therapeutic effects and side effects. The risk-benefit ratio of each drug used in the treatment of insomnia should be assessed bearing in mind: a) effectiveness, b) the development of tolerance, c) withdrawal symptoms; d) adverse reactions.

In addition, the individual characteristics of patients must be considered (personality and psychopathology). Certain personality types are predisposed to dependence on drugs or substances[114]. If this is the case, it must be considered as a contraindication for prescribing CNS depressants.

It is not uncommon for a patient who complains of chronic insomnia to be a chronic user of CNS depressants. Continued use of hypnotics should be avoided as far as possible, as there are studies that show there is an abuse of benzodiazepine prescriptions, and particularly so in PC in Spain[115].

Between 23 - 25% of patients treated with benzodiazepines (BZDs) receive it because of insomnia. In 80% of cases, the first prescription was from the general practitioner, and the patient profile was mostly women over 65, 46% of whom had been under treatment for than a year[115,116]. At these ages, the perception of the risks of the use of BZDs is lower in patients than practitioners[117].

In these cases, the gradual withdrawal of the drugs, or *removing dependency*, is a priority, and often requires the simultaneous use of non-pharmacological techniques (eg, cognitive behavioural therapy, standardised interviews with successive visits). These have proved successful in the Spanish PC[118]. Appendix 10 includes a protocol for gradual withdrawal from BZDs proposed by the Spanish Agency of Medicines.

When drug therapy is the option best suited to the patient, it is important to follow up the intervention by checking for adverse effects, and to prevent long-term dependency by scheduling a drug reduction programme, as far as is possible. Although approximately one third of patients do not succeed in overcoming their addiction to hypnotics, it was seen that for those who took no medication for eight weeks, their insomnia and anxiety symptoms were less severe. They also had more positive perceptions of health and self effectiveness to avoid taking drugs in different situations. We must therefore take into account the problems arising from prolonged drug treatment[119].

Objective methods based on sleep polygraph records are chosen to study the effectiveness of different drug treatments, and they have clearly demonstrated their superiority over more subjective methods[120]. One important aspect of effectiveness is their maintenance or loss over time for use on consecutive nights (or tolerance). Appendix 7 includes variables that are used to evaluate such effectiveness.

Hypnotics

Hypnotics used currently for the treatment of insomnia fall into two major groups according to their chemical structure: *benzodiazepines and non-benzodiazepines*. The latter in turn have three subgroups: cyclopyrrolones, imidazopyridines and pyrazolopyrimidines. Hypnotics are benzodiazepine receptor agonists (BRAs), and act on the GABA-benzodiazepine-receptor complex, although the different types act on different receptor subunits.

For about 30 years, the pharmacological treatment of insomnia has been dominated by the use of benzodiazepine hypnotics (BZDs). The most recent studies are based on the comparing the effectiveness of non-benzodiazepine drugs with BZDs.

Benzodiazepines (BZDs)

BZDs are nervous system depressants and promote mental and physical relaxation by reducing nerve activity in the brain (GABAergic action). They are a heterogeneous group of drugs with different chemical structures, pharmacokinetic properties and pharmacodynamic properties.

The chemical structure has two types: the 1,4 benzodiazepines and triazolobenzodiazepines. Both are different, as shown by the fact that there is no cross-tolerance between them and their different adverse reaction profiles. There are also marked differences in the pharmacokinetic and pharmacodynamic properties between them[120].

There have been no significant developments on the pharmacological characteristics of BZDs for about 20 years. Studies recommend their use only for occasional and short-term insomnia. At present, research is focused on the comparison of the effectiveness of this type of hypnotic with non-benzodiazepines[73,74,76].

CPG (SR and RCT) 1++,1+

There are several studies that assess either the effectiveness of the BZD or the benefits and risks of its use. Among these drugs are: flurazepam, estazolam, triazolam, quazepam, loprazolam, nitrazepam, midazolam, temazepam, flunitrazepam, brotizolam, diazepam and lorazepam. The comparison is with a placebo and the following outcome variables were used: sleep onset latency, number of nocturnal awakenings, total sleep time, sleep quality and daytime side effects (dizziness, drowsiness, numbness and weakening of daytime functions, such as memory). The evaluation is performed either by questionnaires and sleep diaries or by polysomnography[73,76,121].

CPG (SR and RCT) 1++,1+ Meta-analysis 1++

Using the two types of evaluation, studies conclude that BZD versus placebo is more effective in the short term for sleep duration. The decrease in sleep onset latency is only seen in the subjective evaluation. Also, the importance of the side effects associated with these drugs should not be neglected. Further research could investigate the risk-benefit ratio of the treatments[73,76,121].

Side effects have been observed with the use of BZDs in relation to daytime drowsiness, headache, dizziness, nausea, fatigue and others. After 2 weeks of using a BZD, there is an increased risk of development of tolerance, physical and psychological dependence, and long-term use has been associated with increased risk of traffic accidents. In case of abrupt termination or stopping treatment, signs of withdrawal are produced. Moreover, effects such as memory loss and the risk of falls are also important as they mostly affect older people, who are major consumers of drugs and more sensitive to side effects. Clinically significant interactions with other drugs and with alcohol have also been reported[20,75,76,122].

SR 1+

Expert opinion 4

CPG (different types of studies 2++, Expert opinion 4)

As a unit, the drugs with a shorter half-life, greater power and a "triazolo" chemical structure (triazolam, brotizolam, estazolam and alprazolam) have a worse risk-benefit ratio. Triazolobenzodiazepines have certain pharmacodynamic properties, such as direct action on the noradrenergic system, increasing their potential to cause certain side effects[123].

Expert opinion 4

Withdrawal symptoms are more likely and more intense with drugs of a high potency and shorter half-life[123]. These phenomena are associated both with dependency and the development of tolerance or loss of efficacy (the faster, the shorter the half-life, and the greater the affinity for the receptor/power).

Concern for BZD dependence has led to the following recommendations: the use of BZDs in the treatment of insomnia be restricted to acute insomnia only, treatment be done with the lowest dose possible for rapidly cleared drugs, those with a short half-life are not used and treatment to last for no more than 2-4 weeks[73,74,124,125].

CPG (SR and RCT) 1++,1+ SR 1++

During pregnancy, there is insufficient evidence to determine whether the potential benefits for the mother offered by BZDs outweigh the potential risks to the foetus[126-129]. If they are needed to be used, the lowest effective dose of BZD for the shortest treatment time possible, and as monotherapy, should be adopted, to reduce the potential risk of birth defects. In advanced stages of pregnancy or during lactation, BZDs may cause adverse effects on newborns (neonatal hypotonia, withdrawal syndrome, sedation and hypothermia)[130-133].

SR of different types of studies 2++

Observational studies 2+

There are few studies on the long-term efficacy of these hypnotics. Some authors have studied the characteristics of long-term consumers of BZDs, as well as the perceptions and attitudes of patients and health practitioners. As for the perception of patients about the effectiveness of a drug, this was related to the choice on whether to continue or stop treatment, and this choice had been previously made. However, no conclusions could be drawn, due to the sample size, the methodological quality and subjective burden of the results[73].

CPG (Qualitative research)

More RCTs are needed to assess the long term use of BZDs for insomniac patients.

Non-benzodiazepines

In the past 20 years, several drugs belonging to three chemical groups: cyclopyrrolones (zopiclone and eszopiclone), imidazopyridine (zolpidem) and pyrazolopyrimidine (zaleplon), have entered the market. These hypnotics were developed with the aim of overcoming some of the side effect disadvantages of BZDs, for example, next day sedation, dependence and the effects of drug withdrawal.

Although insomnia is often a chronic condition, the only non-benzodiazepine drug approved by the FDA (US Food and Drug Administration) for use without a specific time limit is Eszopiclone (this drug has not been approved in Spain, and so is not marketed). The other non-benzodiazepines have been approved for a limited use of 35 days or less[20].

When evaluating the effectiveness and safety of non-benzodiazepine versus placebo, the outcome parameters used were: sleep onset latency, wake time after sleep onset, sleep efficiency and total sleep time. Evaluation methods used were polysomnography and sleep diaries.

SR 1+

Non-benzodiazepine hypnotics produced a significant improvement in the treatment of chronic insomnia in adults. The results obtained by sleep diaries were statistically significantly more favourable than those obtained with polysomnography. The results are related to the short-term treatment of insomnia. It also concluded that adverse effects were significantly higher in the drug group than in the placebo[134].

Meta-analysis 1-

A meta-analysis evaluating the effectiveness for insomnia of non-benzodiazepine hypnotics (zolpidem, zopiclone, zaleplon) was performed. It made comparisons between them and with BZDs. The outcome variables were sleep onset latency, total sleep time, number of nocturnal awakenings, sleep quality and side effects, which may or may not be related to the central nervous system (vertigo, drowsiness, nervousness, dizziness, headache, fatigue and gastrointestinal problems)[125,135].

In the comparison of the non-benzodiazepines among themselves, the effectiveness of zaleplon was higher than zolpidem for sleep onset latency, and zolpidem was more effective than zopiclone. Zolpidem was more effective then zaleplon for sleep quality and duration results, while zaleplon was best for lack of rebound insomnia.

Effectiveness outcomes depend on the characteristics of each drug. Zaleplon is absorbed and eliminated more quickly, this leads to poor sleep onset latency and no increase in sleep duration, when compared with zolpidem. The "best hypnotic" depends on what aspects of sleep are problematic for a patient: not being able to sleep or waking up several times. And because the differences among these drugs are so small in absolute terms, the advantage of zolpidem over zaleplon needs to be established from further studies[125,135].

The results from this review should be interpreted with caution. The capacity of this review to reach a conclusion is hampered by the limitations of the RCT data. It was difficult to properly quantify the differences in effectiveness between the various non-benzodiazepine hypnotics and to evaluate the clinical significance of any difference. Many studies included did not have a high methodological quality and had potential conflicts of interest, making it difficult for the meta-analysis authors to extract and compare the data to answer the review question.

More RCTs without the existence of potential conflicts of interest and with a minimum of four weeks to allow direct comparisons between these drugs are needed to reach reliable conclusions.

The adverse effects found for non-benzodiazepine hypnotics are: daytime drowsiness, dizziness, fatigue, headache, hallucinations, nausea, disorientation and confusion, anxiety or panic attacks, weakness, trembling, palpitations, and tachycardia. Some studies have also described rebound insomnia, withdrawal syndrome (at both supratherapeutic and normal doses) and the danger of dependence, especially after prolonged use. They are therefore recommended for short-term use, and must be monitored if used in the long term. As with BZDs, zopiclone was recognised as a potential replacement for alcohol in people addicted to it, even with standard daily doses. Therefore, it is recommended to be prescribed cautiously in patients with alcohol and/or drug abuse[125,136]. No specific studies have been carried out during pregnancy. Some studies also suggest an increased risk of traffic accidents with the consumption of these drugs (zopiclone, zolpidem)[137].

Meta-analysis 1-

SR of different types of studies

1-, 2+, 3

Observational study 2+

The most recent studies with non-benzodiazepine hypnotics focused on other treatment regimens, such as intermittent use, use "on demand according to patient's needs" and the slow-release formulation.

Among alternative regimens to the daily use of hypnotics for insomnia, there is the expectation that intermittent treatment for patients improves their quality of life by reducing the possibility of drug dependence, as they are the ones who control the drug and not vice versa. There are several RCTs, some of them in the context of PC, which evaluate the efficacy of zolpidem used intermittently as compared with daily. Most of the studies show statistically significant efficacy for intermittent administration and favourable risk-benefit ratio compared to placebo. However, the daily treatment has a greater efficacy[138-140].

RCT 1+, 1-

There are studies conducted in the PC field regarding the administration of zolpidem "on demand according to patient's needs". Some of these used the drug on demand with the support of behavioural stimulus control for the days when the medication was not used. These RCTs however did not conclude any proven, statistically significant effectiveness for this alternative form of administration[138,141]. Some patients who alternated stimulus control with the drug did, however, manage to improve their quality of life and reduce medication use[141].

RCT 1+, 1-

More RCTs are needed, especially in the long term, to confirm any results for these discontinuous zolpidem administration regimens, both intermittent and on demand. Moreover, any favourable results with zolpidem may not apply to other hypnotics.

According to RCTs comparing the efficacy and safety of zolpidem extended release against placebo, this formulation demonstrated its effectiveness by decreasing sleep onset latency and increasing both sleep maintenance and daytime functioning. However, more RCTs without the potential conflicts of interest, both short and long term, are needed to provide reliable information and general findings[142,143].

RCT 1+

Benzodiazepines (BZDs) versus non-benzodiazepines

The aim of some reviews and meta-analyses was to compare the effectiveness and/or safety of BZDs in the treatment of insomnia with non-benzodiazepine hypnotics. The drugs studied include zolpidem, zopiclone, zaleplon, diazepam, loprazolam, lorazepam, temazepam, nitrazepam and lormetazepam. The outcome variables used were latency and total sleep time[124,135].

Systematic reviews and meta-analysis 1+,1-

The results of these RCTs do not currently give convincing evidence of a clinically useful difference between the use of the non-benzodiazepine hypnotics and BZDs studied[124,135]. From the standpoint of efficacy, side effects and potential for dependence or abuse, there is no evidence to suggest that if a patient does not respond to one of the families of these hypnotics, he will respond to another. So changing from one hypnotic to another does not seem a useful strategy to follow[124].

Despite the lack of consistency found in the description of the side effects of BZDs and non-benzodiazepine hypnotics included in these reviews, there are no statistically significant differences regarding rates of adverse events between both drug families. The side effects found for the two types of drugs were mainly: vertigo, drowsiness, nervousness, dizziness, headache, fatigue and gastrointestinal problems. Except for a lower risk of aggravation of conditions that involve breathing, clinical practice has shown that non-benzodiazepine hypnotics may have the same drawbacks as benzodiazepine hypnotics of similar pharmacokinetic characteristics.

Systematic reviews and meta-analysis 1+,1-

Also, there were no differences when the residual effects the following day were compared[124,125].

The most prominent case is that of zolpidem, whose clinical use has shown that is associated with unwanted side effects in a similar way to, for example, triazolam. Moreover, although some early studies reported no rebound insomnia, the data demonstrate its presence[144-148]. These examples suggest the need for independent studies with appropriate methodology.

Case reports 3

Regarding abuse and dependence, it should be noted that the BZDs were often used with higher doses and over longer periods than would be recommended today. This contributed to the addiction that a large number of patients developed due to taking BZDs. By contrast, the use of non-benzodiazepines is more recent, when attitudes towards the use of hypnotics and sedatives in general have changed. They may therefore be less likely to be used for long periods, as BZDs were, and there is less information about their addictiveness. As a result, researchers propose restrictions on prescribing, and recommend they be used only on patients with disabling insomnia[125,136].

Meta-analysis 1-
SR of different types of studies 1-, 2+, 3

According to the authors of the studies, patients are not sufficiently informed about the risks of potential addiction associated with the use or widespread use of hypnotics. In many cases, patients are directly prescribed non-benzodiazepines or have their treatment changed from BZDs to non-BZDs. This is due to the perception that the probability of dependence is less with non-benzodiazepines than with BZDs. However, there is no evidence to support this assumption regarding dependence. Therefore, the increasing abuse of non-benzodiazepines can be added to the abuse of BZDs[124]. More short and long term RCTs without potential conflicts of interest are needed to understand these adverse effects, and in turn to make comparisons between benzodiazepine and non-benzodiazepine hypnotics.

In the reviews carried out, non-benzodiazepine hypnotics have not proven cost-effective compared to BZDs[124,125]. There are economic models submitted by a pharmaceutical company based on the premise that the use of a particular non-benzodiazepine when compared with the use of another or with a BZD prevents traffic accidents or hip fractures caused by falls. The conclusions of these models were not accepted because it was considered that the tests used lacked robustness and additional assumptions proposed were not appropriate. Furthermore, it was considered that there was no reliable evidence to support the idea that the superiority of the price of non-benzodiazepines would be offset by reductions in the use of other medical resources[124].

Systematic reviews and meta-analysis 1+,1-

In summary, comparisons between benzodiazepines and non-benzodiazepine drugs do not provide convincing evidence of superiority, in terms of clinical utility, of one group over the other[125,135]. This is true both in terms of effectiveness and risk. The conclusion is therefore that unless it appears that a patient has side effects directly related to a specific hypnotic, the cheapest drug must be used as opposed to a more expensive alternative[124].

Systematic reviews 1+,1-

Table 11 shows the benzodiazepine and non-benzodiazepine hypnotics with their approved indication in Spain for insomnia, chemical structure, elimination half-life and potency/affinity for the receptor.

Table 11. Hypnotics approved for insomnia treatment

Family		Substance	Average half-life / hours	Dose equivalent to 5 mg of diazepam	Daily dose/ mg
Benzodiazepines*	Short	Midazolam	1-3	7.5	7.5-15
		Triazolam	2-3	0.25	0.125-0.250
Average half-life		Brotizolam	3-8	0.5	0.125-0.5
	Medium	Lormetazepam	9-15	1	0.5-2
		Loprazolam	3-13	1	1-2
	Long	Flurazepam	70-100	15	15-30
		Flunitrazepam	9-30	1	1-2
		Quazepam	40-55	15	7.5-15
Non-benzodiazepines	Imidazopyridines	Zolpidem	1.5-3	2.5	5-10
	Cyclopyrrolones**	Zopiclone	1.5-3	≈ 2	3.75-7.5
	Pyrazolopyrimidines	Zaleplon	1	2.5	5-10

Source: Therapeutic Prescription Guide, Health and Consumer Affairs Ministry, Spanish Medicines Agency, May 2009, amended.

*There are many other benzodiazepines used as hypnotics, but they do not have the indication noted in their technical data, eg, lorazepam, diazepam, alprazolam.

Nitrazepam and temazepam are benzodiazepine hypnotics which are not marketed in Spain.

**Eszopiclone, authorised in the U.S. for chronic insomnia, is not available in Spain. Zaleplon, in the pyrazolopyrimidine family, is no longer available.

Table 12 summarises the main side effects reported with the use of hypnotics. These side effects or adverse reactions are of two basic types according to their predictability: expected and unexpected. The first is an extension of the therapeutic action of the drug, while the second is not expected by the doctor or patient and are often anti-therapeutic in action.

Table 12. Most common adverse reactions to hypnotics

Expected*	Unexpected**
• CNS depression - Excessive daytime sleepiness - Impairment of psychomotor task performance (driving) - Amnesia with maximum drug concentration - Poor motor co-ordination - Others	• Hyperexcitability - Pre-awakening sleeplessness - Daytime anxiety • Amnesia the following day • Psychiatric - Confusion - Psychotic symptoms - Lack of inhibition - Others

*Depend on the half-life, potency and dosage.

**Especially with drugs like triazolam and zolpidem

There are two other aspects to be considered in the pharmacological treatment of insomnia: withdrawal symptoms or rebound phenomena, which occur when the drug is no longer used; and those that appear while the drug is still being used, or hyperexcitability phenomena. The latter occur in association with the development of tolerance. Table 13 summarises these phenomena.

Table 13. Rebound/hyperexcitability phenomena

Rebound phenomena*	Description
Rebound insomnia	– Significant increase in night time awakenings compared with baseline values. – May occur after very short periods of use.
Rebound anxiety	– Analogous to rebound insomnia: increased anxiety. – Appears in both hypnotics and sedatives (used at night and/or during the day).
Withdrawal syndrome	– In addition to aggravating initial symptoms (insomnia or anxiety) other symptoms appear: motor, sensory, vegetative, emotional, cognitive. – Appear after prolonged use, at either therapeutic or supratherapeutic doses.
Hyperexcitability phenomena**	Description
Early morning awakening insomnia	Significant increase in wakefulness in the final hours of the night, after one or two weeks of administration.
Daytime anxiety	Progressive increase in anxiety in the days after administration.

*These are more intense with more powerful drugs (benzodiazepines and non-benzodiazepines) and those with a shorter half-life.

These can be the source of dependency.

**Appear with benzodiazepine and non-benzodiazepine drugs with short or very short half-life.

Evidence for treatment with benzodiazepine and non-benzodiazepine hypnotics for insomnia

Benzodiazepine hypnotics	
1++,1+	The benzodiazepine hypnotics flurazepam, triazolam, quazepam, loprazolam, midazolam, flunitrazepam, brotizolam, diazepam, lorazepam, nitrazepam, estazolam and temazepam have proven effective in sleep duration[73,76,121].
1++,1+	BZDs have greater short-term effectiveness compared with placebo for sleep duration and latency, but they also have more frequent side effects[73,76,121].
1++,1+	There is no evidence for effectiveness in the long-term use of BZDs for insomnia[73].
1+	BZD use is associated with an increased risk of daytime sleepiness, tolerance, traffic accidents, physical and psychological dependence, memory loss, fall hazards and effects after withdrawal, as well as interactions with other drugs and with alcohol[20,75,76,122].

4	Drugs with high potency, shorter half-life and "triazolo" chemical structure have a worse risk-benefit ratio. Withdrawal symptoms are more likely and more intense with drugs of a high potency and shorter half-life and, in turn, are associated with the development of tolerance and dependence.
2++ **2+**	During pregnancy, the evidence is insufficient to determine whether the potential benefits of BZDs for the mother outweigh the potential risks to the foetus[126-128].
2++ **2+**	There are adverse effects in newborns when prescribed in advanced stages of pregnancy or during lactation (neonatal hypotonia, withdrawal syndrome, sedation and hypothermia)[130-133].
Non-Benzodiazepine hypnotics	
1+,1-	Non-benzodiazepine hypnotics zolpidem, zopiclone, zaleplon have proven short-term effectiveness in the treatment of insomnia[125,134,135].
1+,1-	Non-benzodiazepine hypnotics show significant short-term improvement in the treatment of insomnia compared with placebo; with the results obtained from sleep diaries being more favourable than those obtained with polysomnography. Also, side effects were more frequent[125,134,135].
1+,1-	There is no evidence for the long-term effectiveness of the use of non-benzodiazepines for insomnia[125,134,135].
1-	There is insufficient evidence for the superior effectiveness of some non-benzodiazepine hypnotics over others[125,135].
1-	The use of non-benzodiazepines is associated with an increased risk of daytime sleepiness, dizziness, fatigue, headache, hallucinations, nausea, disorientation and confusion, anxiety or panic attacks, weakness, trembling, palpitations and tachycardia; as well as rebound insomnia, withdrawal syndrome, dependence and an increased risk of traffic accidents[125,136,137].
1+, 1-	Zolpidem used intermittently compared to daily use suggests a favourable risk-benefit ratio for discontinuous treatment. These results cannot be extended to other hypnotics[138-140].
1+, 1-	RCTs of zolpidem given "as needed" do not show any significant effectiveness for this alternative form of administration. Although patients alternating the drug with stimulus control managed to improve their quality of life and reduce medication use[138,141].
1+	Delayed-release zolpidem compared with placebo appears to decrease sleep onset latency and increase both sleep maintenance and daytime functioning, but more short and long-term RCTs are needed[142,143].
Benzodiazepines (BZDs) compared with non-benzodiazepines	
1+,1-	There are no clinically significant differences between the use of non-benzodiazepine and BZD hypnotics in the treatment of insomnia[124,135].
1+,1-	There are no statistically significant differences between non-benzodiazepine and BZD hypnotics in side effects, including next day residual effects, abuse and dependence[124,125].
1+,1-	There is no evidence (effectiveness, side effects, dependence or abuse) to suggest that if a patient does not respond to a family of hypnotics he may respond to another[124].
1+,1-	Non-benzodiazepine hypnotics have not proven cost-effective compared to BZDs[124,125].

Recommendations on the treatment with benzodiazepine and non-benzodiazepine hypnotics for insomnia

B	If hypnotics are to be used for treating insomnia, it is recommended that treatment is short-term (not more than four weeks) and at the lowest possible dose.
C	Long-term use of hypnotics is not recommended. If doing so, it should always be monitored, with a diagnosis and at a specific regimen.
B	To prevent dependence on BZDs, it is recommended that use be restricted to acute insomnia, at the lowest dose possible and for no longer than 2-4 weeks.

B	As first choice hypnotics for insomnia, either a benzodiazepine or non-benzodiazepine can be chosen, as no significant differences in clinical or adverse effects have been demonstrated between the two types.
B	If a patient does not respond to treatment with a hypnotic, it is not recommended to change to another, unless there are side effects directly related to a specific hypnotic drug.
B	It is recommended to use the hypnotic which is most efficient and responsive for the patient, unless side effects directly related to the chosen hypnotic are observed.
B	If a BZD is needed during pregnancy, it should be used at the lowest effective dose and for the shortest time possible to avoid the risk of birth defects.
B	The new discontinuous zolpidem treatment regimens, either intermittent or on demand according to the patient's needs, supported by stimulus control techniques, can be used in the short term as an alternative to continuous dosing.
√	When prescribing hypnotics, patients should be informed of the therapeutic objectives, the duration of treatment and possible side effects, including tolerance and dependence problems associated with their use, as well as the lack of studies reporting long-term efficacy.
√	When prescribing hypnotics, the following parameters must be considered: age, previous treatment, tolerance, potential pregnancy, side effects, patient preferences and costs of equally effective choices.

Other medicines

Other drugs that may be considered in the treatment of insomnia are:

Antidepressants

Antidepressants with a sedative profile are the tricyclics (doxepin, trimipramine and amitriptyline), trazodone and mirtazapine. The sedative effects in the tricyclics appear to be associated with antihistamines and possibly with the antagonistic effects of the alpha-1 adrenergic receptor. In the trazodone, they seem to be related to the antagonism of 5-HT2 receptors and possibly the alpha-adrenergic (ref). Another possible mechanism of action in the case of trazodone, trimipramine and doxepin would be by reducing the hypercortisolaemia that chronic insomniacs have[149].

These drugs are used as hypnotics at lower doses than when used for the treatment of depression. Their use for the treatment of insomnia has grown substantially over the last ten years in some countries, which is striking if one considers that there are few objective studies in the sleep laboratory on the hypnotic effects of these drugs for insomnia[149].

Therefore, the frequency of use of antidepressants, their possible action on the pathophysiology of insomnia and the frequency of chronic insomniacs presenting anxiety and depression psychopathology, even at sub-threshold, mean the above studies are necessary.

CPG (SR and RCT) 1++,1+

Sedating antidepressants are used in the treatment of insomnia, however, they were not originally approved for this essential purpose. The most obvious indication for antidepressants in the treatment of insomnia is when it is a symptom of a depressive syndrome. This is so because there is little evidence of the effectiveness and safety of antidepressants for the treatment of insomnia which is not associated with depression disorders[73,76].

Trazodone:

Research with trazodone emerged in the 1990s and lasted for a decade with the expectation that it was one of the best pharmacological alternatives for the treatment of insomnia. The results of studies conducted mainly in patients with insomnia associated with depression, showed clinical improvements in parameters of sleep quality and number of nocturnal awakenings, but data related to latency, total sleep time and wake time after sleep onset failed to give statistically significant results.

SR from different types of studies 1+, 1-

Due to the scarcity of studies for insomnia not associated with depression, and because the doses used would be smaller than those for treating depression, no definitive conclusions can be drawn on the severity of side effects. These and others are associated with daytime sleepiness and "difficulty in awakening". More RCTs are needed to evaluate the effectiveness of trazodone, both objectively and subjectively, to determine its efficacy in the treatment of insomnia not associated with depression[150].

Doxepin:

Studies with doxepin have shown clinical improvement for the first nights, but there are no significant differences by the fourth week of treatment. Researchers have envisaged the possibility of using it for the treatment of acute insomnia, although more RCTs are needed for its short and long-term safety and effectiveness[151-153].

RCT 1+,1 -

Amitriptyline and mirtazapine:

The hypnotic and clinical efficacy of amitriptyline and mirtazapine for primary insomnia has not been investigated. Effectiveness data available for these drugs are for patients with psychiatric illness (mainly depression) and insomnia complaints. There is no evidence to support its use in acute and chronic insomnia[154,155].

RCT 1-

In short, studies of antidepressants in the treatment of insomnia are few, which together with their low methodological quality does not provide convincing evidence for the treatment of insomnia with these drugs. Researchers agree that although some antidepressants are known for their sedative effects, such as amitriptyline and trazodone, there is little information on their use for treating non-depressive insomnia[75,76].

CPG (SR and RCT) 1++,1+

Moreover, due to the importance of their adverse effects, the use of antidepressants as sleep inducing agents, in the absence of symptoms of depression, remains a source of controversy. Therefore, taking into account their potential toxicity, the guidelines selected conclude that they should be reserved only for their more specific indication, depression[73].

CPG (SR and RCT) 1++,1+

Ramelteon

Ramelteon is a synthetic receptor agonist of MT1 and MT2 melatonin. In 2005, the FDA (US Food and Drug Administration) approved its indication (with a recommended dose of 8 mg taken within 30 minutes of bedtime) for treatment of "insomnia characterised by difficulty in falling sleep". However, the European Medicines Agency (EMEA) has not yet approved its use for Europe and has issued a negative opinion for its use as a hypnotic, due to the need for more studies to confirm efficacy and safety [156].

Reviews of different types of studies 1+, 1-

When evaluating the efficacy and safety obtained with ramelteon against placebo for the treatment of insomnia, there were small, but statistically significant, decreases in sleep onset latency for the drug, although with no clear clinical significance. The total time and sleep efficiency of sleep effects are less marked and were not reviewed[157,158].

RCT 1-

Adverse effects associated with the use of ramelteon included headache, drowsiness, dizziness, fatigue and nausea. There were no significant rates for cognitive impairment, rebound insomnia, withdrawal effects or abuse[157,158].

More research without the existence of potential conflicts of interest and with a larger sample size is needed, to determine the clinical significance of the changes that have had significant results in RCTs conducted thus far. RCTs are also needed on the long-term use of ramelteon compared with other drugs to determine their relative efficacy for insomnia, compared with other pharmacological options.

Others

Other drugs that have been considered in the treatment of insomnia include:

Gaboxadol:

Gaboxadol is a selective $GABA_A$ agonist, and was originally developed in the 1970s as a possible anticonvulsant. It has shown some effectiveness in treating insomnia.

RCT 1-

When evaluating the efficacy of gaboxadol (with different doses: 5, 10, 15 and 20mg) compared with placebo, the superiority of the drug was demonstrated for maintaining sleep, such as in wake time after sleep onset and total sleep time. The most effective dose turned out to be 20 mg. There were no significant improvements in regard to sleep onset latency.

Gaboxadol was generally well tolerated, although it was found that the incidence and severity of adverse effects were dependent on increasing the dose. The use of gaboxadol was not associated with residual effects the next day. The small sample size of the studies mean more RCTs are necessary to study both the short and long-term effectiveness of gaboxadol in the treatment of insomnia, and to establish the appropriate dose[159,160].

Atypical antipsychotics and anticonvulsants:

The evidence for efficacy in the treatment of insomnia, (as well as potential side effects) of drugs like gabapentin, tiagabine, quetiapine and olanzapine is insufficient[75]. **CPG (SR and RCT) 1++,1+**

Not recommended

Drugs such as chloral hydrate, meprobamate and barbiturates, approved by the FDA for insomnia, are not recommended, due to their low therapeutic index and significant adverse effects (which include the likelihood of tolerance and dependence)[75]. **CPG (SR and RCT) 1++,1+**

Evidence for other drugs in the treatment of insomnia

Antidepressants	
1++,1+	The effectiveness and safety of antidepressants for insomnia associated with depression disorders has been demonstrated[73,76].
1++,1+	There is little evidence on the effectiveness and safety of antidepressants in the treatment of primary insomnia[73,76].
1+,1-	Trazodone has shown efficacy in the clinical improvement of the quality of sleep and in the number of nocturnal awakenings in patients with insomnia. For latency, total time and wake time after sleep onset, no statistically significant results were found. More RCTs are needed to determine its efficacy in the treatment of insomnia not associated with depression[150].
1+,1-	Doxepin has demonstrated some efficacy in the treatment of acute insomnia, but there are no significant differences by the fourth week of treatment. More RCTs are needed for short and long-term safety and effectiveness[151,152].
1+,1-	There are insufficient studies to draw conclusions about the efficacy of amitriptyline and mirtazapine for the treatment of insomnia[154,155].
Ramelteon	
1+,1-	Ramelteon compared to placebo has small but significant decreased sleep onset latency, but without clear clinical significance. The effects on total time and sleep efficiency of sleep are less marked[157,158].
Others	
1++, 1+,1-	There is insufficient evidence on the effectiveness (as well as potential side effects) of drugs such as gaboxadol, gabapentin, tiagabine, quetiapine and olanzapine[75].
Not recommended	
1++, 1+	There is evidence of low therapeutic index and significant adverse effects (most notably the likelihood of tolerance and dependence) in drugs like chloral hydrate, meprobamate and barbiturates[75].

Recommendations for other drugs in the treatment of insomnia

Antidepressants	
B	There is enough evidence to recommend the use of antidepressants for insomnia associated with depressive disorder, but not for primary insomnia.
B	There is insufficient evidence to recommend the use of trazodone and doxepin until results from long-term studies are obtained.
B	There is insufficient evidence to recommend the use of the antidepressants amitriptyline and mirtazapine in the treatment of insomnia.
Others	
B	More long-term comparative studies are needed to recommend the use of ramelteon in the treatment of insomnia.
Not recommended	
B	The use of chloral hydrate, meprobamate and barbiturates are not recommended for the treatment of insomnia.

7.5 Other treatments

7.5.1 Melatonin

It has been suggested that exogenous melatonin can be used as a hypnotic, but this issue is controversial. Melatonin is a natural hormone produced by the pineal gland. Its nocturnal secretion and suppression during the day due to the effect of sunlight regulate the sleep-wake (chronobiotic) circadian rhythm. It is also associated with a hypnotic effect and increased sleep propensity. There are some substances such as tobacco, alcohol and some drugs that decrease the production of melatonin.

The secretion of melatonin decreases with age and may contribute, in part, to the etiology of sleep disorders of older people.

It is not currently commercially available in Spain, although its indication is approved for people over 55 years with insomnia.

Meta-analysis 1+

There are two meta-analyses that suggest there is sufficient evidence to propose the use of melatonin as a hypnotic. One evaluates the safety and efficacy of melatonin compared to placebo for short-term treatment of insomnia. It included studies with patients with insomnia and sleep phase delay syndrome (SPDS). Among the results found was that there were no statistically significant differences in the parameter of wake time after sleep onset or the sleep efficiency, total time and quality of sleep. Melatonin did lead to a shortening of sleep onset latency in both types of patients, but this shortening was five times higher in patients with SPDS than those with insomnia, which suggests a more chronobiotic effect than hypnotic. The most common associated adverse effects were headache, pharyngitis, back pain and fatigue, although there were no differences between melatonin and placebo[161,162].

The second meta-analysis included studies with subjects ranging from healthy volunteers to patients with schizophrenia and insomnia, and patients with Alzheimer's disease. The observed changes in sleep onset latency, sleep efficiency and total sleep time were clinically irrelevant[163].

As the results were based on a small number of studies, more research is needed in this area, with RCTs of greater sample size to determine the efficacy, withdrawal effects and adverse reactions of melatonin in patients with chronic insomnia, properly selected and belonging to various age groups. In addition, any appropriate dosages would need to be determined.

RCT 1+

Some studies conducted in the PC field have focused on whether the use of melatonin may facilitate the discontinuation of BZDs in patients with insomnia. There were two RCTs where patients with insomnia had been taking a BZD (diazepam) for more than three months. The dose of benzodiazepine was gradually reduced over a fortnight and supplemented with melatonin or placebo. As the sample size of both studies was small and the mean dose of BZD used in the treatment group was low, the results were not conclusive in indicating whether melatonin is useful for stopping the use of BZDs[164].

More studies with larger samples taking into account the possible influence of dose on the facilitating effect of melatonin to stop the use of BZDs are required.

Evidence for melatonin use in the treatment of insomnia

1+	Melatonin significantly decreased sleep onset latency, but not the parameters for wake time after sleep onset, sleep efficiency, total time and sleep quality[161-163].
1+	The usefulness of melatonin for the discontinuation of prolonged use of BZD has not been shown[164].

Recommendations on treatment with melatonin for insomnia

B	There is insufficient evidence to recommend the use of melatonin in the treatment of insomnia until good quality methodological trials demonstrate its effectiveness.
B	There is not enough evidence to recommend the use of melatonin for the interruption of prolonged use of BZDs.

7.5.2 Acupuncture

Acupuncture is a therapeutic procedure in which specific body areas (meridian points) are injected with fine needles. It is one of the main forms of treatment in traditional Chinese medicine.

Aside from traditional acupuncture with needles, other forms of acupuncture have been developed, including electroacupuncture, laser acupuncture, acupressure, auricular therapy and transcutaneous electrical nerve stimulation (TENS).

A review evaluating the efficacy and safety of acupuncture in people with insomnia was performed for various types of acupressure therapy, auricular magnetic seed acupuncture and transcutaneous electrical nerve stimulation (TENS). The review concluded that although the results of individual studies indicated that these acupuncture interventions could improve results for sleep quality, efficacy data on other outcome parameters such as latency, total sleep time, number of nocturnal awakenings, wake time after sleep onset, total wake time and sleep efficiency were inconsistent or not measured[112]. **SR 1+**

A review of auricular therapy was performed to evaluate its effectiveness. The intervention compared well with western medicine (diazepam), placebo, and false auricular therapy. The review concluded that auricular acupuncture therapy is more effective than control treatments, manages to increase sleep maintenance (up to 6 hours more) and increases sleep efficiency. However, it also stressed that, due to the weak methodological quality of the RCTs and their short duration, more studies are needed to obtain definitive conclusions[165]. **SR 1-**

Some studies have shown that acupuncture can be useful in the treatment of comorbid insomnia, associated with psychiatric or medical disorders, for example. So if standard treatments of pharmacotherapy, psychotherapy or a combination of the two are not effective for one type of secondary insomnia, patients could be referred for acupuncture intervention [166]. **SR 1+**

There is very little information on adverse effects associated with the use of acupuncture. Only one trial of the reviews mentioned above includes an adequate description of adverse effects. These are usually types of pain, infections, inappropriate needle placement, tissue ischaemia or necrosis [166]. **SR 1+**

Current evidence on the use of acupuncture is still not rigorous enough to allow conclusions about the extensive application of any form of acupuncture for the treatment of insomnia, from any cause and for any age group. Also, the long-term effects of acupuncture and/or its variants and their potential adverse effects are still not completely clear.

Randomised, double-blind, larger sample size RCTs of high quality and a longer follow-up are required, in addition to investigating the efficacy and safety of acupuncture for the treatment of insomnia.

Evidence for acupuncture treatment for insomnia

1+,1-	There are no studies of sufficient methodological quality to draw conclusions about the efficacy or safety of acupuncture for the treatment of insomnia[112,165,166].
1+,1-	The long term effects of acupuncture and/or its variants are not known[112,165,166].
1-	Auricular acupuncture therapy appears effective in treating insomnia, increasing sleep maintenance (up to more than 6 hours) and sleep efficiency, however, more methodologically rigorous RCTs are needed[165].
1+	Acupuncture may be effective in the treatment of comorbid insomnia associated with psychiatric or medical disorders[166].

Recommendations on acupuncture treatment for insomnia

B	There are no studies of enough methodological quality to recommend the use of acupuncture in the treatment of primary insomnia.

7.5.3. Herbal medicines

The use of herbal medicines to treat sleep disorders, including insomnia, is very old. Herbal medicines are popular, are used globally and could be considered a treatment option for insomnia if they were shown to be effective and safe. The healthcare practitioner must be able to acknowledge both the benefits and risks that these preparations have. This will prevent a rejectionist attitude that can lead patients concealing their use and masking possible adverse effects.

Valerian (Valeriana officinalis)

Valerian, for its attribution of sedative and sleep-inducing properties, is one of the most commonly used medicinal herbs for insomnia. It is used as a dried herb, extract or tincture.

SR of RCT 1+,1-

Various reviews have investigated the effectiveness and safety of valerian for the treatment of sleep problems and insomnia. With a number of exceptions, comparing it with a BZD or another herb, the studies included in the review evaluated the effectiveness and safety of valerian compared to placebo[167,168].

SR of RCT 1+

These reviews suggest that valerian may be effective in improving sleep quality, but the methodological problems of the studies limited the ability to draw firm conclusions about it. Valerian was found to be safe, with few reported side effects and, when they did appear, were no different from those associated with the use of placebo, and less than those associated with the use of BZDs[168].

The reviews conclude that there is insufficient evidence to establish the effectiveness of valerian compared with placebo for treating insomnia. RCTs involving larger samples and comparing valerian with placebo or other interventions used for treating insomnia are needed. Also, those products on the market containing valerian need to be determined, as well as for the doses at which they may be effective.

RCT 1+

Recent studies focused on evaluating the effectiveness of a combination of valerian with other plants. One RCT compared the administration at night for 28 days of two tablets of valerian combined with hops (Humulus lupulus L) against placebo. Both sleep outcome parameters and quality of life were assessed using sleep diaries and polysomnography[169].

The study concluded that the combination of plants showed a greater (albeit modest) hypnotic effect than placebo; associating improved sleep above all with an increased quality of life. No significant secondary or residual effects were found, and no rebound insomnia was found after discontinuation. The treatment could be useful in cases of mild to moderate insomnia[169].

Another RCT compared administration over 4 weeks of valerian, a valerian and hops combination and placebo. Both valerian preparations were superior to placebo, but only with the combination of plants was the superiority significant[170]. **RCT 1+**

More RCTs of greater sample size to evaluate the sedative activity of this or other plant combinations are needed, however.

Other herbs:

Passion Flower (Passiflora incarnata L.), **California poppy** (Eschscholtzia californica Cham), **lavender** (Lavandula angustifolia Mill), **melissa** (Melissa officinalis L.), **linden** (Tilia cordata Mill).

These plants are often combined with other medicinal plants with sedative properties. In the review conducted for the preparation of this guide, however, no studies evaluating specific efficacy in insomnia of these herbal treatments were found.

Evidence on herbal treatment for insomnia

1+,1-	There are insufficient studies to draw conclusions on the effectiveness of valerian for treating insomnia[167,168].
1+	The combination of valerian and hops has demonstrated some efficacy in treating mild-moderate insomnia, however, RCTs with larger sample sizes are needed to confirm the results[169,170].

Recommendations on treatment with herbal medicines for insomnia

B	There is not enough evidence to recommend the use of valerian alone or in combination with hops for the treatment of insomnia.
√	Professionals should ask patients about any herbal product they are taking or have taken.

7.5.4 Self-help treatments

Self-help programmes can be an alternative for the treatment of insomnia in Primary Care. The alternatives currently used are those of bibliotherapy and support via programmes online.

Bibliotherapy

Bibliotherapy is defined as the guided use of reading for therapeutic aims. It basically consists in the acquisition of knowledge and therapeutic practices by reading specific selected literature, recommended by the therapist. Manuals are used for this, which explain methods that are easy to learn and implement.

There are few studies evaluating the effectiveness of bibliotherapy for considering this type of self-help as an additional method and facilitator for the treatment of insomnia.

RCT 1+

One RCT, however, compared three interventions: bibliotherapy alone based on CBT principles, bibliotherapy with consultation/weekly telephone follow-up and a waiting list control group. For 6 weeks, patients were sent a weekly treatment brochure, and half of them also received minimal professional follow-up via a weekly phone consultation of 15 minutes duration. During the same period, participants in the control group continued to monitor their sleep with sleep diaries. Participants who received bibliotherapy obtained significant improvement in the major outcome variables after treatment (total wake time and sleep efficiency). This improvement was enhanced in those with the telephone follow-up, although both treatments were comparable in the follow-up. The results suggest that bibliotherapy may be an effective approach for treating primary insomnia[171].

On-line programmes

Self-help programmes on-line, based on the principles of CBT, may be a valid alternative for the treatment of insomnia in primary care. Recipients of this type of therapy may be patients with some kind of personal or geographic isolation with limited access to face-to-face psychological consultation, or people who have moved away or travel frequently. Alternatively, they may be individuals who are familiar with using the Internet and find that this gives them the freedom to control the time devoted to treatment and the advantage of anonymity[113].

Self-help interventions via the Internet are similar to bibliotherapy programmes relying on telephone follow-up, however, the Internet has other advantages. It can provide support without having to keep telephone appointments, the therapist can save time by collecting previous questions and answers and setting up a Web page with frequently-asked questions, with answers, and treatment can be controlled time-wise to a regimen, with automatic advice[113].

RCT 1+

As happened with bibliotherapy, studies evaluating the effectiveness of self-help programmes via the Internet for the treatment of insomnia are scarce. One RCT evaluated such a programme, where the evaluation, treatment and monitoring were performed over the Internet. It compared a sleep management intervention based on the Morin manual, which included sleep restriction, stimulus control, sleep hygiene, cognitive restructuring, applied relaxation and/or information about withdrawal from medication, compared with a waiting list control group. The therapists were psychologists and the programme lasted 5 weeks, although all participants had previously filled in an at-home sleep log for two weeks as well as a series of different questionnaires[113].

The premise was that self-help intervention via the Internet could be a potential alternative treatment for chronic insomnia. However, the control group, who only received information about the study and completed an at-home sleep log and questionnaires, also improved in most outcome parameters.

The study concluded that the Internet could serve as a means of psychological treatment of insomnia. However, further RCTs are required to investigate the effectiveness and efficiency of this novel form of self-help, as well as the possibilities of its implementation[113].

Evidence on self-help treatment for insomnia

1+	A self-help programme with bibliotherapy, based on CBT, with or without a weekly 15-minute telephone follow-up, proved effective in the treatment of patients with insomnia by reducing the total wake time and increasing sleep efficiency [171].
1+	There is insufficient evidence to draw any conclusions about the effectiveness of on-line self-help programmes, based on CBT, for the treatment of insomnia[113].

Recommendations on self-help treatment for insomnia

B	The application of bibliotherapy based on CBT principles via self-help manuals and guided by professionals is recommended in health centres

7.6 Treatment of the elderly

Therapeutic recommendations for the elderly with primary insomnia do not show marked differences with respect to the foregoing. However, it is also necessary to remember the features of sleep in the elderly (Table 4) and to make some special considerations.

As a general rule, the treatment of the elderly involves assessing a therapeutic level, and taking into account the possible diseases, both somatic and psychiatric, which often occur together within the same person. Also, the possibility of modifying lifestyle factors that may affect sleep quality need to be considered. Another factor not to be ignored is that many patients will be taking a number of drugs, so the contribution that some drugs have on the problem of insomnia must also be considered.

Psychological interventions:

The interventions of cognitive behavioural therapy (CBT), as presented in the previous paragraphs are also applicable to the treatment of insomnia in older people.

CPG (SR and RCT) 1++,1+ SR, Meta-analysis (RCT 1++,1+)

There are several reviews that assess the effectiveness of CBT in the quality, duration and sleep efficiency of sleep in people over 60 years. Outcome variables included in studies measure the difficulties in falling and staying sleep, the sleep efficiency and sleep onset latency, problems of delayed sleep and poor daytime functioning. The types of interventions were sleep hygiene, stimulus control, muscle relaxation, sleep restriction and cognitive therapies. Primary and secondary results, sleep quality and quality of life measurements were considered.

The conclusions of these studies show that the effectiveness achieved by treatment with CBT was lower in the elderly than that achieved in younger people, however, this treatment was still particularly beneficial in the short term. The effects, however, are not always long-lasting and, as already emphasised in previous sections, more long-term studies are needed[73,101,172].

SR, Meta-analysis (RCT 1++,1+)

After further analysis of the different outcome parameters included, the only clinically important improvement obtained is the wake time after sleep onset. Improvements were seen in latency and sleep maintenance, but they were not clinically significant and decreased over time. Sleep efficiency results also showed a modest benefit at first, but faded with time[172].

SR of RCT

The most effective interventions are stimulus control (either individually or in a group) and the sleep restriction [73,91,173]. Some studies emphasise the importance of sleep hygiene as an adjunct to these techniques[73].

RCT 1+

A later RCT, taking into account the findings of the studies cited above, compared CBT with zopiclone for treatment of insomnia in older people. CBT was given by psychologists in individual weekly sessions of 50 minutes and included: sleep restriction, stimulus control, cognitive techniques, and progressive relaxation. The comparison was made against drug treatment of zopiclone or placebo. The duration of the intervention was 6 weeks with a follow-up of the active treatments at 6 months. Using sleep diaries and polysomnography, the parameters evaluated were total wake time, total sleep time, sleep efficiency and delayed sleep problems.

CBT showed a statistically significant clinical efficacy compared with zopiclone or placebo for sleep efficiency, delayed sleep problems and total wake time, both short and long-term. With polysomnography, there were no significant changes in effectiveness among the three treatments for total sleep time, but on the assessment made by the sleep diaries, participants showed greater improvement with CBT[174].

This study adds further evidence for the effectiveness of CBT in both the short and long term to treat insomnia in older people.

Pharmacological treatment:

Drug therapy for insomnia in the elderly should take into account a number of factors that can modify the response to these drugs. These factors can be summarised as follows:

- *Social and cultural*: A large number of the elderly manage their own medication. Circumstances associated with old age can affect compliance with treatment, such as memory loss, loss of vision, making it difficult for them to read the names of drugs, and hearing loss, which may impede their understanding of how to use the medication.
- *Comorbidity and polypharmacy*: The elderly suffer multiple conditions to a greater extent than the young, and tend to combine hypnotics with other substances. This association may be the cause of occurrence of interactions and side effects[73].
- *Pharmacodynamic changes*: These refer to the number of receptors for the drugs, once the special sensitive of the CNS to such substances has been objectified[73].
- *Pharmacokinetic changes*: The different phases of the drug through the body can be modified. Changes in absorption do not influence significantly. Changes in the liver result in a reduction of the effect of the first phase, increasing drug bioavailability. The distribution volume is determined by the degree of plasma protein binding and body composition, which in older people are modified. Hepatic metabolism and renal elimination are also slowed[73,175,176].

Hypnotics:

Given that hypnotics, and especially the BZDs, are the drugs most commonly used for older people with insomnia, all the changes mentioned above, may lead to drug accumulation and a resulting increase in adverse effects. Especially those linked to a loss of balance and increased risk of falls and fractures[73,177-180].

There is little evidence to quantify and compare the potential benefits and risks of using hypnotics for patients over 60 years. A meta-analysis confirmed that the drugs are significantly superior to placebo, although their effect is very small. However, at the same time, adverse effects are significantly higher in the group of patients with drug treatment than for placebo. The conclusion is, therefore, that the risk-benefit ratio for treatment with hypnotics is unfavourable[180]. **Meta-analysis 1-**

However, it is difficult to draw conclusions from this study due to its methodological limitations: the heterogeneity in terms of half-life, the strength and dosage of hypnotics grouped in the meta-analysis, the difference in outcome measures used and lack of homogeneity of patient characteristics.

There is insufficient information on the comparison between the use of benzodiazepine and non-benzodiazepine hypnotics in older people. A review clarifies that the non-benzodiazepine are safer because they do not seem to cause a deterioration in daytime performance according to cognitive and psychomotor tests, and their interruption does not cause rebound insomnia, agitation or anxiety. However, more RCTs with good quality methodology are needed, to make comparisons between the two families of drugs[134]. **SR 1+**

Antidepressants:

Studies are needed to be carried out in patients with insomnia not associated with depression regarding the use of antidepressants such as trazodone, mirtazapine, and escitalopram[73,75]. **CPG (S R and RCT) 1++,1+ SR of RCT 1+**

Regarding trimipramine, the lack of methodological quality of studies carried out does not allow any meaningful conclusion for its effectiveness[181]. **RCT 1-**

Clomethiazole:

Although the use of clomethiazole is indicated for adults with insomnia by the Spanish Drug Agency, there are insufficient studies to reach conclusions about the effectiveness of this drug in the treatment of insomnia for this group of people[182]. **Expert opinion 4**

Other drugs:

Because of their significant adverse effects, other drugs such as barbiturates and antipsychotics are not recommended, especially in the elderly. The same applies to some antihistamines such as diphenhydramine, hydroxyzine, doxylamine which, although they have hypnotic properties, are not recommended for elderly patients due to their strong anticholinergic action[162].

SR of RCT 1+

Moreover, there are some internationally accepted expert consensus criteria (Delphi modifiers) for the use of medication in the elderly, known under the name of the "Beers criteria". These describe the drugs whose use would be potentially inappropriate in the elderly. The criteria have been used during the last decade for their usefulness in reducing problems associated with drug treatment in the elderly. After updating, the inappropriate drugs for older people with insomnia are listed in Table 14[183]. It outlines the drug, the reason its use is inappropriate, and a severity index if it is used:

Expert opinion 4

Table 14. Updated Beers criteria, for potentially inappropriate drug use in the elderly with insomnia, regardless of diagnosis or condition[183]

Drug	Concern	Severity Rating
Long half-life benzodiazepines	Possibility of prolonged sedation and increased The risk of falls and fractures.	High
Flurazepam	This benzodiazepine hypnotic has extremely long half-life in elderly patients (often days), producing prolonged sedation and increasing the incidence of falls and fractures.	High
Doses of short-acting benzodiazepines: doses greater than lorazepam (Ativan), 3 mg; oxazepam (Serax), 60 mg; alprazolam (Xanax), 2 mg; temazepam (Restoril), 15 mg; and triazolam (Halcion), 0.25 mg	Because of increased sensitivity to benzoadiazepines in elderly patients, smaller doses may be effective as well as safer. Total daily doses should rarely exceed the suggested maximums.	High
Amitriptyline	Because of its strong anticholinergic and sedation properties, amitriptyline is rarely the antidepressant of choice for elderly patients.	High
Doxepin	Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice for elderly patients.	High
Anticholinergics and antihistamines: diphenhydramine, hydroxyzine	All nonprescription and many prescription antihistamines may have potent anticholinergic properties. Diphenhydramine May cause confusion and sedation. Should not be used as a hypnotic, and when used to treat emergency allergic reactions, it should be used in the smallest possible dose.	High

Modified from Fick et al[183]

Observational study 2+

In a Dutch observational case-control study, the clinical value of the Beers criteria for the use of BZDs was investigated; and, in particular, an observational association between inappropriate use and risk of fracture. The results suggest that the inappropriate use of BZDs according to the Beers criteria is not associated with increased risk of fracture. There was, however, a greater risk with the use of high doses and in treatments exceeding 14 days[184].

RCT 1+

There are two RCTs that evaluate the effectiveness of various methods of BZD drug treatment interruption in patients over 60 with insomnia. The methods compared were: gradual reduction of the drug, CBT and a combination of the two methods. The average age of people included in the studies was relatively low (63-67 years). Both RCTs concluded that the practice of gradual reduction of the drug in combination with CBT is more effective in helping people over 60 with insomnia to reduce or stop their consumption of BZDs. More RCTs with older patients and a placebo group are needed before any formal conclusions can be drawn[185,186].

Qualitative research

In the process of discontinuation of hypnotics in older people, questions such as the following should be considered: the role that patient motivation takes in minimising the problems (side effects) associated with these drugs; and the overstatement, on the part of physicians, of the difficulties that withdrawal of the drug can lead to[187].

Expert opinion 4

The French National Health Authority (HAS) prepared a programme with global and cross-actions for reducing the consumption of prescription hypnotics in older people. It was proposed from an improvement in the diagnosis of sleep problems (including insomnia) for reduction and interruption of the consumption of these drugs[188].

Other treatments:

Melatonin:

SR of RCT 1+

There are other types of treatment evaluating the effectiveness of treating insomnia in the elderly.

There were reviews that tried to assess the effectiveness of melatonin in older people with insomnia, whose endogenous melatonin levels were lower. The results obtained (significant reductions in sleep onset latency, but no change in sleep maintenance) suggest that treatment with melatonin may be effective for these patients. However, the review opined that more conclusive RCTs of a larger sample size were needed[189].

RCT 1+

A more recent RCT, with patients aged 55 or older, diagnosed with primary insomnia according to DSM-IV, excluded patients with insomnia associated with other sleep disorders or other pathologies. The study compared the effectiveness and safety of slow-release melatonin against pla-

cebo. Patients were divided into two groups according to the severity of their insomnia. The study lasted seven weeks, with three weeks of a nocturnal use treatment diary. The results showed that melatonin administration improves the quality of sleep, as well as daytime sleepiness indices compared with placebo. This improvement was statistically significantly more pronounced in the most serious group[190].

There was no significant evidence of rebound insomnia or withdrawal effects after discontinuation of the treatment. The study concluded therefore that melatonin may prove to be effective and safe for the elderly with primary insomnia[190].

Currently, in Spain, melatonin has been approved for use in people over 55 years with insomnia. However, it is not yet commercially available.

Physical exercise:

SR of RCT 1+

Some recent research was done based on the assumption that physical exercise may have benefits for sleep problems. It concerned anxiolytic (anti-anxiety) and antidepressant effects, and their role in the changing circadian cycle.

There was a review that evaluated the effectiveness of active participation in exercise programmes designed for patients over 60 years of age with sleep problems. Only one trial was found, with 43 patients over 60 with insomnia. It compared endurance training with moderate exercise (4 weekly sessions of 30-40 minutes, with gentle aerobic exercise and a brisk walk) with a control group waiting list, and lasted 16 weeks.

Significant results were obtained for latency, duration and sleep quality and a slight improvement in the sleep efficiency parameter. The review concluded that due to the small sample size, the results could not be generalised, pointing to the need for future research[191].

Bright light therapy:

SR of RCT 1+

Another technique evaluated was treatment with bright light therapy. There was a review that evaluated the effectiveness of this intervention in improving the quality of sleep in adults over 60 years. In fact, the RCTs reviewed did not meet the criteria for inclusion of patients with primary insomnia, because they were for patients with other disorders like dementia (including Alzheimer's) and depression. For these patients, treatment with bright light therapy was effective in synchronising uneven sleep timing and reducing the frequency of behavioural disorders[27].

Considering the lack of evidence, the review concluded that bright light therapy treatments could not be recommended for the treatment of sleep problems among older adults without associated pathology. However, in view of the promising results obtained with other disorders, it concluded that future research in patients with primary insomnia was justified[27].

A subsequent RCT evaluating the efficacy of bright light therapy for sleep onset problems in older persons with insomnia compared daily exposures of 10,000 lux intensity for 60 days, for either 20 minutes or 45 minutes. An assessment of the results was made after 3 and 6 months of treatment. The results showed a significant and lasting improvement for the parameters of latency and total sleep time in the 45-minute group. However, the methodological quality of the trial, with no control group, as well as the finding that the effects obtained did not necessarily result from the therapy, require the implementation of more RCTs to recommend this treatment[192]. **RCT 1-**

Evidence on the treatment of insomnia in the elderly

1++,1+	The effectiveness of behavioural therapy and CBT techniques for the elderly in the short term is demonstrated, although the benefits achieved are lower than those achieved in younger persons. Long-term studies are required[73,101,172].
1++,1+	The best results with behavioural techniques and CBT are obtained for wake time after sleep onset, followed by latency, sleep maintenance and sleep efficiency. However, they diminish over time[172].
1++,1+	The most effective behavioural and CBT interventions for the elderly are stimulus control (individually or in a group) and sleep restriction. Sleep hygiene is important as an adjunct to these techniques[73,101,173].
1+	Compared with zopiclone or placebo, CBT showed statistically significant clinical efficacy for sleep efficiency, delayed sleep problems and total wake time, both short and long-term[174].
1-	For older people, adverse effects of hypnotics compared with placebo, outweigh the benefits. The risk-benefit ratio is unfavourable for treatment with hypnotics[180].
1+	There is insufficient information on the comparison between the use of benzodiazepine and non-benzodiazepine hypnotics in older people[134].
1+	Studies are needed in older patients with insomnia not associated with depression, to demonstrate the efficacy of antidepressants such as trazodone, mirtazapine and escitalopran[73,75].
4	Studies are needed for the use of clomethiazole to demonstrate efficacy in the treatment of insomnia for older people[182].
1+	The treatment in older persons of barbiturates, antipsychotics, and certain antihistamines, such as diphenhydramine, hydroxyzine, and doxylamine, has significant adverse effects[162].
1+	The practice of gradually reducing hypnotics combined with CBT is the most effective way to help people over 60 with insomnia to reduce or stop consumption of BZDs. More RCTs are needed with older patients and a placebo group to reach conclusions[185,186].
1+	Slow-release melatonin is safe and effective (improving sleep quality and daytime sleepiness rates) for people of 55 or older with primary insomnia[190].
1+	Participation in physical exercise programmes is effective for latency, duration, sleep quality and sleep efficiency. However, RCTs, with larger sample sizes are needed to draw conclusions[191].
1+/1-	The use of bright light therapy appears effective in latency and total sleep time. However, more methodologically rigorous RCTs are needed in older patients with insomnia which is not associated with other pathologies[27,192].

Recommendations on the treatment of insomnia in the elderly

√	Any concurrent conditions, the possibility of modification of lifestyle factors affecting sleep quality and the contribution that some drugs can have on insomnia must first be taken into account.
B	Either behaviour therapy or cognitive behavioural therapy (CBT) is recommended in older people with insomnia; especially stimulus control and sleep restriction, supported with sleep hygiene education
√	The use of hypnotics in older people is generally not recommended, due to the unfavourable risk/benefit ratio.
B	There is enough evidence to recommend the use of antidepressants for insomnia associated with depressive disorder, but not for primary insomnia.
√	There is insufficient evidence to recommend the use of clomethiazole in the treatment of insomnia in older people.
B	The use of barbiturates, antipsychotics or antihistamines, such as diphenhydramine, hydroxyzine, and doxylamine, is not recommended for older people with insomnia.
√	When prescribing any hypnotic in the elderly, it is recommended to start with half the usual adult dose.
B	For elderly long-term users of hypnotics, a gradual reduction of the drug combined with CBT is recommended, to help slow or stop the consumption of BZDs.
B	Slow-release melatonin* may be used in patients aged 55 or over with primary insomnia, as it improves sleep quality and daytime sleepiness.
B	More long-term comparative studies are needed to generalise the use of exercise in the treatment of elderly patients with insomnia.

* Melatonin is approved for use in Spain for people over 55 with insomnia, however, it is not commercially available.

8. Patient information and adherence to treatment

Questions to answer:

- What is the basic information to be provided for patients with insomnia?
- How can compliance/adherence in the treatment of insomnia be improved?

Numerous health-related behaviours frequently act as barriers to the process of adherence to treatment of a patient. The most significant barriers may be social and economic in origin, from the health care team or system, the characteristics of a particular disease, treatments as well as patient-related factors[193,194].

Expert opinion 4

For insomnia, as with other health problems, it is important to take into account the experience, preferences and expectations of the patient regarding treatment decisions to be taken, so they can take an active part in the process of adherence[193]. A number of actions should be taken after a diagnosis of primary insomnia:

1. Provide all information to the patient, including general information about insomnia and the effective treatment interventions that currently exist. Patient information is part of the integrated management of insomnia at the PC level[193].

Case series 3

2. Determine if a patient is a better candidate or has a preference for psychological or pharmacologic intervention. In other words, determine the degree of commitment and motivation of the patient for a psychological approach, bearing in mind that this type of treatment means changing daily life routines or habits and needs to be sustained over time.

An important determinant for adherence to CBT and behavioural interventions for treating insomnia is the perception of self-efficacy (a term referring to the beliefs in individual capacities to organise and implement the actions required to produce an estimated result). Despite the inconvenience that insomnia causes, commitment and motivation are required to implement the clinical recommendations of the healthcare staff (regarding sleep hygiene, stimulus control, sleep restriction, relaxation, etc), at least in the beginning. Some patients show little confidence in their ability to maintain the prescribed changes, and others will not initiate behavioural therapy because of low self-efficacy. The relationship between the perception of self-efficacy and long-term adherence to treatment has been shown, with the former being an important predictor of the latter[195].

3. Think about the patient and inform him about common barriers that can occur with the implementation of psychological interventions[196], such as: **Case series 3**

– It requiring a significant investment in time and effort on the part of patients.

– Difficulties arising from integrating new patterns of behaviour in the lifestyle of patients, such as having to maintain the same sleeping hours every day, regardless of weekends and holidays, which may involve or affect the rest of the family.

– Boredom and discomfort associated with specific interventions, such as having to get out of bed at night until you feel sleepy again, in the case of sleep restriction.

– Inconveniences arising from having to remove certain patterns of consumption of substances such as tobacco and alcohol.

4. Consider the existing association between the positive results of psychological interventions and patients' own adherence to them. In a study, strategies were evaluated to assess adherence to sleep restriction therapy. The results suggested that maintaining a regular sleeping schedule, recommended for this therapy, may be more therapeutic than the reduction of time in bed. However, a direct causal relationship between the positive results and follow-up reflected in the at-home sleep log (adhesion) cannot be established, since the effectiveness of the treatment itself may be causing greater post-treatment adherence, or good adherence could lead to better results[197]. **Case series 3**

Information for the patient and family is given in Appendix 11, **"Learning about insomnia and managing it"**, as support for the integrated management of insomnia by PC practitioners.

Evidence on patient information and adherence to treatment in insomnia

4	Information for patients with insomnia, including general information about the problem and effective treatment interventions that currently exist, is part of the integrated management of insomnia at the PC level[193].
4	The experiences, preferences and expectations of patients with insomnia, with regard to treatment decisions, are important for improving adherence to treatment[193].
3	An important determinant of adherence to behavioural interventions and CBT is the patient's perception of self-efficacy (belief in individual abilities to produce a given action)[195].
3	The most frequent barriers that occur with the implementation of psychological interventions are investing significant time and effort, boredom, discomfort and difficulty in integrating new patterns of behaviour in daily habits, and inconvenience of having to give up certain substances[196].
3	There seems to be a positive association between the results of psychological interventions and patients' own adherence to them[197].

Recommendations on patient information and adherence to treatment in insomnia

D, √	It is recommended to provide information for patients with insomnia, including general information about the problem and effective interventions (see Appendix 11 - patient Information.
D, √	To improve treatment adherence and facilitate shared decision-making, patient experiences, expectations and preferences regarding treatment decisions must be taken into account.
D, √	It is recommended to encourage the patient to acquire a certain degree of motivation to carry out the clinical recommendations of health professionals regarding sleep hygiene education, stimulus control, sleep restriction and relaxation therapies.
D, √	Patients must be informed of the barriers they need to overcome and the effort involved in compliance with certain psychological interventions, in connection with the adoption of new patterns of behaviour, (eg, keeping to the same sleep timetable every day, getting out of bed until feeling sleepy again and stopping certain habits-tobacco and alcohol.

9. Nursing role

The involvement of nursing professionals for the treatment of insomnia is essential, both in individual and group approaches in primary care.

The assessment of Behaviour Patterns can be used to structure the clinical interview (see Table 15) to detect sleep-related problems. This assessment can be completed with the questionnaires mentioned previously in the guide.

Table 15. Assessment of Behavioural Patterns

- Perception / Control of health:
  - How he describes his health.
  - Knowledge regarding the sleep problem.
  - What he has done to improve it.
  - Use of drugs (prescribed or self-medication).
- Nutritional:
  - Daily food and drink intake patterns.
  - Intake of substances that may affect sleep (coffee, tea, alcohol, etc).
  - Fatigue (+++)
- Toilet visits:
  - Presence of nocturia.
- Activity / exercise:
  - Description of daily routine activities.
- Rest / sleep:
  - Normal sleep pattern.
  - Difficulties with sleeping.
- Self-perception:
  - What concerns the patient most.
  - His aims in relation to his current situation.
  - If his perception has changed as a result of having this problem.
- Role / relationships:
  - Thoughts on family and social life.
- Sexuality:
  - If there has been any change.
- Change / stress:
  - Losses or changes in his life during the past year.
  - If there is anything he would change in his life.
  - How he handles or has handled other stressful situations.

This assessment may help in detecting changes that may lead to a diagnosis of insomnia or troubled sleep patterns that require action by nursing staff. If it is insomnia, it must be addressed in the best way possible to stop it from becoming a chronic problem.

As specified in Chapter 5, the NANDA classification (International Nursing Diagnoses and Classifications) includes the diagnosis of insomnia in its classification, with its defining characteristics and related factors (see Table 6)[63].

The Nursing Interventions Classification (NIC) and Nursing Outcomes Classification (NOC) in relation to insomnia are presented below.

Table 16. Classifications NIC and NOC

NOC	
0004. Sleep 000403. Sleep pattern 000404. Sleep quality 000405. Sleep efficiency 000407. Sleep habit 000417. Dependence on assistance for sleeping (Scale: 1 Severe, 2 Substantial, 3 Moderate, 4 Slight, 5 None)	Evaluation scale: 1. Severely compromised 2. Substantially compromised 3. Moderately compromised 4. Slightly compromised 5. Not compromised

NIC
1850. Improving sleep
Include the regular sleep/wake cycle of the patient in care planning. Determine the effects of medication in the patient's sleep pattern. Observe/record the pattern and number of hours of sleep the patient has.
Check the patient's sleep pattern and observe the physical circumstances (sleep apnea, airway obstruction, pain/discomfort and urinary frequency) and/or psychological ones (fear/anxiety) that disrupt sleep.
Show the patient how to control the sleep patterns.
Control participation in activities that cause fatigue during waking hours to avoid excessive fatigue.
Adjust the environment (light, noise, temperature, mattress and bedding) to promote sleep.
Encourage the patient to establish a routine when going to bed to ease the transition from wakefulness to sleep.
Help to eliminate stressful situations before going to bed.
Help the patient to refuse food or drinks that interfere with sleep just before going bed.
Help the patient to limit sleep during the day by providing an activity to promote wakefulness, if appropriate.
Show the patient how to perform autogenic muscle relaxation or another non-pharmacologic sleep induction exercise.
Group activities to minimise the number of awakenings. Allow sleep cycles of at least 90 minutes. Adjust the medication programme to help the patient's sleep/wake cycle.
Explain those factors that contribute to disturbing the sleep pattern to the patient and loved ones (physiological, psychological, lifestyle, frequent changes of shift, rapid time zone changes, excessively long working hours and other environmental factors).
Discuss techniques to promote sleep with the patient and family. Provide written information, pamphlets etc, on sleep promotion techniques.

The use of nursing diagnoses, along with the classification of results (NOC) and nursing interventions (NIC) allow the following:

– To standardise interventions by practitioners.

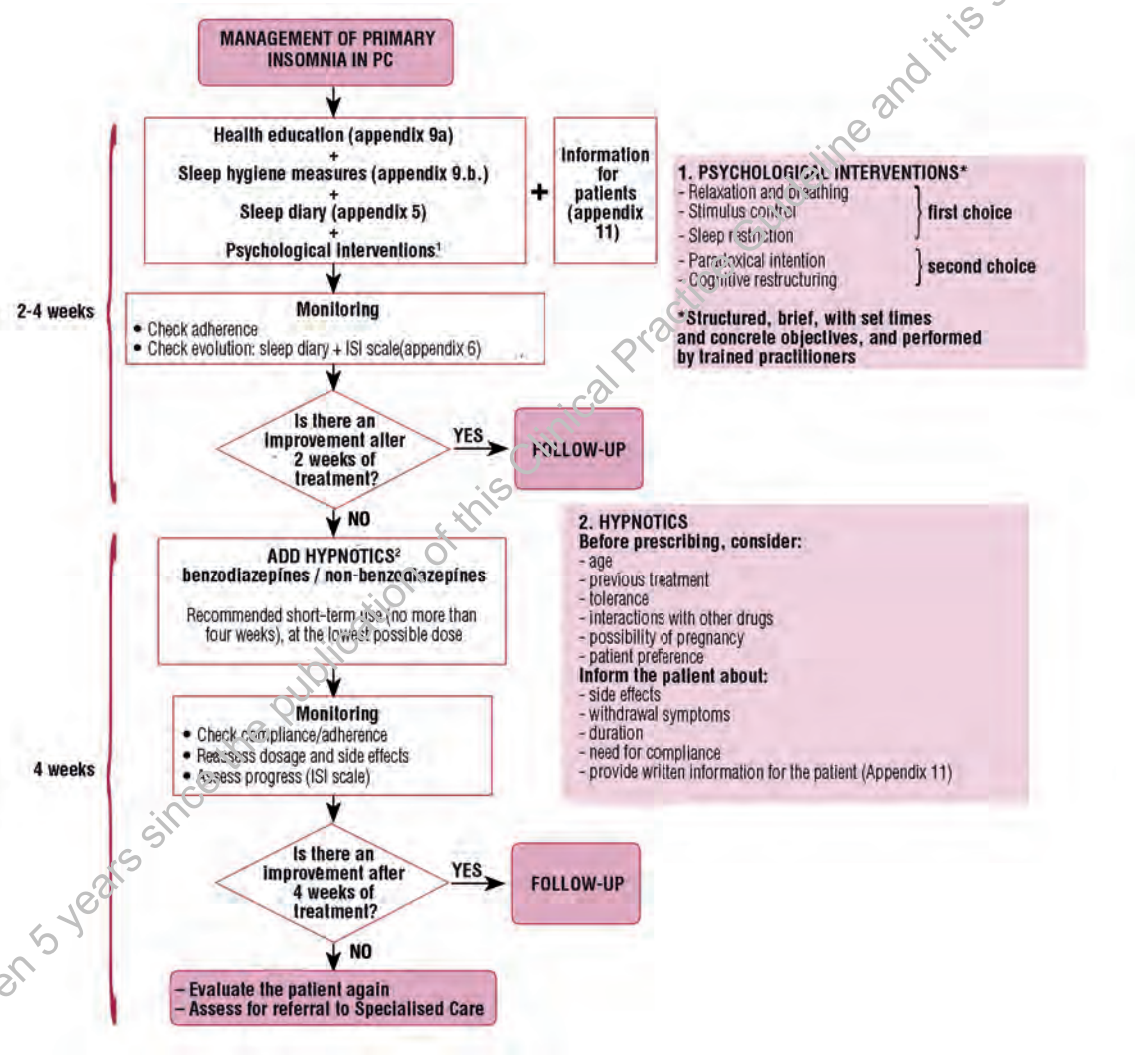
– To perform a follow-up to quantify the evolution of the problem through specific indicators.

10. Diagnostic and therapeutic strategies

Questions to answer:

- What are the steps to follow with primary insomnia patient's?

The steps to follow for a patient with primary insomnia are shown in the management algorithm below:



Additional comment: For those patients who are suspected of insomnia caused by other sleep disorders such as apnea or restless leg syndrome, the patient should be referred to Specialised Care for further diagnostic testing (polysomnography and actigraphy. See glossary, Appendix 12)[30,39,198].

11. Dissemination and implementation

- What is the dissemination and implementation strategy of this guide?
- What are the indicators for monitoring the key recommendations?

11.1 Dissemination and implementation strategy

The clinical practice guidelines are useful for improving the quality of care and patient outcomes. The big challenge now is to get professional adherence to the recommendations of these guidelines. This calls for an implementation strategy aimed at overcoming the barriers in the field of application.

The plan for implementing the guide for the management of insomnia in patients in PC includes the following interventions:

- Presentation of the guide to the media by the health authorities.
- Presentation of the guide to Primary Care and Specialised Care management in the various Regional Health Services.
- Institutional presentation of the guide in collaboration with the Quality Agency of the Ministry of Health and Social Policy to the various scientific and professional organisations involved.
- The information produced for the patient will be highlighted in all its forms to facilitate its distribution to all health personnel, and thus in turn to patients with this health problem.
- Effective and targeted distribution to the professional groups involved (PC physicians, nurses and social workers, psychiatrists, psychologists and specialists in Mental Health) to facilitate its dissemination.
- Interactive presentation of the guide in health centres by local opinion leaders.
- Posting of the guide in electronic format on the websites of the Ministry of Health and Social Policy of the Health Guide, the Health Technology Evaluation Unit (UETS) and companies involved in the project.
- Publication of the guide in scientific journals.
- Establishment of criteria for good care of patients with insomnia for the programme and clinical management contracts, as provided for in the guide.
- Evaluating effectiveness of implementation, establishing systems of clinical decision support, integrating the guide and the indicators selected in the software used in PC.

11.2 Proposed indicators

The authors of this CPG have designed a series of indicators that must be measurable, through the information system in PC, to evaluate both health care for patients with insomnia and the potential impact of the implementation of the guide. It was not the purpose of the authors to design a comprehensive and detailed evaluation involving the use of all proposed indicators. The intention was to provide a tool for those practitioners and managers concerned, which may be useful in the specific design of the evaluation of care for patients with insomnia in Primary Care.

Two types of indicators are proposed:

– *Monitoring indicators:* This set of indicators would monitor the distribution of patients according to the use of the treatments and tools suggested in the guide.

– *Compliance indicators:* These are based on the recommendations proposed in this guide and therefore the available scientific evidence and consensus of the profession. Although the proposed compliance standards should be 100%, the reality of the PC field must be taken into account when establishing such standards.

Evaluation criteria	Monitoring indicators
1. Diagnosis of insomnia	Percentage of patients with insomnia seen in primary care
2. Treatment options	The number of patients with insomnia receiving psychological treatment (and type of intervention) or pharmacological treatment (and type of drug) or a combination (psychological and pharmacological) or another.
3. Using scales	Percentage of patients with insomnia evaluated with the scales proposed in the guide
4. Referral to Specialised Care	Percentage of patients with insomnia referred to specialist care of all patients with these disorders treated in Primary Care.

Good care criteria	Monitoring indicators	Standard
1. Diagnosis of insomnia	1. Percentage of patients diagnosed with insomnia following the clinical criteria in the guide.	90%
2. Patient information	1. Percentage of patients with insomnia offered information about their condition reflected in the guide.	100%
3. Treatment options	1. Percentage of patients with insomnia receiving psychological treatment interventions as suggested in the guide. 2. Percentage of patients with insomnia receiving drugs as proposed in the guide in their pharmacological treatment.	80%

12. Recommendations for future research

12.1 Definition and diagnosis of insomnia

Longitudinal studies are needed to identify those observing factors affecting the incidence, natural history and remission of insomnia. Questions could be added on chronic insomnia in the ongoing observational studies that evaluate many potential determinants of insomnia incidence, persistence, and remission.

Also needed are specific studies on the genetic etiology of chronic insomnia. It is important to quantify the importance of family history, with a systematic search for specific genes.

12.2 Psychological interventions

Studies of psychological interventions for insomnia must define the components used of cognitive behavioural therapy (CBT) with less variability.

Additional studies must be conducted to compare CBT interventions and behavioural interventions only. In addition, each technique applied must be compared as the only technique in relation to the outcome parameters.

More research is needed to check if it is more effective to provide a combination of behavioural interventions and CBT as compared to a single therapy, as well as identifying for which groups of patients a combination or single intervention would be more appropriate.

Valid instruments must be used for assessing both objective and subjective outcomes to assess the effectiveness of interventions.

The limitation of the outcome parameters used in behavioural and CBT intervention studies is that they focus on the symptoms of insomnia and do not assess effects such as reduced morbidity or more qualitative ones, such as an improvement in the quality of life and daytime functioning of patients. It would be necessary to determine whether insomnia can lead to disability or sick leave and whether the treatment can improve intellectual and working functioning.

Longer studies (increased follow-up) are needed to draw conclusions about the long term efficacy of psychological therapy. As there are a significant number of patients with chronic insomnia still benefitting from short-term therapy, they remain vulnerable to recurrent episodes, and further studies are needed to assess both the efficacy of this type of long-term treatment, such as maintenance techniques to prevent or minimise the recurrence of insomnia.

In the area of PC in Spain, research should increase the understanding of the effect of psychological therapies applied in this context, while also measuring long-term effects, including control groups and blind procedures, as well as everything that assesses the effect on the consumption of hypnotics.

Here, the effectiveness of these interventions must be validated when implemented by PC practitioners.

Additional studies are also needed for the cost-effectiveness of different psychological interventions for treating insomnia.

There is also a need for information on adherence to psychological treatment for insomnia, to ensure that patients are able to easily assimilate, adapt and feel comfortable practising these techniques they have learned at home.

12.3 Pharmacological interventions:

Hypnotics:

More short and long term RCTs without the existence of potential conflicts of interest are required to investigate the adverse effects of hypnotics and to compare benzodiazepines and non-benzodiazepines.

More studies on the risks and benefits of treatment with hypnotics are needed.

Longer RCTs are needed to draw conclusions about the long-term efficacy and safety of hypnotics, both benzodiazepine and non benzodiazepine. Questionnaires including indicators to measure the quality of life for patients taking the medication are also required.

For patients complaining of chronic insomnia who are taking drugs, it would be appropriate to conduct studies of drug addiction programmes, as well as evaluating their effectiveness.

More short and long-term RCTs are needed to confirm the results for:

– The effectiveness and feasibility of drug treatment used intermittently or "as required by patient needs", in the short and especially the long term.

– The effectiveness of slow-release formulation for some hypnotics.

Antidepressants:

More studies on the safety and objective and subjective effectiveness of sedative antidepressants, trazodone, doxepin, amitriptyline and mirtazapine, are needed for the treatment of insomnia not associated with depressive disorders.

Further research is needed, without potential conflicts of interest and with a larger sample size, to determine the clinical importance of the significant results found in RCTs performed to date with these drugs.

Other drugs:

RCTs are needed on the long-term use of ramelteon compared with other medication options to determine its efficacy for insomnia.

More work is needed on the efficacy and safety of anticonvulsant and antipsychotic drugs such as gabapentin, tiagabine, quetiapine and olanzapine.

12.4 Other treatments:

Further research is needed with larger sample size RCTs to determine the efficacy, withdrawal effects and adverse reactions of melatonin in patients with chronic insomnia, as well as to determine an appropriate dosage.

Studies are also needed, using larger samples that also take into account the possible influence of dose, to obtain conclusive evidence on the usefulness of melatonin as a facilitator for stopping the use of BZDs.

Further randomised, double-blind studies with a larger sample size are needed for providing information about the long-term effect and its potential adverse effects of acupuncture and/or its variants, and to draw final conclusions on its usefulness.

RCTs including larger samples comparing valerian with placebo or other interventions used to treat insomnia are needed, as well as determining which of the product presentations on the market and Valerian dose may be efficacious. Also, an RCT with a greater sample size is required to evaluate the sedative activity of this plant with other combinations of plants.

Studies to assess the specific efficacy of herbal treatments for insomnia using sedative plants like passion flower, California poppy, lavender, lemon balm and linden are needed.

Further well-designed tests with a sufficient number of patients to compare the effect of herbal medicines with other treatments used in chronic insomnia are needed to draw robust conclusions about the effectiveness and safety of this therapy as a treatment option.

Prospective studies are needed to identify self-help treatments applicable in PC to provide satisfactory results (bibliotherapy and on-line programmes). In the context of PC, the feasibility of using a directed form of self help manuals should be examined. The benefits attached to their use should be assessed, as well as determining the optimal duration of the intervention in each case. The level of professional involvement required to produce a positive change in patients with insomnia needs also to be established.

12.5 Treatment of the elderly:

Studies are needed to quantify and compare the potential benefits and risks of using benzodiazepine and non-benzodiazepine hypnotics for patients over 60 years.

More RCTs are needed with methodological quality (homogeneity regarding the half-life, strength, and dosage of hypnotics used and the characteristics of patients and outcome measures used) to make comparisons among the different families of hypnotics.

Studies are needed in patients with insomnia not associated with depression to reach meaningful conclusions on the effectiveness of trazodone, mirtazapine, escitalopram and trimipramine.

There is a need to clarify the effectiveness or otherwise of clomethiazole in the treatment of insomnia in the elderly.

More RCTs are needed with older patients and a placebo group to draw conclusions about the effectiveness of various methods of interrupting BZD drug treatment in patients over 60 with insomnia. Issues such as the following should be considered: the role that motivation in elderly patients plays in minimising the disadvantages (side effects) of consumption of these drugs; and the overstatement by physicians of the difficulty that reduction and withdrawal might entail.

More conclusive RCTs are needed with a larger sample size to show the effectiveness of melatonin in older people with insomnia, whose endogenous melatonin levels are frequently lower.

There is a need for further research on the effectiveness of physical exercise programmes designed for patients over 60 years of age.

Given the promising results obtained with bright light therapy in sleep disorders associated with conditions such as dementia (including Alzheimer's) and depression, future research is justified in patients with insomnia not associated with other disorders.

13. Appendices

Appendix 1. Levels of evidence and grades of recommendation

Table 1. Levels of evidence and grades of recommendation from SIGN[1,199]

Levels of evidence	
1++	High quality meta-analyses, systematic reviews of clinical trials or high-quality clinical trials with very low risk of bias.
1+	Well-conducted meta-analyses, systematic reviews of clinical trials, or well-conducted clinical trials with little risk of bias.
1–	Meta-analyses, systematic reviews of clinical trials or clinical trials with high risk of bias.
2++	High quality systematic reviews of cohort or case-control studies. Cohort or case-control studies with very low risk of bias and with high probability of establishing a causal relationship.
2+	Well conducted cohort or case-control studies with low risk of bias and a moderate probability of establishing a causal relationship.
2–	Cohort or case-control studies with a high risk of bias and a significant risk that the relationship is not causal.
3	Non-analytical studies such as case reports and case series.
4	Expert opinion.

Qualitative research[1]

1. This category includes qualitative methodology studies and is not covered by SIGN. Studies incorporated have been evaluated at a methodological level, including more rigorous studies in this category.

Grades of recommendation	
A	At least one meta-analysis, systematic review or clinical trial rated as 1++ directly applicable to the target population of the guide; or a body of evidence consisting of studies rated as 1+ and showing overall consistency of results.
B	A body of evidence consisting of studies rated as 2++, directly applicable to the target population of the guide and showing overall consistency of results; or evidence extrapolated from studies rated as 1++ or 1 +.
C	A body of evidence consisting of studies rated as 2+ directly applicable to the target population of the guide and showing overall consistency of results; or evidence extrapolated from studies rated as 2++.
D	Evidence level 3 or 4; or evidence extrapolated from studies rated as 2+.

Studies classified as 1- and 2- must not be used in the process of developing recommendations due to their high potential for bias.

$\surd^{2}$	Recommended practice based on clinical experience and the consensus of the editorial team.

2. Sometimes the development group wishes to highlight an important practical aspect for which there is probably no supporting evidence. In general, these cases are related to an aspect of treatment generally accepted to be good clinical practice, and is evaluated as a point of good clinical practice. These messages are not an alternative to the recommendations based on evidence, but should be considered only when there is no other way of highlighting that aspect.

Q	Evidence taken from relevant, good quality qualitative studies. This category is not included in SIGN.

Table 2. Levels of evidence and formulation of recommendations for questions about Diagnosis[1,200]

(Adapted from NICE, from the levels of evidence of the Oxford Centre for Evidence-based Medicine and the Centre for Reviews and Dissemination.))

Levels of evidence	Type of evidence
Ia	Systematic review with homogeneity of level 1 studies.
Ib	Level 1 studies.
II	Level 2 studies. Systematic review of level 2 studies.
III	Level 3 studies. Systematic review of level 3 studies.
IV	Consensus, expert opinion without explicit critical evaluation.
Level 1 studies	Comply with: • Masked comparison with a valid reference test (gold standard). • Adequate spectrum of patients.
Level 2 studies	Have only one of these biases: • Population not representative (the sample does not reflect the population where the test applies). • Inadequate comparison with the reference standard (gold standard) - the test that will be evaluated is part of the gold standard, or the test result affects the implementation of the gold standard. • Comparison not masked. • Case-control studies.
Level 3 studies	Have two or more of the criteria described in level 2 studies.

Recommendation	Evidence
A	Ia or Ib
B	II
C	III
D	IV

Appendix 2. Physiology of sleep

There are two distinct types of sleep: REM (rapid eye movement) or paradoxical sleep and slow wave sleep, also known as non-REM sleep[31,32].

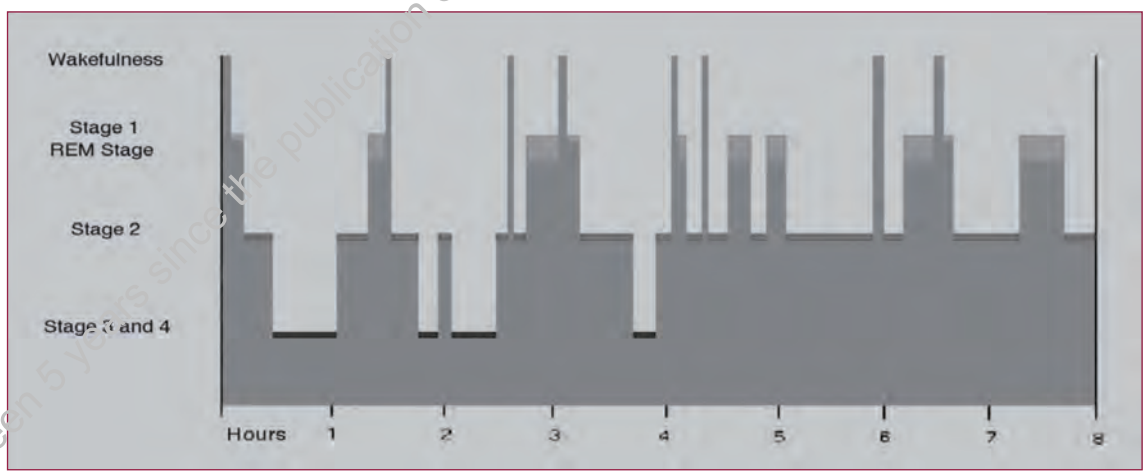
Slow wave or non-REM sleep consists of four stages related to the different degrees of depth of sleep. Stages 1 and 2 appear first, the superficial or light sleep, followed by stages 3 and 4, corresponding to slow wave or deep sleep[31,32]. During the latter, heart rate, blood pressure and cerebral blood flow decrease, while muscle blood flow and the secretion of growth hormone increase[201].

REM or paradoxical sleep is characterised by rapid eye movements, muscle weakness and an EEG much like the waking state[31,32]. Heart rate and blood pressure fluctuate, with frequent bradytachyarrythmias. Cerebral blood flow is similar to wakefulness, with marked neuronal and metabolic activity[201].

In an adult, 75-80% of total sleep during a normal night is non-REM sleep, distributed as follows: 5% stage 1, 50% stage 2 and 20% for stages 3 and 4. The duration of REM sleep therefore occupies between 20-25% of total sleep[202].

When we fall asleep, stage 1 starts. It lasts a few minutes, is followed by stage 2 and then deep or slow sleep, stages 3 and 4, start. This period of non-REM sleep is followed by an REM period; this normally appears 60-90 minutes after the start of stage 1. Non-REM sleep and REM sleep then alternate during the night in cycles of 90-120 minutes each, repeated 4-6 times during a night. The composition of these cycles varies during the night. The first third of the night is dominated by slow-wave sleep. As sleep progresses, the percentage of shallow sleep and REM sleep increase. The arousal index in a healthy adult is 10 per hour of sleep, with moments of waking during sleep of less than 5%[202,203].

The graphical representation of the different stages of sleep throughout the night is known as a hypnogram.



To evaluate physiological sleep, it is important to maintain the relative percentages of different stages as well as evaluating sleep architecture.

This architecture can be modified by various factors, sleep deprivation, sleep onset time, ambient temperature, the consumption of toxic substances (coffee, alcohol, nicotine, marijuana), use of drugs (benzodiazepines, hypnotics, antidepressants) and the existence of some sleep disorders and medical disorders.

The proportion of each sleep stage relative to total sleep changes during a person's lifetime. In the neonatal period, the transition from waking to sleep takes place in REM (active sleep), which accounts for 50% of sleep time. The non-REM-REM alternation happens every 50-60 minutes, chained in groups of 3 or 4 cycles separated from each other by periods of wakefulness wth no circadian distribution. The number of hours of sleep at this age is around 16. In childhood, the amount of slow wave sleep is greatest, decreasing about 40% in the second decade[203].

In the elderly, sleep onset latency is not usually lengthened, but an early onset of awakenings and the inability to go back to sleep is a common complaint. Sleep is more fragmented, with a larger number of alerts (27 per hour of sleep), which means the night time waking periods increase to occupy 12-15% of sleep time. Furthermore, the elderly are more likely to take a nap during the day than younger people. They also often lose the ability to recover sleep, ie the appearance of long periods of uninterrupted sleep that younger people have after periods of sleep deprivation.

Deep, slow sleep appears earlier over the years. From the age of 40, the proportion of stage 4 progressively decreases, and may even disappear entirely by the age of 70. Thus in the elderly the percentage of slow wave sleep is 5-10%, while there is an increase of stage 1, which represents 4-10% of total sleep.

REM sleep changes little with age and its proportion remains stable in healthy subjects until very old age. However, its distribution throughout the night is affected: the first REM appears much earlier in the elderly than in younger people and it tends not to increase throughout the night. Therefore, the first REM is longer than in the young, with notable differences in subsequent cycles.

A common circadian alteration of the elderly is the advance of the sleep-wake circadian rhythm phase, which gives rise to both early evening sleepiness and early morning awakening[203].

Appendix 3. Key questions for a history of sleep

Prompt questions	Supplementary questions
1. Presentation of the Sleep Complaint	
Patterns	
Can you describe the pattern of your sleep on a typical night?	Time to fall asleep? Number and duration of wakenings? Time spent asleep? Nights per week like this?
Could you talk about your sleeping habits?	Do you have any problems with noise? With heat? With light? Any disruptions? What time do you go to bed and get up during the week? And the weekends?
Quality	
How do you feel about the quality of your sleep?	Refreshing? Enjoyable? Restless?
Daytime effects	
How does your night's sleep affect your day?	Tired? Sleepy? Poor concentration? Irritable? Particular times of day? Under what circumstances (motor)?
2. Development of the Sleep.	
Do you remember how this spell of poor sleep started?	Event and circumstances? Dates and times? Variation since then? Exacerbating factors? Alleviating factors? Degree of impact/intrusiveness?
3. Lifetime History of Sleep Complaints	
Did you used to be a good sleeper?	Sleep in childhood? Sleep in adulthood? Nature of past episodes? Dates and times? Resolution of past episodes?
4. Psychopathology and History of Psychological Functioning	
Are you the kind of person who usually copes well?	Psychological problems? Anxiety or depression? Dates and times? Resourceful person? Personality type?

Modified from Morin et al[16]

Appendix 4. Key interview questions for suspected primary insomnia

DSM-IV-TR Criteria	Questions
A. The predominant complaint is difficulty initiating or maintaining sleep, or not having a good sleep for at least 1 month.	– Do you have trouble sleeping at night – Once you decide to go to sleep, does it takes longer than half an hour to do so? – Does it take more than 2 hours? – Do you wake during the night and stay awake for half an hour without wanting to, or an hour in total? – Do you wake up not having slept 6 hours? – Do you wake up more than two hours before you want? – Do you feel tired when you wake with the feeling of not having rested at all? If yes: How many nights a week does this happen: 3 or more? Have you had this problem for at least a month?
B. Sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment of a social, occupational or other important nature.	– Does this difficulty in sleeping make you feel so tired, fatigued or sleepy that it has led to a deterioration in your daily activities?
C. The sleep disturbance does not occur exclusively during the course of another sleep disorder.	– Explore whether the problem occurs exclusively during the night: o Narcolepsy. o Breathing-related sleep disorder. o Circadian rhythm disorder. o Parasomnia. o Restless leg syndrome – Obtain information from the person sleeping with the patient
D. The disturbance does not occur in the course of a mental disorder.	– Check especially for: o Major depressive disorder. o Generalised anxiety disorder. o Panic disorder. o Delirium.
E. The disturbance is not due to the direct physiological effects of a substance (eg, recreational or prescription drugs)	Check if the patient takes something to be able to sleep or if there is an abuse of stimulants.
F. The disturbance is not caused by the effects of a medical condition.	Check for medical conditions.

Modified by Vázquez C and American Family Physician[204,205]

Appendix 5. Sleep Diary

Patient instructions:

– Fill in every morning, according to your memory of the night before (a sleep diary is not a precision instrument).

– Fill in every night, describing any sleep during the day (eg, a nap).

– Keep up to date to obtain an overview of sleep changes over time, especially during the observation period

DATE

DD/MM/YY		8:00	9:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00	24:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00
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Shade the boxes that correspond to the hours of sleeping and taking a nap

1. Show the information below by typing the appropriate letter:
   Bedtime: **A**
   Waking up time: **L**
   Time that you turned off the light (darkness): **O**
   No of awakenings: **D**
   Light on: **E**

For example

DD/MM/YY		8:00	9:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	1700	18:00	19:00	20:00	21:00	22:00	23:00	24:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00
	1																		AO				D			

DD/MM/YY		8:00	9:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	1700	18:00	19:00	20:00	21:00	22:00	23:00	24:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00
	1						L												AE	O						

Appendix 6. Insomnia measuring instruments (questionnaires)

ISI[81]: Insomnia Severity Index.

1. Indicate the severity of your current sleep problem(s):

	None	Mild	Moderate	Severe	Very severe
Difficulty falling asleep	0	1	2	3	4
Difficulty staying asleep:	0	1	2	3	4
Problems waking up too early	0	1	2	3	4

2. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very satisfied	Satisfied	Moderately satisfied	Dissatisfied	Very dissatisfied
0	1	2	3	4

3. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

4. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all Worried	A little	Somewhat	Much	Very Much Worried
0	1	2	3	4

5. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

Guidelines for Scoring/Interpretation:

Total score:

Add the scores for all seven items (1a +1b + 1c + 2 + 3 + 4 + 5) = ____

The total score range is 0-28.

Interpretation:

0–7 = No clinically significant insomnia

8–14 = Subthreshold insomnia

15–21 = Clinical insomnia (moderate severity)

22–28 = Clinical insomnia (severe)

PSQI[206,207]: Pittsburgh Sleep Quality Index.

INSTRUCTIONS: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?
BED-TIME: _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
NUMBER OF MINUTES: _____

3. During the past month, what time have you usually gotten up in the morning?
GETTING-UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)
HOURS OF SLEEP PER NIGHT: _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you….?

(a) Cannot get to sleep within 30 minutes:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(b) Wake up in the middle of the night or early morning:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(c) Have to get up to use the bathroom

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(d) Cannot breathe comfortably:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(e) Cough or snore loudly

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(f) Feel too cold:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(g) Feel too hot:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(h) Had bad dreams

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(i) Have pain

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(j) Other reason(s), please describe: _____

¿How often during the past month have you had trouble sleeping because of this?

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

6. During the past month, how would you rate your sleep quality overall?

❑ Very good

❑ Fairly good

❑ Fairly bad

❑ Very bad

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

8. During the past month, how often have you had trouble staying awake while driving, eating meals or engaging in social activity?

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

❑ No problem at all

❑ Only a very slight problem

❑ Somewhat of a problem

❑ A very big problem

10. Do you have a bed partner or roommate?

❑ No bed partner or roommate

❑ Partner/roommate in other room

❑ Partner in same room, but not same bed

❑ Partner in same bed

If you have a roommate or bed partner, ask him/her how often in the past month you have had.....

(a) Loud snoring

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(b) Long pauses between breaths while asleep

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(c) Legs twitching or jerking while you sleep

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(d) Episodes of disorientation or confusion during sleep

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

(e) Other restlessness while you sleep, please describe:

❑ Not during the past month ❑ Less than once a week ❑ Once or twice a week ❑ Three or more times a week

Interpretation: The first 4 questions are answered specifically. The rest are answered using a scale with four grades. The first 18 questions are self-rated, while the last 5 questions are answered by the bed partner. Seven scores are obtained providing information about different components of sleep: subjective quality, latency, duration, normal efficiency, sleep disturbances (frequency of disturbances such as coughing, wheezing, feeling heat, cold, etc), use of sleeping medication, daytime dysfunction (readiness in falling asleep while carrying out an activity, such as fatigue). Each discrete component receives a score ranging from 0-3. A score of 0 indicates no problems in this regard, while 3 indicates serious problems. The sum of the scores for each component is assessed, and can range from 0-21. According to Buysse et al, a score of 5 is the cut-off point separating subjects with good quality of sleep from those with poor sleep: a score equal to or less than 5 signals a good sleeper.

Appendix 7. Outcome measures used to evaluate the efficacy/effectiveness of therapeutic interventions for insomnia

Primary outcome	
Patient's subjective report about the quality of night time sleep (eg, satisfaction with the time it takes to fall asleep or stay awake at night, with nocturnal sleep duration, feeling of getting a good night's sleep, and so on).	
Secondary outcomes	
1. Sleep parameters*	
Sleep onset latency (minutes)	Time taken to fall asleep after going to bed.
Total sleep time (minutes)	Total time spent asleep during the night.
Sleep maintenance (number)	Number of awakenings during the night.
Wake time after sleep onset (minutes)	Total time spent awake at night between first falling sleep and finally getting up.
Sleep efficiency (%)	Percentage of sleep obtained with respect to time in bed. Calculated using the following formula: [(total sleep time) / (total time in bed)]*100 Sleep efficiency < 85% is considered clinically significant.
Total wake time (minutes)	Total wake time at night.
Slow wave sleep (minutes and %)	Time and relative amount of slow wave sleep (stage 3, Appendix 2) obtained while recording with polysomnography (PSG).
REM sleep (minutes and %)	Time and relative amount of REM sleep (Appendix 2) obtained while recording with polysomnography (PSG).
2. Sleep quality Global score on standardised scales related to sleep (eg, Pittsburgh Sleep Quality Index, Insomnia Severity Index, Appendix 6).	
3. Daily functioning Global score on standardised scales related to fatigue or excessive daytime sleepiness (eg, Fatigue Severity Scale, Fatigue Scale from the Mood status Profile, Epworth Sleepiness Scale). Performance in tasks requiring attention and concentration (eg, computerised tasks or "paper and pencil" reaction time).	
4. Quality of life Global score on standardised scales related to the quality of life (eg, Short Scale Medical Outcomes, SF-36).	
5. Frequency of side effects Quantity, persistence and frequency of unwanted side effects (eg anxiety upon awakening, gastrointestinal problems, etc).	
** The sleep parameters referred to are those obtained from an at-home sleep log, actigraphy or a PSG, except for the relative amount of time and sleep stages, which can only be obtained by PSG.*	

Appendix 8. Recommendations to help change sleeping beliefs and attitudes

- **Be realistic about the amount of night time sleep that you can get.**
- **Think about possible causes of insomnia**. Sometimes insomnia is caused by controllable factors (eg, drinking alcohol) and sometimes not (eg, poor digestion, a recent disappointment).
- **Do not blame insomnia for everything bad that happens during the day.**Think about other reasons for poor performance, bad temper or feeling tired.
- **Do not turn a bad night's sleep into a disaster.**
- **We can all have a sleepless night at some point.** Do not give so much importance to sleep.
- **Develop some tolerance to the effects of a sleepless night.** It is normal to feel exhausted after a sleepless night, so do something enjoyable, and do not blame insomnia for everything bad that happens.
- **Do not try too hard to sleep.** Sleep is a physiological process; you must never force yourself to sleep if you are not sleepy.

Appendix 9. Therapeutic goals of insomnia management tools

a. Health Education

Objectives:

- Provide adequate information on sleep
- Facilitate the acceptance and compliance with treatment

b. Sleep hygiene

Objectives:

- Promote better sleeping habits
- Increase awareness and knowledge of the impact of health habits and environmental factors in sleep.
- Protect against factors potentially harmful for sleeping: lifestyle and the environment, including diet, exercise, substance abuse, eg of alcohol; as well as noise, light and temperature.
- Break with the belief that these factors are not important and have no effect on you.

Although inadequate sleep hygiene alone is rarely the primary cause of insomnia, it can hinder progress and interfere with clinical efforts to change other patterns of inappropriate behaviour and dysfunctional beliefs.

c. Breathing control procedure to help sleep

Objectives:

- Reduce the level of physiological arousal.
- Reduce the time taken to fall asleep.

There is an increase of carbon dioxide in the blood when sleeping, which has a sedative effect. This breathing procedure aims to increase the CO_2 concentration in the blood.

d. Stimulus control

Objectives:

- Break the conditioning between environmental stimuli and insomnia.
- Encourage other stimuli to induce sleep.

The way in which conditioning occurs between certain environmental stimuli and insomnia tends to be as follows:
The patient typically goes to bed in a state of emotional and physiological arousal incompatible with sleep. However, they stay in bed trying to sleep without getting up or leaving the room. Therefore, the fact of being awake in bed is associated with environmental stimuli (the room, bed, etc). If this association occurs frequently, the conditioning will become stronger, and insomnia occurs more frequently as the sleeping environment itself becomes a stimulus (conditioning) not to sleep. When the patient develops a fear of not sleeping, the conditioning triggers reactions incompatible with sleep (excessive emotional arousal) even before going to bed, and thus other environmental stimuli or other behaviour will be conditioned (eg, routine before sleeping, reading a book when you cannot sleep, etc). The same applies if it is a problem with waking up through the night, as the individual's problem is the inability to return to sleep after awakening.

e. Sleep restriction

People with insomnia tend to spend an excessive time in bed to compensate for their lack of sleep and to make sure they get their necessary part of sleep. Over time, this strategy only succeeds in perpetuating insomnia.

Objectives:

- To produce a state of mild sleep deprivation to produce a more immediate onset of sleep, thereby improving sleep continuity and facilitating a deeper sleep (with more stages 3 and 4).
- To reduce the number of hours spent in bed (trying to get as close as possible to the estimated sleep time).
- Gradually increase time until achieving an optimal sleep duration.
- The time allowed in bed will be adjusted according to the sleep efficiency (E). This is calculated using the formula: [total sleep time (TS)/Total time in bed (TB)] x 100 = E.

Time in bed will increase from 15 to 20 minutes when E is more than 85% the previous week. It reduces by the same extent when E stays below 80%, and remains unchanged when E is between 80% and 85%. Periodic adjustments are made until there is an optimal duration of sleep.

Indications:

a) Time in bed should not be reduced to less than 4 or 5 hours a night, no matter how unsatisfactory the sleep "efficiency". It is best to initially restrict time in bed as much as the patient can tolerate.

b) The specific E criteria used to modify the time allowed in bed can be changed according to each clinical situation.

c) Changes in the allowed time in bed are usually done weekly, although it may occasionally be necessary to make more frequent changes.

d) Sleep restriction involves choosing a specific "sleep window" (when going to bed and getting up), rather than a mandatory amount of time that should be spent in bed.

e) The patient must be able to choose both bedtime and getting up time. For example, a person can choose to go to bed at 11pm, but he must get up five hours later (ie, at 4 am). It is best therefore to have a regular getting up time and to change the bedtime only.

f) The minimum and maximum allowable time in bed must be based on both sleeping time at night as well as daytime functioning.

Appendix 9a. Health education (patient format)

Some things that every person with insomnia should know are:

- Sleeping is not a uniform activity. During sleep there are different stages with different levels of sleep.
- The need for sleep decreases with age.
- Insomnia is especially common in older people.
- Sleep is as important as other biological needs (eating, drinking, etc). However, the quantity and quality of sleep may be affected by biological, physical and psychological factors.
- Each person has their own need for sleep. Although it is usually 7-8 hours a day, some people need to sleep more and others less without having any sleep disturbance problems.
- Sleep disorders are very common, with insomnia the most common.
- The fact of having insomnia does not lead to irreversible health consequences. However, it can affect daytime activity and difficulty with tasks requiring attention, as well as producing drowsiness.
- Physical factors can affect falling and staying asleep: extreme temperatures, noise, etc.
- Health problems can lead to insomnia. Among them are chronic pain, restless leg syndrome, sleep apnea, hyperthyroidism.
- There are substances that can cause sleep disorders: central nervous system stimulants (caffeine, amphetamines, etc), corticoids, adrenergic blockers, bronchodilators.
- There are substances causing withdrawal symptoms leading to difficulties in sleep: cocaine, cannabis, antihistamines, barbiturates, benzodiazepines.
- Sleeping pills lead to "tolerance" (the usual dose has less effect, so higher doses are needed) and "withdrawal symptoms" (which occur when a person addicted to a substance stops using it). These may be needed at critical moments, but their consumption must not be extended unnecesarily.
- Psychological techniques are effective but require active patient participation.

Appendix 9b. Sleep hygiene (patient format)

Sleep hygiene is intended to create better sleeping habits and break with the belief that these factors are not important or have no effect.

The below are sleep hygiene measures:

1. Go to bed and get up at the same time, including weekends and holidays.
2. Stay in bed for an appropriate period, according to the real needs of sleep. Reducing the time in bed improves sleep, whereas staying a long time in bed can cause fragmented and light sleep.
3. Avoid naps. In specific cases, a nap may be allowed after a meal, but lasting no more than 30 minutes.
4. Avoid beverages containing caffeine. Even when drunk in the afternoon, they can affect sleep without people realising.
5. As well as affecting health, alcohol and tobacco upset sleep. So no alcohol should be drunk within several hours of bedtime.
6. Take regular exercise: at least one hour a day in sunlight, preferably in the evening and always at least three hours before bedtime.
7. As far as possible, make sure the bedroom is at a comfortable temperature with minimum levels of light and noise.
8. Hunger and heavy meals can disrupt sleep. Do not go to bed within two hours of having dinner. If you're used to it, have a light snack befote bedtime (eg, biscuis, milk or cheese); but do not eat chocolate, or large amounts of sugar or excess fluid. If you wake up in the middle of the night, do not eat anything or you may start to wake up regularly at the same time feeling hungry.
9. Do not carry out activities like watching TV, reading, listening to the radio while in bed.
10. Avoid intense exercise or using computers for two hours prior to sleeping at night.

Older patients should also bear in mind the following:

1. Limit fluid intake in the evening, especially if frequent urination is a problem.
2. Spend time outdoors and enjoy the sunlight.
3. Go for walks and exercise as much as possible, but not before bedtime.
4. Remember the effects that certain medications can have on sleep. Stimulants at bedtime and sedatives during the day can adversely affect sleep.

Appendix 9c. Breathing control to facilitate sleep

(patient format)

1. Lie on your back in a relaxed position, with your head at body height or lower.
2. Close your eyes.
3. Breathe in gently. Do not overinflate your lungs. Exhale all the air, and repeat 3 times.
4. The third time, release all the air and hold your breath for as long as possible. Then repeat the process of three gentle breaths and holding your breath at the end of the third one.
5. To help you hold your breath longer, concentrate on a nice/pleasant mental image.
6. Once you have repeated this process 5-8 times (3 breaths followed by a maximum exhalation and a period of holding your breath), you will feel a desire to breathe normally, in a relaxed, sleepy manner. Breathe gently and normally, and sleep should come easily.

Appendix 9d. Stimulus control (patient format)

To break the association between the sleeping habits and insomnia, follow the below instructions:

1. Do not use the bed or the bedroom for activities other than sleep. Do not read, watch TV or talk on the phone. Try not to think of things that concern you, do not argue with your partner and don't eat in bed. The only exception to this rule is sexual activity in bed.

2. Establish a series of routines as a signal that your bedtime is approaching. For example, close doors, brush your teeth, set the alarm and do all those things which are normal for that time of night. Do them every night in the same order. Adopt the sleeping position you like and arrange pillows and blankets as you like them.

3. When in bed, you must turn off the lights with the intention of sleeping immediately. If it takes a while to sleep (about 10-15 minutes), get up and go into another room. Do something until you start to feel sleepy, and then go back into the bedroom to sleep.

4. If you can't sleep within a short period of time, repeat the above sequence, and do it as often as necessary during the night. Use the same procedure if you wake up in the middle of the night and you can't get back to sleep within about 10 minutes.

5. Set the alarm and get up at about the same time every morning, on weekdays and weekends, regardless of the time you have gone to bed. It helps to regulate the internal biological clock and synchronises the sleep-wake rhythm.

6. Do not take a nap during the day. If you stay awake all day, you will be sleepier at night. However, if you feel very sleepy you can take a short nap after lunch, on condition that it lasts no longer than half an hour.

7. Try to relax at least one hour before going to bed. Avoid using the bed to mull over your concerns. You can keep 30 minutes at another time of day to think about what concerns you, and try to find solutions (it may help to write them on a sheet of paper.) If you are in bed and you begin to think about these things, tell yourself: "That's enough. I'll think about it tomorrow. Now it's bedtime."

8. Do not use the computer before going to bed because the brightness of the screen can act as a neural stimulus.

Appendix 9e. Sleep restriction

People with insomnia tend to spend more time in bed than necessary to compensate for not having slept well. Over time, this strategy only prolongs insomnia.

This technique aims to produce a state of mild sleep deprivation. This state helps you to fall asleep sooner, to sleep with less disruption and achieve a deeper sleep. To achieve this, you must reduce the number of hours spent in bed and try to match the time spent in bed as closely as possible with the time necessary to get to sleep.

Instructions:

a) You must initially restrict the time in bed as much as you can. Although, this should not be less than 4 or 5 hours a night.

b) Sleep restriction involves fixing times to go to bed and to get up, rather than the mandatory amount of time that should be spent in bed.

c) You can choose both your bedtime and getting up time. For example, you can choose to go to bed at 11pm, but you must get up five hours later (ie, at 4 o'clock). It is therefore preferable to maintain a regular getting up time and to change the bedtime only.

d) Changes in the allowed time in bed are usually done weekly, although it may be necessary to make more frequent changes.

Appendix 10. Gradual withdrawal from BZDs

Protocol for gradually reducing BZD intake, contained in the Therapeutic Prescription Guide of the Spanish Drug Agency[182].

Benzodiazepine intake can be reduced in fortnightly stages by approximately one eighth (between 10-25%) of the daily dose. The following protocol can be suggested for a patient who finds withdrawal difficult:

1. Change the patient's treatment to an equivalent daily dose of diazepam, preferably at night.
2. Reduce the dose of diazepam every 2-3 weeks by 2-2.5 mg. If withdrawal symptoms occur, maintain this dose until an improvement is seen.
3. Reduce the dose gradually, if necessary in smaller steps. It is better to reduce the dose very slowly than too quickly.
4. Completely stop the medication. The time required for complete cessation can range from about 4 weeks to a year or more.

Appendix 11

Learning how to recognise and cope with insomnia

Patient information

This patient information pack was prepared by the development group for the Clinical Practice Guideline (CPG) on Insomnia in Primary Care, as part of the Quality Plan for the National Health System, Ministry of Health and Social Policy, 2009. Clinical Practice Guidelines in the SNS: UETS No. 2007/5-1.

This information is also available electronically at the GuíaSalud and UETS websites. These also include both the full and summary versions of the CPG.

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Edited: Agencia Laín Entralgo.
Health Technology Evaluation Unit (UETS)
Gran Vía, 27, 28013, Madrid, Spain.

Index

Why do we need to sleep?

— Human beings spend on average a third of their lives sleeping. Sleep is a necessary activity, because it restores physical and psychological equilibrium.

— The need for sleep varies in a person, according to age, health status, emotional state and other factors. The ideal time for sleep is one that allows us to perform daily activities normally.

What is insomnia?

Talking about insomnia:

— When problems of quality and/or quantity of sleep make your daily life very difficult.

— When there are difficulties in a person's ability to adapt to the negative consequences arising from these problems, causing symptoms such as mood changes, difficulty in concentrating, feelings of sleepiness with difficulty in sleeping during the day, physical and mental fatigue, a general state of nervousness, tension and anxiety.

The main features of insomnia are difficulty in falling or staying asleep or waking up too early. In short, a lack of sleep.

Sleep and insomnia in the elderly:
- Older people do not sleep less, but differently. Sleep is lighter, and waking up during the night is more frequent.
- Changes brought about by retirement-affect sleep in the elderly, as well as the higher incidence of health problems and increased use of medication.

If you are one of the many people who have trouble sleeping, there is no need to be discouraged as, with proper care, it can be overcome. Even if insomnia does not completely disappear from your life, you can learn to live with it.

"I don't sleep like I used to before. I used to sleep like a log, but now I usually wake up, four, five, six times a night. And I don't manage more than an hour and a half, two hours maximum before I wake up again..."

"If I don't sleep, I wake up really tired, irritable, nervous. You feel too cold, or too hot, you're completely out of sorts. It's horrible..."

What types of insomnia are there?

There are two main types of insomnia:

— **Primary Insomnia**: When the cause is not easily identified or associated with any other condition.
— **Secondary insomnia**: This is due to illness, mental disorder, the use of certain substances or medication, the existence of environmental problems (noise, temperature), social factors (family and work problems, work schedule changes due to travelling).

Also, insomnia can be classified according to duration:

— **Transitory:** Lasting less than a week.
— **Short-term or acute:** Lasting between 1 and 4 weeks.
— **Chronic:** Lasting longer than 4 weeks.

"I haven't slept well for a long time. I always used to sleep well, but then suddenly I couldn't. It was a summer holiday, I went to the doctor, I told him about it, he gave me some pills..."

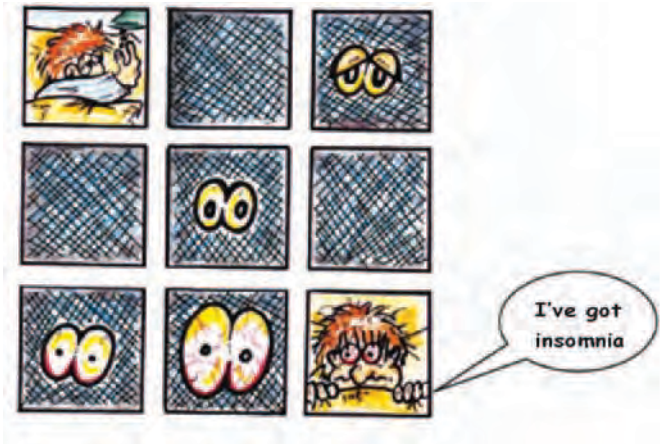
What factors influence insomnia?

There are many factors involved in the onset and maintenance of insomnia. Among the most important are psychological ones (a tendency to think about things too much, difficulty in handling negative emotions, mistaken beliefs about sleep, with consequent inappropriate behaviour), stress and fear of not sleeping. Sometimes, heredity or family and social/occupational factors may influence the onset of insomnia.

"Some people don't take their problems to bed with them. We do."

"I don't know what comes first: whether I start thinking about my problems because I can't get to sleep, or if I start thinking about my problems and then I can't sleep".

How is it diagnosed?



Different tools can be used to establish the diagnosis of your problem.

- **Clinical history:** You will be asked about some aspects of family history or other conditions you may have.
  "I've got insomnia"
- **Sleeping patterns**: You need to establish your sleeping patterns, 24 hours a day. To do this, you need to start an at-home sleep log ", where you record information about your sleeping. This can be a useful tool. Sometimes, it may also be useful to get information from the person who sleeps with you, who can tell us how you sleep and possible influences from your environment.
- **Physical examination**: Helps us to find out if your symptoms are due to something other than insomnia.
- **Questionnaires:** These may be used at your health centre to help in diagnosis or to monitor changes experienced over time.

To rule out any other sleep disorder or other illness, your general practitioner may need to perform some additional tests.

What are the treatment options?

Treating insomnia is about improving your satisfaction with sleep, to improve its quality and quantity, and to get rid of the negative effects it has on the following day.

Standard treatments are sleep hygiene measures, psychological and pharmacological interventions.

— **Sleep hygiene measures:**
Recommendations on healthy habits to help improve sleep.

— **Psychological interventions:**
These may be individual or in a group, with varying degrees of complexity. The aim is to change how you manage the thoughts and behaviours that maintain insomnia and/or its consequences.

— **Medication:**
Hypnotics are the drugs used most in the treatment of insomnia. Although they may seem the easiest solution, their use is limited to cases where no response is seen from the previous measures (sleep hygiene, psychological interventions), and for the shortest possible time, because of their side effects.

Your general practitioner is the right person to tell you which drug is the most suitable, how long you need it for and what the possible side effects might be.

Tell your health centre about any substance, drug, herbal products or alternative medicine you are taking.

To find the right treatment for your problem, contact your health centre. Prepare in advance what you are going to say in the consultation. Tell them about your physical symptoms and sleeping habits; it may help if a family member accompanies you. Don't be afraid to ask if you're not sure about anything.

Also, make sure you tell your general practitioner about your preferred treatment option from the different ones available.

Your recovery is in your own hands. You are the most important person in this process and you may have to make some changes in your lifestyle to sleep better. Ask the healthcare practitioners who treat you about the possibilities in the health centre, and discuss your treatment with them. Your opinion is very important before any treatment option is decided.

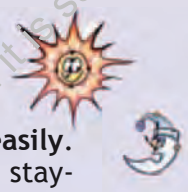
Some misconceptions about insomnia and tips for sleeping well?

Our beliefs also influence the initiation and maintenance of insomnia. Sometimes we must try to correct certain erroneous ideas and attitudes held about insomnia. The following recommendations will help in this regard.

- Think about possible causes of insomnia. Sometimes insomnia is caused by controllable factors (eg, drinking alcohol) and sometimes not (eg, a recent disappointment).
- Never force yourself to sleep if you are not sleepy. Sleep is a physiological process.
- Don't give so much importance to sleep. We can all have a sleepless night at some time.
- Be realistic about the amount of night time sleep you can get.
- Don't turn a bad night's sleep into a disaster. You have to downplay the inability to sleep for a night, otherwise your own fear about not sleeping can actually cause you not to sleep, giving you insomnia.
- Develop some tolerance to the effects of a sleepless night. It is normal to feel exhausted after a sleepless night, so do something enjoyable. Not everything bad that happens is due to insomnia.
- Don't blame insomnia for everything bad that happens during the day. Think about other reasons for poor performance, bad temper or feeling tired.

What can I do to help my insomnia problem?

There are a number of recommendations, or sleeping habits, that people with insomnia can take to reduce their problem, thus promoting normal sleep.



- **Go to bed and get up at set times, including weekends and holidays.** Constant changes in your sleeping hours increase the likelihood of having serious and chronic difficulties in sleeping.
- **Don't lie in bed any longer than is necessary to fall asleep easily.** Reducing the time you spend in bed improves sleep and, conversely, staying too long in bed can cause fragmented and light sleep.

  - **If 30 minutes have passed since you lay down and you are still not asleep, get out of bed, go to another room and do something not too strenuous, like reading a magazine or watching television, for example.** When you feel sleepy again, go back to your bedroom. The goal is for you to associate your bed with falling asleep as soon as possible.
  - **Avoid taking naps and situations leading to it.** In specific cases, a short snooze of no more than 30 minutes after eating is allowed.
- **Do not do anything else in bed**, such as watching television, reading, listening to the radio, eating, talking on the phone, arguing, etc. Our brains need to associate the bedroom and the bed with the activity of sleeping. If other activities are performed in bed, the brain receives a double message and is confused.

- **Take gentle exercise (eg, walking) for at least an hour a day in the sunlight, preferably in the evening and always at least three hours before bedtime.** If vigorous exercise is performed within 3-4 hours of bedtime, it can activate the nervous system and you lose the feeling of sleepiness.
- **Repeat the same nightly routine to help you prepare mentally and physically to go to bed.** Brush your teeth, put on pyjamas, lay out clothes for the next day, etc.
- **Doing relaxation exercises before bedtime can help you sleep better.** Practise slow and relaxed breathing. Think of a balloon being inflated and deflated slowly. Imagine passing clouds and write each one of you worries on them, then mentally blow them away. You can practise, for example, with the exercises available on the Health Guide website. (http://www.guiasalud.es/egpc/insomnio/pacientes11_ejercicio_relajacion.html).

• **Taking a bath with water at body temperature has a relaxing effect, and promotes sleep.**

• **Drinks containing caffeine, like cola and coffee, when drunk in the evening, disrupt sleep even in people who do not realise it.** Caffeine is a nervous system stimulant. Furthermore, although it does not cause addiction (physical dependence in the body), it can cause psychological dependence.

• **Alcohol and tobacco, as well as damaging health, disturb sleep. You should therefore avoid drinking alcohol several hours before bedtime.** Alcohol is a nervous system depressant. Although it may help in falling sleep, it wakes you up through the night and also causes addiction (physical dependence). Nicotine is a nervous system stimulant (not a tranquiliser, as some smokers believe) and also causes addiction.

• **The bedroom should be at a comfortable temperature with minimum levels of light and noise.** It should be comfortable, safe, quiet and conducive to sleep.

• **Don't go to bed within two hours of eating dinner.** Hunger and heavy meals can disrupt sleep. If you wake up in the middle of the night, it is best not to eat or you may start to wake up regularly at the same time feeling hungry.

• **Don't drink too much in the late evening and night,** so you don't have to get out of bed to go to the bathroom during the night.

• **Don't use your computer in the two hours before sleeping at night.** The light of the computer screen can increase your state of activation.

• **Don't mull things over while in bed.** You can set aside 30 minutes in another part of the day to think about what concerns you. Try to find solutions (it might help to write them on a piece of paper). If you start to think too much while in bed, say: "That's enough. I'll do it tomorrow. Now it's bedtime."

• **Don't resort to self-medication.** Taking medications on your own can exacerbate the problem. What may work for one person with insomnia may not be suitable for another.

Finally, remember that you can learn to handle insomnia and gradually make it less of a problem.

"I'm sleeping ! They give you a few sleep hygiene guidelines, get you to change your lifestyle, what you do every day. It's a bit difficult at first, but..."

How can I check my progress with insomnia?

The *at-home sleep log* is a tool for gathering information on sleep patterns, but it can also help you see the progress you have made after implementing the advice offered above.
You record the time you go to bed, fall asleep, how often you wake during the night and the time you get up in the morning.
Below is a template for this at-home sleep log

AT-HOME SLEEP LOG

- Fill it in every morning, according to your memory of the night before.
- Fill it in every night, for information about any sleep during the day (eg, naps).
- Fill in the boxes corresponding to the hours of sleep.
- Include the information below by writing the corresponding letter on the sheet:

Bedtime: A
Getting up time: L
Time you turned off the light (darkness): O
Number of awakenings during the night: D
Switch the light on: E

AT-HOME SLEEP LOG

DATE

DD/MM/AA		8:00	9:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00	24:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00
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For example:

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Where can I learn more about insomnia?

Some books to read

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Estivill E. Dormir bien para vivir más. Alteraciones del sueño en las personas mayores. DeBolsillo. 2007.

Patient and family associations

ASENARCO. Spanish association for sleeping disorder sufferers.
Phone: 976 282765 (Zaragoza)
E-mail: asenarco@hotmail.com
Website - http://www.asenarco.es/

Internet Resources

www.nlm.nih.gov/medlineplus/spanish/tutorials/sleepdisordersspanish/htm/index.htm http://familydoctor.org/online/famdoces/home.html
http://www.sleepfoundation.org/
http://www.iis.es/
http://www.fisterra.com/Salud/1infoConse/insomnioP.asp

Appendix 12. Glossary and abbreviations

GLOSSARY

Actigraphy: A test using a sensor placed on the wrist of the patient to record circadian activity. When it registers no movement, the patient is asleep, so is therefore an indirect method to measure the amount of sleep. This technique is not suitable alone for a diagnosis of insomnia or to evaluate the severity of the problem.

Arousal: Abrupt change from deep sleep to a more superficial or waking state, which may or may not lead to an awakening. The waking state is short lived and the individual is not conscious of it. It is recognised in polysomnographic recordings, mainly by taking into account changes in the electroencephalogram and electromyogram.

AGREE (Appraisal of Guidelines, Research and Evaluation for Europe): International Initiative to facilitate the design and evaluation of clinical practice guidelines.

DALY (disability-adjusted life years): a measure of the global burden of disease by reflecting the number of years a person would have lived and lost due to premature mortality and years of productive life lost due to disability.

Bibliotherapy: Guided reading with a therapeutic function. It consists of acquiring knowledge and therapeutic practices by reading specific literature selected and recommended by the therapist.

Burden of disease: An indicator for measuring the health loss due to fatal and non-fatal disease of a population. It is measured in disability-adjusted life years (DALYs).

Cochrane Library: An efficacy database produced by the Cochrane Collaboration, composed, among other things, of original systematic reviews performed by this organisation.

Dyssomnia: Type of primary sleep disorder characterised by an alteration of the quantity, quality or timing of sleep.

DSM-IV: Fourth edition of the Diagnostic and Statistical Manual of Mental Disorders from the American Psychiatric Association. It is a classification of different types of mental disorders based on sets of criteria with defining features. It is used for clinical, educational and research purposes, and provides clear descriptions of diagnostic categories. Clinicians and researchers use it to diagnose, monitor and exchange information and deal with various mental disorders.

RCT (randomised clinical trial): A study design in which subjects are randomly assigned to two groups: the experimental group, who receive the test treatment, and the comparison or control group, who receive standard treatment (or sometimes a placebo). The two groups are followed to observe any difference in results to assess the effectiveness of treatment.

Sleep efficiency: Percentage of sleep with respect to time in bed. It is calculated as follows: [(total sleep time)/(total time in bed)] * 100. A sleep "efficiency" < 85% is considered clinically significant.

Multiaxial assessment in the DSM-IV: Evaluation over several branches, each of which concerns a different area of information that can help the clinician in planning treatment and predicting outcomes.

Embase: Dutch database produced by Excerpta Medica with clinical medicine and pharmacology content.

Open trial: 1. Clinical trial in which the researcher is aware of the intervention given to each participant. 2. Clinical trial with an open sequential design.

In-depth interview: A qualitative research technique to obtain information using a conversation between an interviewer and an informant with previously established characteristics.

Blind and double blind trials: Clinical trials in which the participants (blind) or both participants and medical personnel (double blind) do not know which of the therapies is received by an individual.

Case-control study: A study that identifies cases, ie people with a disease (eg, lung cancer), and compares them with a group without the disease (control). The relationship between one or more factors (eg, tobacco) related to disease is examined by comparing the frequency of exposure to these or other factors between cases and controls.

Cohort study: Consists of one or more groups of individuals, with something in common, having different degrees of exposure to a risk factor where the onset of the disease or condition under study is measured.

Primary study: Studies containing original data. The primary studies differ from the synopses and reviews that include results from individual primary studies. They also differ from systematic reviews, which summarise the results of a group of primary studies.

Cross-sectional study: This is a study describing the frequency of an event or exposure in a given time (single measurement.) It allows the relationship between a risk factor (or exposure) and effect (or outcome) to be studied in a defined population at a given time. They are also sometimes called prevalence studies.

Discussion group: Qualitative research technique used to identify the attitudes, positions, values or perceptions that a group of individuals have about something or someone.

Internalisation hypothesis: The fear of sleeplessness is internalised, producing emotional and somatic arousal. This comes to the fore and exacerbates pre-existing excessive physiological arousal, leading to insomnia in a circular and growing fashion which establishes a conditioned form of chronic insomnia.

Confidence interval: The interval within which the true magnitude of an effect (which is never known exactly) is found, at a pre-set level of safety or confidence. We often speak of a "95% confidence interval" (or "confidence limits of 95%"). It means that the true value would be found within this range in 95% of cases.

Crisis intervention: A classic action that consists of suspending a series of events that cause abnormalities in the normal functioning of individuals. This model is based on ego psychology, stress theory, learning theory, role theory and the theory of homeostasis (among others).

Qualitative research: A methodology that includes a plurality of theoretical trends, methods and techniques, and is characterised by studying phenomena in their natural context. The aim is to find their meaning or interpretation from the meanings people attach to them. To do this, empirical materials (interviews, observations, texts, etc) are used that best describe both routine and problematic situations, and what they mean in the lives of individuals.

Sleep onset latency: the time between going to bed and sleeping.

Sleep maintenance (number): Number of awakenings throughout the night.

Medline: Predominantly clinical database produced by the US National Library of Medicine available on CD-Rom and the Internet (PubMed).

Meta-analysis: A statistical technique that allows results from different studies to be integrated (diagnostic tests, clinical trials, cohort studies, etc) into a single estimate, giving more weight to the results of larger studies.

Morbidity: Disease or its frequency occurring in a population.

Mortality: Death rate or the number of deaths due to a particular disease in a group of people and during a certain period.

NICE: Part of the NHS (UK National Health Service) whose role is to provide physicians, patients and the general public with the best available evidence, primarily in the form of clinical guidelines.

Participant observation: A qualitative research technique that establishes a deliberate communication between the observer and the observed phenomenon. The researcher notes the important points of the observations, interprets what is happening and thereby obtains a systematic and comprehensive knowledge of the observed reality.

Parasomnia: Sleep disorder associated with brief or partial episodes of waking, without causing significant sleep disruption or disturbance of daytime alertness. The presenting symptom is often related to the behaviour itself. Parasomnia does not involve an abnormality of the mechanisms governing the circadian rhythm or sleep-wake timetable.

Placebo: A substance administered to the control group of a clinical trial, ideally identical in appearance and flavour to the experimental treatment, which is believed to have no specific effect for this disease. In the context of non-pharmacological interventions, placebo treatment is commonly referred to as simulated.

Polysomnography: This technique records various sleep-related parameters of a patient throughout the night, eg electrical brain activity, muscle tone, and is represented by a hypnogram. It is considered as an additional test in the medical history and diagnosis of insomnia. It is indicated when the initial diagnosis of insomnia is uncertain or the treatment is ineffective.

Prevalence: The proportion of people with a finding or disease in a given population at a given time.

Cognitive restructuring: An intervention that involves asking questions to help individuals challenge stereotyped and repetitive thoughts and images that increase fears, and substitute these irrational or distorted thoughts with more rational ones.

Relaxation: Training in relaxation and self-control techniques for symptoms without questioning beliefs. It is based on the principle that when a person learns deep muscle relaxation, it reduces the body tension and anxiety experienced.

Systematic review (SR): A review in which evidence on a subject has been systematically identified, evaluated and summarised according to predetermined criteria. It may or may not include a meta-analysis.

Case series: Analysis of a series of patients with a disease.

SIGN: Scottish multidisciplinary agency that develops clinical practice guidelines based on the evidence and methodological documentation of their design.

Dropout rate: The number of people leaving during the test and specific exclusions after selecting at random.

Cognitive behavioural therapy (CBT): A structured form of psychotherapeutic intervention using various techniques to try to change dysfunctional attitudes and negative automatic thoughts.

Total sleep time: Total time slept during the night.

Wake time after sleep onset: Total time spent awake during the night between falling asleep and final awakening.

Total wake time: Total waking time at night.

Tolerance: State that occurs when the body is used to a drug, and a larger amount of the medication is needed to provide a similar effect.

ABBREVIATIONS

AD: Antidepressants
AEN: Spanish Association of Neuropsychiatry
AGREE: Appraisal of Guidelines Research and Evaluation for Europe
APA: American Psychiatric Association
ASDA: American Sleep Disorder Association
BRA: benzodiazepine receptor agonist
BZD: Benzodiazepine
CBT: Cognitive Behavioural Therapy
CI: Confidence Interval
CINAHL: Cumulative Index to Nursing & Allied Health Literature
CINDOC: Scientific Information and Documentation Centre of the National Research Council
CNS: Central Nervous System
COPD: Chronic Obstructive Pulmonary Disease
CPG: Clinical Practice Guideline
DALY: Disability-Adjusted Life Year
DARE: Database of Abstracts of Reviews of Effects
DBAS: Dysfunctional Beliefs and Attitudes about Sleep
DSM: Diagnostic and Statistical Manual of Mental Disorders
EEG: Electroencephalogram
ESS: Epworth Sleepiness Scale
FDA: Food and Drug Administration
HTA: Health Technology Assessment
ICD: International Statistical Classification of Diseases and Related Health Problems
ICD-10: International Statistical Classification of Diseases and Health Problems
ICPC-2: International Classification of Primary Care
ICSD: International Classification and Sleep Disorders: Diagnostic and Coding Manual
INAHTA: International Network of Agencies for Health Technology Assessment
ISI: Insomnia Severity Index
MH: Mental Health
NANDA: North American Nursing Diagnosis Association
NHS: National Health Service
NICE: National Institute for Clinical Excellence
Non-REM: Non-Rapid Eye Movement
PC: Primary Care
PICO: Patient/Intervention/Comparison/Outcome or Result
PSAS: Pre-Sleep Arousal Scale
PSQI: Pittsburgh Sleep Quality Index
RCT: Randomised Clinical Trial

REM: Rapid Eye Movement

SC: Specialised Care

SEG: Spanish Society of Geriatrics and Gerontology

SEMERGEN: Spanish Society of Primary Care Physicians

SEMFYC: Spanish Society of Family and Community Medicine

SENFEC: Spanish Society of Clinical Neurophysiology

SEP: Spanish Society of Psychiatry

SES: Spanish Society of Sleep

SIGN: Scottish Intercollegiate Guidelines Network

TCA: Tricyclic antidepressants

TENS: Transcutaneous Electrical Nerve Stimulation

UESCE: Spanish Union of Scientific Nursing Societies

UETS: Health Technology Evaluation Unit

WONCA: World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians

Appendix 13. Declaration of interest*

All group members have declared no conflict of interest.

Guzmán Artiach, Geiser, Mª Isabel del Cura González, Mª Jesús de la Puente, Julio Fernández Mendoza, Ana García Laborda, Alicia González Avia, Pedro José González Gil, Susana Martín Iglesias, Pablo Pascual, Mª Teresa Rubio Moral, Violeta Suárez Blázquez, Antonio Vela Bueno have declared no conflict of interest.

Mª Isabel Villalibre Valderrey has participated in a research project funded by Sanofi-Aventis.

* The methodological document, available on both the GuíaSalud and UETS websites, has information on the CPG methodological process in detail, and also includes the standard form used to facilitate the collection of the declarations of interest.

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