



Complete Summary

GUIDELINE TITLE

Practice parameters for the nonpharmacologic treatment of chronic insomnia.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Sleep Medicine. Practice parameters for the nonpharmacologic treatment of chronic insomnia. *Sleep* 1999 Dec 15;22(8):1128-33. [10 references]

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SCOPE

DISEASE/CONDITION(S)

Chronic insomnia

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Neurology
Psychiatry
Sleep Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations for the practice of sleep medicine regarding the use of nonpharmacologic therapies to treat chronic insomnia.
- To review the empirical evidence regarding the short- and long-term efficacy, and practical advantages and limitations, of non-pharmacological interventions for the clinical management of insomnia.

TARGET POPULATION

Individuals with chronic insomnia

INTERVENTIONS AND PRACTICES CONSIDERED

1. Stimulus control
2. Progressive muscle relaxation
3. Paradoxical intention
4. Biofeedback
5. Sleep restriction
6. Multi-component cognitive behavioral therapy
7. Sleep hygiene education
8. Imagery training
9. Cognitive therapy

MAJOR OUTCOMES CONSIDERED

The following outcome measures were used in assessing the therapeutic efficacy of non-pharmacological treatments for chronic insomnia:

- Sleep onset latency
- Wake after sleep onset
- Number and/or duration of awakenings
- Total sleep time
- Sleep quality
- Sleep log/diary
- Polysomnography
- Behavioral assessment devices (actigraphy)

Additional outcome measures of the clinical significance of treatment-related changes:

- The proportion of patients who reached a dual improvement, i.e., (1) a 50% reduction on the main target symptoms (sleep onset latency or time awake after sleep onset) plus (2) an absolute value of that symptom falling near or below the 30-min criteria typically used to define insomnia
- The proportion of patients whose sleep efficiency moved from a dysfunctional to a normative level (i.e., >80%-85%)
- A reduction of hypnotic usage

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Treatment studies selected for review in the companion technical review were identified through PsycLIT and MEDLINE searched (1970-1997) using the following key words: Insomnia, nonpharmacological-nondrug, behavior-cognitive-psychological, treatment-therapy-intervention-management. In addition, bibliographies of meta-analyses or other literature reviews and references cited in empirical studies themselves were also systematically reviewed. The criteria for inclusion of a study were as follows: (a) the main sleep diagnosis was insomnia, (b) one of the treatment conditions was nonpharmacological, (c) the dependent measures included one or more of the following variables: Sleep onset latency, number and/or duration of awakenings, total sleep time, or sleep quality, and (d) the study design was a group design with a control/comparison condition or a clinical case series evaluating a well-defined treatment modality with a minimum of 10 clinical patients. Case reports and single-subject design studies were excluded, as were studies whose sample was composed predominantly of college students.

The initial search yielded approximately 100 treatment studies, but more than half were excluded because they did not meet inclusion criteria. The main reasons for exclusion were that treatment was exclusively pharmacological, the study included less than 10 patients, or the sample was composed predominately of college students recruited on a university campus. The companion technical review paper is based on the evidence from 48 individual studies (n>2,000 patients) that met inclusion criteria; those studies are listed in Table 1 of the technical review document. In addition, findings from two meta-analyses (see Table 2 and 3 of the technical review document [see "Companion Documents"]), which were themselves quantitative reviews of individual treatment studies, are used in estimating treatment efficacy and improvement rates for the different treatment modalities.

NUMBER OF SOURCE DOCUMENTS

48 source documents

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Recommendation Grades

A (Evidence Level I)

- Randomized well-designed trials with low-alpha & low-beta errors*

B (Evidence Level II)

- Randomized trials with high-beta errors*

C (Evidence Level III)

- Nonrandomized controlled or concurrent cohort studies

C (Evidence Level IV)

- Nonrandomized historical cohort studies

C (Evidence Level V)

- Case series

* 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.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Studies meeting the inclusion criteria were systematically reviewed with the use of evidence tables. In addition, findings from 2 meta-analyses, which were themselves quantitative reviews of individual treatment studies, were used in estimating treatment efficacy and improvement rates for the different treatment modalities.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When scientific data were insufficient or inconclusive, recommendations were based on consensus opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendation

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.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Board of Directors of the American Academy of Sleep Medicine approved these recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Supported by Level II (randomized trials with high beta errors), Level III (non randomized controlled or concurrent cohort studies), level IV (non-randomized historical cohort studies) and/or Level V (case series) evidence, the following practice parameters are Grade B and/or C recommendations. Recommendation grade (A-C) and recommendation levels (standards, guidelines, or options) are defined at the end of the Major Recommendations field.

Treatments:

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

Level II Evidence; Recommendation Grade: B

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

Level II And III Evidence; Recommendation Grade: B-C

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

Level II And III Evidence; Recommendation Grade: B-C

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

Level II And III Evidence; Recommendation Grade: B-C

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

Level II, III And V Evidence; Recommendation Grade: B-C

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

Level III and Substantial level V Evidence; Recommendation Grade: C

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

Definitions:

Recommendation Grades

A (Evidence Level I)

- Randomized well-designed trials with low-alpha & low-beta errors*

B (Evidence Level II)

- Randomized trials with high-beta errors*

C (Evidence Level III)

- Nonrandomized controlled or concurrent cohort studies

C (Evidence Level IV)

- Nonrandomized historical cohort studies

C (Evidence Level V)

- Case series

* 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.

Levels of Recommendation

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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The conclusions are based on evidence from studies in peer-reviewed journals, as described in the evidence tables in the companion technical paper. For each recommendation, the strength of the recommendation, based upon the level of evidence, is identified. The type of supporting evidence for each recommendation is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

The data outlined in the guideline indicate the 70-80% of patients treated with non-pharmacological intervention benefit from treatment, 50% achieve clinically meaningful outcomes, and about one third become good sleepers. For a typical patient with persistent primary insomnia, treatment is likely to reduce the main target symptoms of sleep onset latency and/or wake time after sleep onset below or near the 30 min criterion initially used to define insomnia severity. Sleep duration is also increased by a modest 30 minutes and sleep quality and patient satisfaction with sleep patterns are significantly enhanced. Sleep improvements achieved with these behavioral interventions are sustained for at least 6 months after treatment completion, according to recent studies.

Specific Benefits

Stimulus control has been shown to reduce the average self-reported sleep onset latency from 64 min at baseline to 33 min at post-treatment and wake time after sleep onset from 84 to 44 min.

Sleep restriction reportedly reduces sleep latency from an average of 48 min at baseline to 19 min at post-treatment, and time awake after sleep onset is reduced from 111 min to 31 min, with a corresponding increase in sleep efficiency from 67% at baseline to 87% following treatment.

Standard progressive muscle relaxation: According to meta-analyses, progressive muscle relaxation reduces self-reported sleep latency and wake after sleep onset by an average of 20-30 min from baseline to post-treatment with equivalent increases in total sleep time. The subjective quality of sleep is also enhanced.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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 judgment 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Sleep Medicine. Practice parameters for the nonpharmacologic treatment of chronic insomnia. *Sleep* 1999 Dec 15;22(8):1128-33. [10 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999

GUIDELINE DEVELOPER(S)

American Academy of Sleep Medicine - Professional Association

SOURCE(S) OF FUNDING

American Academy of Sleep Medicine

GUIDELINE COMMITTEE

Standards of Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Committee Members: Andrew L. Chesson, Jr; W. McDowell Anderson; Michael Littner; David Davila; Kristyna Hartse; Stephen Johnson; Merrill Wise; Jose Rafecas.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the American Academy of Sleep Medicine's Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of interest with regard to this subject.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Morin CM, Hauri PJ, Espie CA, Spielman AJ, Buysse DJ, Bootzin RR. Nonpharmacologic treatment of chronic insomnia. An American Academy of Sleep Medicine review. *Sleep* 1999 Dec 15;22(8):1134-56.

Print copies: Available from the Standards of Practice Committee, American Academy of Sleep Medicine, One Westbrook Corporate Center, Suite 920, Westchester, IL 60154. Web site: www.aasmnet.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 19, 2000. The information was verified by the guideline developer on January 15, 2001.

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