Practice Parameters for the Nonpharmacologic Treatment of Chronic Insomnia

An American Academy of Sleep Medicine Report
Standards of Practice Committee of the American Academy of Sleep Medicine

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Abstract: Insomnia is the most common sleep complaint reported to physicians. Treatment has traditionally involved medication. Behavioral approaches have been available for decades, but lack of physician awareness and training, difficulty in obtaining reimbursements, and questions about efficacy have limited their use.

These practice parameters review the current evidence with regards to a variety of nonpharmacologic treatments for insomnia. Using a companion paper which provides a background review, the available literature was analyzed. The evidence was graded by previously reported criteria of the American Academy of Sleep Medicine with references to American Psychological Association criteria. Treatments considered include: stimulus control, progressive muscle relaxation, paradoxical intention, biofeedback, sleep restriction, multicomponent cognitive behavioral therapy, sleep hygiene education, imagery training, and cognitive therapy.

Improved experimental design has significantly advanced the process of evaluation of nonpharmacologic treatments for insomnia using guidelines outlined by the American Psychological Association (APA). Recommendations for individual therapies using the American Academy of Sleep Medicine recommendation levels for each are: Stimulus Control (Standard); Progressive Muscle Relaxation, Paradoxical Intention, and Biofeedback (Guidelines); Sleep Restriction, and Multicomponent Cognitive Behavioral Therapy (Options); Sleep Hygiene Education, Imagery Training, and Cognitive Therapy had insufficient evidence to be recommended as a single therapy. Optimal duration of therapy, who should perform the treatments, long term outcomes and safety concerns, and the effect of treatment on quality of life are questions in need of future research.

Key words: Practice guidelines; Practice parameters; Insomnia; Stimulus control; Progressive muscle relaxation; Paradoxical intention; Biofeedback; Sleep restriction; Multicomponent cognitive behavioral therapy; Sleep hygiene education; Imagery training; Cognitive therapy

INTRODUCTION

PRIMARY INSOMNIA IS DEFINED AS THE SUBJECTIVE DIFFICULTY INITIATING OR MAINTAINING SLEEP OR OF NONRESTORATIVE SLEEP, that lasts for at least one month, causes clinically significant distress or impairment in social, occupational or other important areas of function, and is not associated with another disorder.[1] It can affect health, daytime performance, relationships, mood, and psychological wellbeing. Acute insomnia may occur in as many as 30 - 40% of individuals whereas 9 - 12% report inadequate sleep on a chronic basis.[2] Chronic insomnia is a far-reaching and significant problem that affects many individuals in our society.[2-4]

Many practitioners prescribe sedatives, hypnotics, or other sleep-inducing agents as the treatment of choice for insomnia. Pharmacological treatments while often effective may also induce untoward effects such as tolerance or

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rebound insomnia upon discontinuation.[5] Medication therapy has become such a mainstay of modern life that other forms of treatment are often neglected. Nonpharmacologic interventions are therefore not commonly practiced in many centers, and often clinicians are not aware of their effectiveness or appropriate applications.

A broad range of clinical conditions are associated with the chief complaint of difficulty initiating or maintaining sleep. The most recent edition of the International Classification of Sleep Disorders[6] divides chronic insomnia (as classified by DSM-IV) into further subtypes. These include such diverse diagnoses as psychophysiological insomnia, sleep state misperception, idiopathic insomnia, altitude insomnia, food allergy insomnia, insomnia associated with depression and fatal familial insomnia, as well as proposed sleep disorders that would include menstrual-associated sleep disorder. It is beyond the scope of this Standards of Practice report to address specific treatments for each type of insomnia. While some mention has been made in the accompanying review paper of secondary insomnias that are primarily related to underlying medical, psychological and psychiatric conditions, they will not be addressed in detail here. These recommendations will address nonpharmacologic intervention primarily in chronic insomnia as defined in the accompanying review [1.1; 1.2] and as clarified in the text of this paper.

METHODS

On the basis of the accompanying review[4] and noted references, the Standards of Practice Committee of the American Academy of Sleep Medicine, in conjunction with specialists and other interested parties, developed the recommendations included in this paper. The conclusions are based on evidence from studies published in peer-reviewed journals, as described in the evidence tables in the accompanying background paper. For each recommendation, the strength of the recommendation, based upon the level of evidence, is identified.

The Board of Directors of the American Academy of Sleep Medicine approved these recommendations. All members of the Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have none with regard to this subject.

These practice parameters define principles of practice that should meet the needs of most patients in most clinical situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding the propriety of any specific care must be made by the practitioner in light of the individual circumstances presented by the patient and the available diagnostic and treatment options and resources.

Table 1—AASM Classification of Evidence

Recommendation Grades	Evidence Levels	Study Design
A	I	Randomized well-designed trials with low-alpha & low-beta errors*
B	II	Randomized trials with high-beta errors*
C	III	Nonrandomized controlled or concurrent cohort studies
C	IV	Nonrandomized historical cohort studies
C	V	Case Series

ADAPTED FROM SACKETT[7]

*Alpha error refers to the probability (generally set at 95% or greater) that a significant result (e.g., $p<0.05$) is the correct conclusion of the study or studies. Beta error refers to the probability (generally set at 80% or 90% or greater) that a nonsignificant result (e.g., $p>0.05$) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis which projects the size of the study population necessary to ensure that significant differences will be observed if actually present.

The American Academy of Sleep Medicine expects these guidelines to have a positive impact on professional behavior, patient outcomes and, possibly, health care costs. These practice parameters reflect the state of knowledge at the time of development and will be reviewed, updated, and revised as new information becomes available.

The specific methods used for the accompanying task force report for nonpharmacologic interventions will be reviewed briefly. The reader is referred to the accompanying paper for detailed methodology as well as article inclusion and exclusion criteria. In summary, a MEDLINE search as well as a PsycLIT review was done from the time-period of 1970 to 1997. Key words were addressed in a standardized format. As outlined in the accompanying paper, 48 papers which met inclusion criteria were found using this literature search plus a search of bibliographies of recently published meta-analyses.[3,4] Evaluation of these 48 articles revealed that prospective daily sleep logs were the measurement for treatment outcome in the majority of studies. A few studies used polysomnography and various behavioral assessment devices such as actigraphy. In this practice parameter paper, square bracketed references relate to sections or tables in the accompanying background paper. Other citations are noted and refer to the reference list at the end of this paper.

BACKGROUND

The clinical severity of insomnia is determined according to its frequency, duration, and effect on daytime func-

tioning [1.1]. The disorder may be considered one of difficulty in either initiating or maintaining sleep, or both. The criteria for sleep-onset insomnia is most commonly described as a latency to sleep onset of greater than 30 minutes. Sleep maintenance insomnia involves either frequent and/or extended awakenings occuring after sleep onset and totaling more than 30 minutes, or premature awakenings in the morning with less than 6.5 hours of sleep. Sleep efficiency is the ratio of time asleep to time in bed. Less than 85% is usually implied in making a diagnosis of insomnia [1.1; 1.2]. Neither this paper nor the background review specifically address the many types of insomnia separately. When insomnia is not related to other specific medical, psychiatric, or medication related conditions it may be considered primary (psychophysiological, idiopathic or sleep state misperception). Psychophysiological insomnia predominantly involves somatized tension and learned sleep-preventing associations that result in the complaint of insomnia and associated decreased functioning during wakefulness. However, when the disorder exists from childhood without other associated conditions it may be referred to as idiopathic insomnia. This long term inability to obtain adequate sleep may be due to an abnormality of cerebral control of the sleep-awake system. When the insomnia is related to a specific medical, neurological, or other sleep disorder, substance abuse or psychiatric conditions, it is considered to be secondary insomnia [1.2].

The International Classification of Sleep Disorders[6] identifies insomnias lasting for 1 month or less as acute and more than 1 month but less than 6 months as sub-acute. After 6 months or longer in duration, insomnia is classified as chronic. In this practice parameter paper a diagnosis of chronic insomnia (usually primary) is the predominant disorder considered.

RECOMMENDATIONS

Each of the treatments for which practice parameter recommendations were considered will be addressed. The classification for evidence was adapted from the suggestions of Sackett (Table 1) and involves assigning a level and grade to evidentiary references.[7] Practice parameter recommendations are given as standards, guidelines or options, as defined in Table 2. The recommendations in this paper are supported by Level II to Level V evidence.

Relevant, by virtue of the topic, is the issue of evidence levels judged by the American Psychological Association compared to those customarily used for practice parameters by the American Academy of Sleep Medicine. The APA criteria are outlined in Table 3 and will be mentioned further later.

Each of the 48 articles presented in Table 2 of the accompanying task force review paper was evaluated using the evidence-based approach outlined by the Standards of Practice Committee in Table 1 of this paper. The evidence was then evaluated according to methodology presented in Table 2 of this paper to establish a recommendation level (Standard, Guideline, Option). We graded only those articles in which one or more of the 6 therapies recommended as well-established or probably efficacious by the APA could be evaluated as a single treatment modality. Multicomponent (Cognitive) Behavioral Therapy was graded as a single therapy for the purpose of this paper due to progressively more common usage, although direct comparisons to other single therapies were often difficult. Otherwise, if two or more therapies were investigated only as a combined treatment and not evaluated independently, grading the evidence of each component's contribution to the outcome was not attempted. Typically, more than one single therapy was studied in each of the reports, but was at least analyzed independently leading to the use of many articles to provide evidence for more than one therapy. While not included in this paper, the lengthy summary of the articles' evaluations, by AASM criteria, is available upon request.

The AASM review found no level I evidence articles. Level II was assigned if there was a randomized placebo comparison or a superior effect over another therapy in a randomized comparison. Wait list and no treatment comparisons were considered to be level III evidence even if the study was randomized since patients undergoing such controls had no expectation of improvement and were unlikely to have a placebo effect. Such an effect is essential to reduce bias in the comparison.

Most of the studies were confined to patient populations of primary (usually psychophysiological) insomnias or excluded the following from those treated for secondary insomnia: severe psychopathology, obstructive sleep apnea, periodic limb movement disorder, painful conditions, circadian rhythm disorders, severe cognitive disorders, and parasomnias.

Table 2—AASM Levels of Recommendations

Standard
This is a generally accepted patient-care strategy which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.

Guideline
This is a patient-care strategy which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.

Option
This is a patient-care strategy which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

ADAPTED FROM EDDY[8]

Table 3—American Psychological Association Task Force *Report and Recommendations: Criteria for Empirically Validated Treatments.

WELL-ESTABLISHED TREATMENTS

I. At least two good group design studies, conducted by different investigators, demonstrating efficacy in one or more of the following ways:

A. Superior to pill or psychological placebo or to another treatment.

B. Equivalent to an already established treatment in studies with adequate statistical power

OR

II. A large series of single case design studies demonstrating efficacy. These studies must have:

A. Used good experimental designs and

B. Compared the intervention to another treatment as in I.A.

Further criteria for both I and II:

III. Studies must be conducted with treatment manuals.

IV. Characteristics of the client samples must be clearly specified.

PROBABLY EFFICACIOUS TREATMENTS

I. Two studies showing the treatment is more effective than a waiting-list control group.

OR

II. Two studies otherwise meeting the well-established treatment criteria I, III, and IV, but both are conducted by the same investigator.

OR

III. At least two good studies demonstrating effectiveness but flawed by heterogeneity of the client samples.

OR

IV. A small series of single case design studies otherwise meeting the well-established treatment criteria II, III, and IV.

EXPERIMENTAL TREATMENTS

I. Treatments that have not been established as at least probably efficacious

*Adapted from the Task Force on Promotion and Dissemination of Psychological Procedures[9]

RECOMMENDATIONS FOR INDIVIDUAL THERAPIES

1. Stimulus control is effective therapy in the treatment of chronic insomnia. (Standard)

This recommendation is supported by Level II evidence, and is a Grade B recommendation. The objective of this form of therapy is to train the insomnia patient to re-associate the bed and bedroom with rapid sleep onset. This is necessary as the patient may have developed a conditioned response associating the bed and bedroom with resultant poor sleep. [3.2.1; 4.5].

2. Progressive muscle relaxation is effective therapy in the treatment of chronic insomnia. (Guideline)

This recommendation is supported by Level II and III evidence, and is a Grade B - C recommendation. Therapy using these techniques involves a method of tensing and relaxing different muscle groups throughout the body. This therapy was developed and has been observed to be useful in insomnia patients who often display high levels of arousal both at night and during the daytime [3.2.3; 4.5].

3. Paradoxical intention is effective therapy in the treatment of chronic insomnia. (Guideline)

This recommendation is supported by Level II and III evidence, and is a Grade B - C recommendation. This method of treatment involves persuading a patient to engage in his or her most feared behavior, i.e. staying awake. The goal is to eliminate performance anxiety, as it may inhibit sleep onset [3.2.5; 4.5]. Interestingly, the evidence table literature on this topic is generally older, with seemingly less common use in recent insomnia therapy studies, even with combined therapies. Due to variability of response it is not clear which insomnia types might respond.

4. Biofeedback is effective therapy in the treatment of chronic insomnia. (Guideline)

This recommendation is supported by Level II and III evidence, and is a Grade B - C recommendation. This form of therapy provides visual or auditory feedback to patients to help them control some physiologic parameters (e.g. muscle tension) in order to seek reduction in somatic arousal [3.2.3; 4.5].

5. Sleep restriction is effective therapy in the treatment of chronic insomnia. (Option)

This recommendation is supported by somewhat variable Level II, III and V evidence, and is a Grade B - C recommendation. This form of therapy involves curtailing the amount of time in bed to the actual amount of time spent asleep and then lengthening sleep time after sleep efficiency improves [3.2.2; 4.5]. Use of sleep restriction in a majority of the studies was part of combination therapy and a specific contribution of sleep restriction toward each sub-

ject's improvement was often unclear [Table 1].

6. Multicomponent (cognitive) behavioral therapy is effective therapy in the treatment of chronic insomnia. (Option)

This recommendation is supported by Level III and substantial Level V evidence, and is a Grade C recommendation. This form of therapy may include various combinations of both psychological as well as behavioral interventions. The psychological components are aimed at changing patient's beliefs and attitudes about insomnia [3.2.4; 4.5]. Cognitive therapy may be, but is not always, an intergral part of this multicomponent therapy (see section 9). The behavioral component may include therapies such as stimulus control, sleep restriction, or progressive muscle relaxation as previously described. We assessed multicomponent therapy as a single therapy due to its increasingly common use as a single mode. While several of the individual components are recommended as a Standard or Guideline, the evidence for multicomponent therapy as an identified specific combination is still in evolution at the time of this analysis of the literature, leading to its recommendation as an Option. For more information on this form of therapy, the reader is referred to a recent article that details its use in elderly subjects.[10]

7. Sleep Hygiene Education

Insufficient evidence was available for Sleep Hygiene Education to be recommended as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined from the available data.

This form of behavioral intervention targets making patients more aware of health practices (e.g. diet, exercise, substance abuse) and environmental factors (e.g. light, noise, temperature, mattress) that may be either detrimental or beneficial for sleep [3.2.6; 4.5]. Sleep hygiene education is often included in other forms of behavioral interventions such as multicomponent cognitive behavioral therapy described above. Data for assessment as an independent therapy is insufficient.

8. Imagery Training

Insufficient evidence was available for Imagery Training to be recommended as a single therapy. Whether this therapy is effective when added to other specific approaches could not be determined from the available data.

This treatment involves a visualization technique to focus on some pleasant or neutral images. This may actually be a sub-category of relaxation therapy [3.2.3; 4.5].

9. Cognitive Therapy

Insufficient evidence was available for Cognitive Therapy to be recommended as a single therapy.

This form of therapy seeks to alter faulty beliefs and attitudes about sleep and uses multiple patient-specific techniques. Very specific examples may include decatastrophizing, reappraisal, and attention shifting, as well as other techniques to replace specific dysfunctional concepts about sleep with more appropriate ones. The objective of this form of therapy is to diminish the cycle of insomnia, emotional stress, dysfunctional cognitions and further sleep disturbances [3.2.4; 4.5]. There is limited evidence to recommend cognitive therapy as a single therapy. This therapy is increasingly being used in combination with other therapies as a combined treatment trial (see section 6).

The review paper [4.6] identifies 3 treatments (stimulus control, progressive muscle relaxation, and paradoxical intention) as empirically-validated and well-established according to the criteria of the American Psychological Association. Three treatments (EMG biofeedback, sleep restriction, and multicomponent cognitive behavioral therapy) are identified as empirically-validated and probably efficacious. Therapies not meeting these criteria are identified as experimental. The reader is referred to the accompanying task force paper for more and detailed definitions for each of these treatments [3.2.1; 3.2.3; 3.2.5; 3.2.2; 3.2.4; 4.5]. Table 3 summarizes APA criteria which are also addressed in the review paper [4.6].

RECOMMENDATIONS FOR FURTHER RESEARCH

More studies on the ability of the individual therapies alone and in specific combination need to be done with placebo controls. In addition, the maintenance of effect for long periods of time (months to years) needs to be studied as does the effect of treatment on quality of life. The effectiveness of pharmacologic and nonpharmacologic therapies should be directly compared. Research should also be pursued to determine whether the two approaches would be more effective if combined.

Although the nonpharmacologic therapies appear useful, the mechanism of action of these therapies is not clear. More research into the basic mechanisms of insomnia would be helpful to better tailor therapy for individual patients.

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REFERENCES

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders: DSM-IV, 4th Edition. Washington, DC: American Psychiatric Association, 1994.
2. National Commission on Sleep Disorders Research. Wake Up America: A National Sleep Alert. U.S. Department of Health and Human Services, 1993.
3. Murtagh, D.R. and Greenwood, K.M. Identifying Effective Psychological Treatments for Insomnia: A Meta-Analysis. J Consult Clin Psychol, 1995; 63(1):79-89.
4. Morin, C.M., Hauri, P.J., Espie, C., Spielman, A., Buysse, D., and Bootzin, R. Nonpharmacologic Treatment of Insomnia. Sleep, 1999; 22:.
5. Morin, C.M., Culbert, J.D., and Schwartz, S.M. Nonpharmacologic Interventions for Insomnia: A Meta-Analysis of Treatment Efficacy. Am J Psych, 1994; 151(8):1172-80.
6. American Sleep Disorders Association. International Classification of Sleep Disorders, Revised: Diagnostic and Coding Manual. Rochester: American Sleep Disorders Association, 1997.
7. Sackett, D. Rules of Evidence and Clinical Recommendations for the Management of Patients. Can J Cardiol, 1993; 9(6):487-89.
8. Eddy, D.M. A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach. Philadelphia: American College of Physicians, 1992.
9. American Psychological Association. Training in and Dissemination of Empirically-Validated Psychological Treatments: Report and Recommendations. The Clinical Psychologist, 1995; 48(1):3-23.
10. Morin, C.M., Colecchi, C., Stone, J., Sood, R., and Brink, D. Behavioral and Pharmacological Therapies for Late-Life Insomnia: A Randomized Controlled Trial. JAMA, 1999; 281(11):991-9.