# Treatment of Insomnia in Adults

A Systematic Review



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## Summary and Conclusions of the SBU Report:

## Treatment of Insomnia in Adults

### A Systematic Review

## June 2010

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English Translation of the Summary: Joan Bevenius Carrick, Transodont

This is a summary of the results of SBU's evaluation of "Treatment of insomnia in adults". *Insomnia* is a general term which encompasses several types of sleep disorders. Most people who seek treatment for insomnia do so because of perceived problems such as inadequate hours of sleep or poor sleep quality, leading to a diminished sense of well-being and impaired daytime functioning. Examples of common sleep disorders are that it is hard to get to sleep, awakening after falling asleep and finding it hard to get back to sleep, awakening too early in the morning, or combinations of these disorders. Insomnia increases with age and is more common in women.

Those seeking professional help for relief of insomnia usually initially receive individually tailored counselling in self-care, eg to try to maintain a regular diurnal rhythm, to avoid eating and drinking habits known to disturb sleep and to ensure that the environment in the bedroom is conducive to sleep. However, the present evaluation has focused on treatment methods which can be used when such self-care does not give adequate relief.

## **SBU's Conclusions**

☐ When a decision is made to treat insomnia by pharmacotherapy it is important that the prescriber gives preference to preparations with documented effectiveness. Compared with a placebo, short-term treatment with zolpidem, zopiclone och zaleplon – substances related to bensodiazepine – result in a patient falling asleep more quickly and sleeping for longer in total. Such treatment has some risk of side effects. The risk of developing dependence is higher in individuals who already have an addiction or a mental illness.

- ☐ Psychological treatment methods, in the form of cognitive behavioural therapy (CBT) and other behavioural therapy results in the patient falling asleep more quickly and not being awake so long during the night. If greater reliance is to be placed on psychological treatment methods, it is a prerequisite that more therapists be trained.
- ☐ In the elderly patient, both insomnia in itself and medication to treat the condition can increase the risk of accidentally falling. There is however, an inadequate scientific basis on which to assess the magnitude of these risks and the interrelationship between them.
- ☐ There is an inadequate scientific basis on which to assess the effect of alternative and complementary methods for treatment of insomnia. The few studies available are of inadequate quality. This applies both to medication (valerian and various herbal medicines) and other methods (acupuncture, yoga, etc).

## **SBU's Summary**

## **Background and aim**

Insomnia is a common health disorder in Sweden. It increases with age and is more common in women and in socioeconomically disadvantaged groups. According to the prevalence study which was conducted within the framework of this project, at the end of 2008, around 24 percent of the adult population of Sweden reported sleep disorders (defined as "hard to get to sleep more than three times a week" or "awaken during the night more than three times a week"). The gender distribution was 19 percent of men and 29 percent of women. Those who have been diagnosed with insomnia, including problems during the day, are however much fewer, in total around 11 percent, 7 percent of men and around 14 percent of women.

According to other sources, sleep disorders are increasing. The reason is unclear, but it may well be related to our "24-hour society", noise and other disturbances in the home environment, increased demands for greater effectiveness at work, and the increasing overflow of information. Higher consumption of alcohol and other substances which disturb sleep can contribute to the increasing number of people experiencing problems. It is also possible that there is a heightened expectation of good sleep: what was previously regarded as satisfactory duration and quality of sleep is no longer considered acceptable.

A common treatment method is to provide general advice on sleep, often combined with medication. The pharmaceuticals most widely used for treatment of sleep disorders are the so-called hypnotics (benzodiazepines and related agents). Although only short-term treatment is recommended, analyses of prescription practice show that many patients, particularly the elderly, are prescribed this medication treatment for lengthy periods. This is mainly the case when sleep disorders occur together with other medical conditions. During the year 2008 a total of around 750 000 people, of whom half were over 65 years of age and two-thirds were women, were prescribed sleeping pills. Over 90 percent of those issued a prescription for sleeping pills were also taking one or more other form of medicine: just over a third received antidepressives and almost as many received medication for pain relief.

In recent years, cognitive behavioural therapy (CBT) has been shown to be an appropriate treatment for sleep disorders. Natural medicines of various kinds, eg valerian, are very commonly used for self-care. However, there is insufficient knowledge about the long and short-term effects of treatment of sleep disorders, possible side effects associated with the treatment methods and their cost-effectiveness.

The aim of the project has been to evaluate the effects and economic consequences of different methods of treatment of sleep disorders in adults, based on a systematic review of the scientific literature.

#### Limits and questions to be evaluated

The project has been limited to address the treatment of primary and secondary insomnia in adult patients (18 years and older). Both pharmacological and psychological methods have been included, as well as alternative and complementary methods.

The project addressed the following questions:

- a. What effect has treatment of primary and secondary insomnia by hypnotics (in younger/older patients, men/women) on patient-related effect measures, such as time taken to fall asleep, frequency of awakening after falling asleep, time taken to get back to sleep, total sleep time, sleep quality and impairment of daytime function? The effect of different durations of treatment and the manner in which treatment was terminated were also evaluated.
- b. What effect on daytime functioning, health and health-related quality of life can be achieved by treatment of primary and secondary insomnia?
- c. What complications and side effects (eg in the form of drug dependence, drug abuse, accidents due to falls and traffic accidents) are associated with the treatment methods evaluated?
- d. What information is available about the cost-effectiveness of the different treatment methods?
- e. What influence do the organization of care in geriatric institutions and nursing routines have on the occurrence of insomnia?

#### Content and target groups

Chapter 2 describes the methodology applied for the systematic overview of the literature. The results of this overview with respect to the various treatment methods are presented in Chapter 3, which is the most extensive chapter and the key section of the report. The risks of drug dependence, drug abuse and accidents associated with various methods of treatment of sleep disorders are discussed in Chapter 4. The literature available on the association between organization of care and nursing routines and the occurrence of sleep disorders, mainly in various forms of

institutions for the elderly, is summarized in Chapter 5. Ethical and social aspects of treatment of sleep disorders are discussed in Chapter 6. Within the framework of the project, a health economics model analysis was undertaken and is presented in Chapter 7. An outline of current practice for treatment of sleep disorders is presented in Chapter 8 and thereafter a consequence analysis and proposals for changes to current practice in Chapter 9. In the final chapter, Chapter 10, the report presents gaps in knowledge disclosed by the project and fields which warrant priority in future research.

The report is intended for clinicians, primarily those in primary care and psychiatry, who encounter patients with sleep disorders and also for politicians involved with healthcare and health administrators with decision-making responsibilities.

## Methodology for systematic review of the literature

Using the above questions as reference points, systematic database searches were conducted in PubMed and other relevant databases such as EmBase, PsycInfo, HEED and NHSEED.

#### Criteria for inclusion

In order to identify relevant publications, the following criteria were applied in the initial stages of the scrutiny process:

- 1. The study should concern treatment of insomnia in adults and be relevant to Swedish conditions, ie methods which are applied in Sweden.
- 2. The article should be written in English, French, German or a Scandinavian language.

- 3. Treatment studies should comprise randomized controlled trials (RCT) in the first instance, or secondly controlled prospective studies. With respect to the questions about "dependent as a result of treatment" and "organization of care" respectively, other types of study have also been included.
- 4. The diagnosis insomnia should be defined according to ICD-10, DSM-IV, ICSD-R¹ or their equivalent.
- 5. There should be at least 20 patients per study group (experimental and control groups respectively).
- 6. The effect measures in the studies should evaluate sleep quality/ sleep quantity, in terms of one or more of: sleep onset latency (SOL), total sleep time (TST), number of awakenings (NAW), time awake after sleep onset (WASO), daytime function and health related quality of life and measures of side effects.
- 7. Health economics studies should encompass both costs and effects, be relevant to Swedish conditions and include comparisons with the best alternative method. The effects should preferably be measured as quality-adjusted life years (QALY).

#### Assessment of quality

The abstracts of the articles identified by the database search were scrutinized independently by at least two members of the project group. The scrutiny was based on the above-described inclusion criteria. The full text version of all articles considered by at least one of the scrutineers to be relevant was then ordered. Working independently, the same scrutineers assessed these articles according to the inclusion criteria. Articles which neither of the scrutin-

<sup>&</sup>lt;sup>1</sup> International Classification of Diseases (ICD-10), Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition (DSM-IV), International Classification of Sleep Disorders-Revised (ICSD-R).

eers found to be relevant were excluded. The remaining articles were thoroughly assessed with the aid of SBU's evaluation forms in order to determine how well the studies met the different quality criteria in terms of study design, study population, effect measures, analytical methods, etc. From this point of reference, the quality and relevance of each study were determined as high, moderately high or low.

#### Grading the evidence of the results, conclusions

Studies of high or moderately high quality were included in the foundation material for determining the effects and side effects of the treatment methods investigated. For each effect measure, a summary assessment of the study results was made according to the GRADE<sup>2</sup>-system, to serve as a basis for grading the evidence.



<sup>&</sup>lt;sup>2</sup> Grading of Recommendations Assessment, Development and Evaluation (GRADE).

#### **Facts 1** Study quality and strength of the evidence.

**Study quality** refers to the scientific quality of an individual study and its ability to provide a valid answer to a specific question.

Strength of the evidence refers to a judgment of the total strength of all scientific evidence and its ability to provide a valid answer to a specific question. SBU uses GRADE, an international grading system for scientific evidence. Study design is a key element in the overall judgment of each outcome measure. Other factors that can weaken or strengthen the power of the evidence are study quality, relevance, consistency, transferability, effect size, data precision, risk of publication bias, and other aspects, eg, the dose-response relationship.

Grading the strength of the evidence - four levels:

Strong scientific evidence  $(\oplus \oplus \oplus \oplus)$ . Based on high-quality studies containing no factors that weaken the overall judgment.

Moderately strong scientific evidence ( $\oplus\oplus\oplus\bigcirc$ ). Based on highquality studies containing isolated factors that weaken the overall judgment.

**Limited scientific evidence (** $\oplus\oplus\bigcirc\bigcirc$ **).** Based on high- or medium-quality studies containing factors that weaken the overall judgment.

**Insufficient scientific evidence** ( $\oplus \circ \circ \circ$ ). The evidence base is insufficient when scientific evidence is lacking, quality of available studies is poor, or studies of similar quality are contradictory.

The stronger the evidence, the less likely it is that the results presented will be affected by new research findings within the foreseeable future.

#### Conclusions

SBU's conclusions represent our overall judgment of benefits, risks, and cost-effectiveness.

### **Evidence-graded results**

#### Pharmacological treatment

#### **Hypnotics**

- Treatment of insomnia by medication with 10 mg of zolpidem for up to four weeks decreases the sleep onset latency and increases the total sleep time compared with a placebo (strong scientific support ⊕⊕⊕⊕). The quality of sleep increases marginally (moderately strong scientific support ⊕⊕⊕○) and there is a marginal decrease in the number of awakenings (limited scientific support ⊕⊕○○).
- Treatment of insomnia by medication with 7.5 mg of zopiclone for up to four weeks reduces sleep onset latency, increases total sleep time, reduces the number of awakenings after sleep onset and results in improved quality of sleep compared to a placebo (limited scientific support ⊕⊕○○).
- Treatment of insomnia with 10 mg zaleplon for up to four weeks reduces sleep onset latency but does not alter the number of awakenings compared to a placebo (strong scientific support ⊕⊕⊕⊕). There is a marginal increase in total sleep time (moderately strong scientific support ⊕⊕⊕○), while the effect on sleep quality is no different from that of a placebo (limited scientific support ⊕⊕○○).
- Treatment of insomnia with 0.25 mg triazolam for up to four weeks reduces sleep onset latency and increases total sleep time compared with a placebo (moderately strong scientific support ⊕⊕⊕○). There is insufficient scientific support to allow any conclusions about the effect on the number of awakenings and sleep quality (⊕○○○).

- There is an inadequate scientific basis on which to assess the effects of flunitrazepam and nitrazepam compared to a placebo on the effect measures evaluated, because the available studies are of poor quality ( $\oplus \circ \circ \circ$ ).
- Intermittent treatment with 10 mg zolpidem reduces sleep onset latency, increases total sleep time and reduces the number of awakenings compared to a placebo (moderately strong scientific support ⊕⊕⊕○).
- There is an inadequate scientific basis on which to assess the
  effects of 10 mg zolpidem, 7.5 mg zopiclone, 10 mg zaleplon
  and 0.5 mg triazolam for treatment periods longer than four
  weeks (⊕○○○).
- There is an inadequate scientific basis for determining the effect of hypnotics on daytime function, health and quality of life, as these issues have not been extensively investigated in studies to date (⊕○○○).
- Medication with hypnotics is associated with complications and side effects, such as tiredness, dizziness and memory disorders. Paradoxical effects eg sleepwalking can also occur. However, there is an inadequate scientific basis to allow conclusions about the extent of these problems (⊕○○○).

#### Other medication

- There is an inadequate scientific basis to allow conclusions about the effect of propiomazin for treatment of sleep disorders, because the studies available are few in number and of inadequate quality ((())).
- There is an inadequate scientific basis to allow conclusions about the effectiveness of antidepressive medication, neuro-

leptics (alimemazin) and antihistamines for the treatment of sleep disorders, because the available studies are few in number and of inadequate quality  $(\oplus \bigcirc \bigcirc \bigcirc)$ .

#### Melatonin

- There is an inadequate scientific basis to allow conclusions about the effect of treatment with melatonin in its usual form ("fast release") for insomnia (⊕○○○).
- Treatment of insomnia with "sustained release" preparations
  of melatonin results in improved sleep quality (limited scientific support ⊕⊕○○).

#### Psychological treatment

- In the short term, cognitive or other behavioural therapy reduces sleep onset latency, time awake during the night and the severity of sleep disorders and results in improved quality of sleep compared with passive controls, ie patients on a waiting list for treatment (limited scientific support ⊕⊕○○).
- In the long term, cognitive or other behavioural therapy also reduces the sleep onset latency, time awake during the night and the severity of sleep disorders compared with passive controls, ie patients on the waiting list for treatment (limited scientific support ⊕⊕○○).
- Compared with active controls, cognitive or other behavioural therapy reduces sleep onset latency, time awake during the night and the severity of sleep disorders (moderately strong scientific support ⊕⊕⊕○), and results in improved quality of sleep in the short term (limited scientific support ⊕⊕○○).
- Compared with active controls, cognitive or other behavioural therapy also has long-term effects, reducing sleep onset latency

and time awake during the night (limited scientific support  $\oplus \oplus \bigcirc \bigcirc$ ), reduces the severity of sleep disorders and results in improved quality of sleep (moderately strong scientific support  $\oplus \oplus \oplus \bigcirc$ ).

- Cognitive or other behavioural therapy achieves no difference in total sleep time compared with passive controls (patients on the waiting list for treatment), repeated stress management sessions or sleep hygiene counselling (limited scientific support ⊕⊕○○).
- There are so few studies available that there is an inadequate scientific basis on which to draw conclusions about the influence of cognitive therapy on health and quality of life in patients with insomnia (⊕○○○).
- There is an inadequate scientific basis on which to draw conclusions about side effects and complications associated with psychological methods of treatment, because the available studies are few in number and of inadequate quality (⊕○○○).

#### Combined pharmacological and psychological treatment

- There is an inadequate scientific basis on which to assess the effect of combined pharmacological and psychological treatment of patients with insomnia compared with psychological treatment alone (⊕○○○). There are few studies available and most are of inadequate quality.
- There is an inadequate scientific basis on which to assess the
  effects of combined pharmacological and psychological treatment methods on health and quality of life and also on side
  effects and complications (⊕○○○).

 Termination of treatment with sleeping pills is facilitated by cognitive behavioural therapy and gradual phasing out of the medication, in combination or as separate measures (limited scientific support ⊕⊕○○).

#### Other treatment methods

- There is an inadequate scientific basis to allow conclusions about the effect of valerian and other natural medicines (eg hops, camomile, kava, and lavender) for treatment of sleep disorders (⊕○○○).
- There is an inadequate scientific basis to allow conclusions about the risks of side effects associated with treatment of sleep disorders with conventional doses of valerian (⊕○○○). The few reported side effects are mild. Both valerian and several other natural medicines have an effect on liver enzymes which are essential for metabolising several groups of pharmaceuticals. For most of the agents, the extent of the clinical significance of such an effect is virtually unknown. Serious liver damage has been reported for kava.
- There is an inadequate scientific basis for conclusions about the effect of non-medicinal methods for treatment of sleep disorders, such as acupuncture, physical activity, magnetic field therapy, music, tai-chi and yoga) (⊕○○○).

#### Drug dependence, drug abuse

• There is a certain risk for development of dependence related to use of the bensodiazepines and also bensodiazepine-related compounds. The risk is greater in individuals who already have a dependence problem or are mentally ill. The scientific basis is however, inadequate for definite conclusions about the magnitude of the risk of dependence (⊕○○○).

#### Accidents due to falls

• The scientific basis is inadequate to determine whether the bensodiazepines and related drugs, neuroleptics, antihistamines and antidepressants with a sedative effect, which are used in the treatment of insomnia, increase the risk of accidents due to falls (⊕○○○).

#### **Traffic accidents**

- Treatment with sleeping pills (bensodiazepines and related drugs) increases the risk of traffic accidents (limited scientific support ⊕⊕○○).
- The scientific basis is inadequate for assessment of the risk for traffic accidents associated with other medications for sleep disorders, such as antihistamines, antidepressants and antipsychotic drugs (⊕○○○).

#### Organization of institutional care and nursing routines

 The scientific basis is inadequate to allow conclusions about the influence on sleep disorders of the way in which geriatric care institutions are organized, because the available studies are few and lacking in quality (⊕○○○).

#### **Health** economics

• There is an inadequate scientific basis for conclusions about the cost-effectiveness of the methods evaluated (⊕○○○).

### Ethical and social aspects

Sleep disorders are relatively common and if protracted can result in difficulties for the afflicted person to cope with work, as well as enjoy a functional and satisfactory social life. There is also an association between sleep disorders and increased mortality. Thus there is a lot at stake, not only financially but also with respect to quality of life. There is therefore much to be gained by successful treatment and preventive measures.

There are important aspects of equity which need to be addressed, because certain groups in the population are more susceptible to sleep disorders. Women and the elderly are over-represented, as well as socioeconomically underprivileged groups in society. Successful treatment and successful preventive measures can contribute to a reduction in the inequality of health status between particularly vulnerable groups and the rest of society.

## Health economic aspects

Very few health economic studies of treatment of sleep disorders are available. As only one study was considered adequately relevant, SBU has made its own calculations in the form of a model analysis. In summary, this analysis indicates that CBT, for patients for whom this form of treatment is deemed appropriate, can be a cost-effective alternative compared with medication for treatment of sleep disorders. In order to draw definite conclusions, there is a need for more long-term studies comparing CBT and medication, which also take into account both short and long term effects as well as direct and indirect costs.

### **Current practice**

In order to gain an impression of how sleep disorders in adults (18 years and over) are examined and treated in primary care, a questionnaire was sent out to 600 randomly selected general practitioners. The responses showed that sleep disorders were common among patients in primary care. The doctors considered that sleep disorders could lead to the development of other disease conditions. The questionnaire confirmed that for the

most part, sleep disorders were treated with medication, even though the doctors considered that a different form of treatment (CBT and counselling) had a better long-term effect. One explanation for this state of affairs may be that the availability of therapists who can provide CBT is very limited and unevenly distributed through-out Sweden.

Because many district medical officers know their patients well, particularly those with chronic diseases, it is reasonable that they should take preliminary notes of the patient's actual sleep problems and not immediately launch an extensive examination. Concomitant chronic disease can also contribute to the patient's sleep disorders.

## Consequences of proposed changes to current practice

The following are examples of proposed changes to established practice which might contribute to more evidence-based treatment of sleep disorders:

- A change in prescribing of pharmaceuticals that have no scientific support to those which have been identified by the literature overview as having scientific evidence of effect.
- An expanded supply of psychological treatment methods, primarily cognitive behavioural therapy (KBT).
- Better planning and follow-up of treatment measures, particularly for elderly patients, ie thorough investigation of the reasons for and consequences of sleep disorders, and better follow-up of effects on daytime function.

It is difficult to assess the overall health, ethical, social and economic consequences of these proposed changes to current practice. A more qualified and individually tailored treatment approach should result in noticeable improvements for the patients in question. A more evidence-based approach to prescription of pharmaceuticals can reasonably be expected to result in increased cost-effectiveness, which however, does not necessarily imply lower overall costs for sleeping pills. A prerequisite for the proposed expansion of CBT is an increase in the number of therapists being trained. This should be regarded as an investment, which it is hoped will pay a dividend in the form of effective care, but only in the long term. Finally it should be noted that it is difficult to analyse ethical aspects of treatment of sleep disorders and there are examples of conflict between different ethical principles.

## Gaps in knowledge, directions for future research

The systematic review of the literature conducted within the framework of this project has disclosed considerable gaps in our knowledge of this field; it has not been possible to answer all the questions originally formulated. The following is a selection of questions which warrant attention in future research. As explained in the report, such research is expected to provide results which can lead to changes in current clinical practice.

Sleeping disorders are treated primarily by medication. In recent years psychological treatment methods have also gained a footing, both as the sole treatment method and in combination with medication. Many patients request alternative medical or complementary treatment. Which treatment or combination of treatments is best varies from patient to patient. Because the reasons underlying sleep disorders vary, more knowledge is needed about how the treatment strategy should be tailored to suit the individual patient or group of patients.

Pharmaceuticals which are prescribed for treatment of sleep disorders have side effects which can be troublesome for some patients. As treatment is often continued over a lengthy period of time, there is a risk that the patient may develop dependence on the medication. There is limited knowledge available as to how frequently this occurs or whether certain patient categories might be more susceptible than others to developing dependency.

There are almost no studies of how the organization and routines of geriatric institutions influence the development of sleep disorders, nor to what extent changes in nursing routines might improve the patients' sleep.

The availability of health economic studies within this field is very limited. There is a need for producer-independent health economic studies of the costs and effects of various methods of treating sleep disorders.

More detailed analysis is required of the reasons for the variations in established treatment practices, the consequences of these variations and the potential to influence current practice.

In particular, the following are considered important questions for future research:

- Measures and methods of measurement: how should "good sleep" be defined, eg in terms of quality of sleep, daytime function, quality of life and physiological indicators of sleep? How can the effects of various types of treatment be measured in a better, more relevant and patient-centered manner?
- The consequences of long-term treatment with sleeping pills, particularly in elderly people.

- The effects of combined pharmacological and psychological treatment of sleep disorders.
- The effects of alternative medical or complementary treatment of sleep disorders.
- Risks of side effects associated with various methods of treament of sleep disorders.
- Individually tailored treatment strategies for patients with sleep disorders.
- Variations in current practices in treatment of sleep disorders causes, consequences and opportunities for change.

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# SBU Evaluates Health Care Technology

Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.
- SBU shall assess new methods as well as those that are already part of established clinical practice.
- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.
- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.
- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.
- SBU shall contribute to the development of international cooperation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

## Treatment of Insomnia in Adults

SBU's report on Treatment of Insomnia in Adults builds on a systematic, critical review of the scientific literature in the field.

The report is one in a series of reports published by SBU (Swedish Council on Health Technology Assessment).

This document presents the summary and conclusions of the full report, which has been approved by SBU's Board of Directors and Scientific Advisory Council.