



# Consistency of new research with a 2006 *Sleep Medicine* practice parameter for young children

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## BACKGROUND

Clinical practice guidelines are systematic reviews and synthesis of the scientific literature for specific diagnoses and treatment modalities. They provide important guidance to practitioners and patients. However, if a practice guideline is not updated regularly, then readers may not be aware of changes and newer developments in best practices.

We identified a practice guideline that had not been updated since 2006, the American Academy of Sleep Medicine's *Practice Parameters for Behavioral Treatment of Bedtime Problems and Night Wakings in Infants and Young Children*<sup>1</sup>. To determine whether the clinical trials and published research since 2006 remain consistent or conflict, we completed a systematic review.

## METHODS

We constructed research questions based on the guideline recommendations using the Participants, Intervention, Comparator, Outcome (PICO) format<sup>2</sup>, developed search strings based on these questions, and searched ClinicalTrials.gov, the World Health Organization's International Clinical Trials Registry Platform, and PubMed. Studies were screened for eligibility and exclusion criteria based on completion date and relevance. Retained studies were evaluated based on study type and design, stage of completion, and which recommendation they addressed.

## PRACTICE GUIDELINE

The recommendations from the practice guideline are classified into three levels, based on level of scientific support:

Term	Definition
<b>Standard</b>	This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty.
<b>Guideline</b>	This is a patient-care strategy, which reflects a moderate degree of clinical certainty.
<b>Option</b>	This is a patient-care strategy, which reflects uncertain clinical use.

**Table 1: Number of Relevant Studies Addressing Each Clinical Recommendation, by Type**

AASM Practice Parameter Recommendation	Level of Recommendation	Total Number of Relevant Studies*	Study Type			
			Randomized Control Trial	Inter-vention	Case Report	
3.4	Graduated extinction of undesired behavior is an effective and recommended therapy in the treatment of bedtime problems and night wakings.	Guideline	7	6 (4 not yet completed)	1	-
3.5	Delayed bedtime with removal from bed/positive bedtime routines is an effective and recommended therapy in the treatment of bedtime and problems and night wakings.	Guideline	14	13 (4 not yet completed, 2 completed without published results)	1	-
3.6	The use of scheduled awakenings is an effective and recommended therapy in the treatment of bedtime problems and night wakings.	Guideline	9	9 (1 not yet completed, 1 completed without published results)	-	-
3.7	Insufficient evidence was available to recommend any single therapy over another for the treatment of bedtime problems and night wakings. Insufficient evidence was also available to recommend combination, or multi-faceted, interventions for bedtime problems and night wakings over single therapies.	Option	28 (2 head-to-head comparisons)	23 (5 not yet completed, 6 completed without published results)	5	-
3.8	Behavioral interventions are recommended and effective in improving secondary outcomes (child's daytime functioning, parental well-being) in children with bedtime problems and night wakings.	Guideline	34	27 (7 not yet completed, 6 completed without published results)	6	1

\*Grand total of studies is greater than 51 due to multiple studies addressing more than one guideline. Each applicable study was counted under each guideline. Registered clinical trials also associated with a PubMed study were only counted once.

**Table 2: Number of Studies Retained, by Source**

Source	Number of Studies*
ClinicalTrials.gov (CT)	16 (16/51, 31.4%)
International Clinical Trials Registry Platform (ICTRP)	9 (9/51, 17.6%)
PubMed.gov	26 (26/51, 51.0%)

\*Studies that were indexed in both clinical trial databases were counted only in the ClinicalTrials.gov total. Registered clinical trials that also had published results were counted only in the CT or ICTRP total.

## RESULTS SUMMARY

After the screening process, 51 studies were retained for review. Of these, 28 were completed with published results, including 7 randomized controlled trials, 8 non-randomized intervention studies, and 1 case report. The majority of studies addressed more than 1 recommendation of interest and supported the use of behavioral interventions.

## CONCLUSIONS

- Despite up to 40% of parents reporting sleep problems in their young children,<sup>3-4</sup> there is a general dearth of research on specific interventions that may effectively treat them.
- Research over the past 15 years continues to support the general effectiveness of behavioral techniques.
- However, published research and registered clinical studies have not aligned with research gaps that were identified in the 2006 guidelines.
- Although there was a higher average yearly rate of relevant research post guideline publication, there were few completed or registered planned studies that addressed the two specific identified areas for further research of non-pharmacologic treatments for young children.
- Out of 31 studies identified as including multiple or comparison behavioral approaches, only one included a head-to-head comparison of behavioral treatment components and only one included a head-to-head comparison of delivery format; all others implemented their particular mix of behavioral interventions as an uncontrolled pre-post study or to a non-behavioral control group.
- To further advance knowledge for clinical care of infants and young children with bedtime and night-waking problems, future research should target the previously identified research gaps as opposed to continuing to replicate well-established practices.

## REFERENCES

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