Stimulus-control: nonpharmacologic treatment for insomnia

Lucie Baillargeon, MD, MSC Marie Demers, PHD Robert Ladouceur, PHD

ABSTRACT

OBJECTIVES To evaluate the efficacy and applicability of a behavioural treatment for insomnia that can be administered by family physicians in various clinical settings.

DESIGN Efficacy of the treatment was evaluated by single-case experimental designs (multiple baseline across subjects). Applicability was assessed through semistructured interviews with physicians.

SETTING Two private offices, two offices in community health centres, and one office in a family medicine unit.

PARTICIPANTS Six general practitioners and 24 chronic insomniac patients recruited through media advertisements and from physicians' practices. Of an initial 38 subjects screened, six were excluded for sleep-onset latency less than 30 minutes, five for psychological conditions, one for physical handicaps, and two for other reasons.

INTERVENTIONS Physicians used stimulus-control treatment during individual therapeutic sessions. Patients using hypnotics were encouraged to taper off their medications after treatment was initiated.

MAIN OUTCOME MEASURES Time it took patients to get to sleep (sleep-onset latency), amount of hypnotic use, and practitioners' evaluation of the treatment.

RESULTS Fifteen patients completed the treatment; 80% of them reduced their sleep-onset latency. Six of the seven patients using hypnotics at the beginning of the study reduced or stopped their medications. All therapeutic gains were maintained at 3 and 6 months. Physicians thought stimulus-control treatment could be used in medical practice, but specified that it was most useful for highly motivated patients.

CONCLUSION Family physicians can use stimulus-control treatment effectively for patients with chronic insomnia. This nonpharmacologic approach could help motivated patients reduce their use of hypnotics.

RÉSUMÉ

OBJECTIF Évaluer l'utilité et l'applicabilité d'une thérapie comportementale que peuvent utiliser les médecins de famille dans divers contextes cliniques pour traiter l'insomnie.

DEVIS Évaluation de l'utilité du traitement par des devis expérimentaux appliqués à des cas individuels (avec multiples points de comparaison entre les sujets). Des entrevues semi-structurées avec les médecins ont servi à évaluer l'applicabilité.

MILIEU Deux cabinets privés, deux cabinets dans des centres de santé communautaire et un cabinet dans une unité de médecine familiale.

PARTICIPANTS Six omnipraticiens et 24 patients souffrant d'insomnie chronique recrutés par des annonces dans les médias et dans les pratiques des médecins. À partir d'un groupe initial de 38 sujets, six furent exclus parce que leur période de latence avant de s'endormir était inférieure à 30 minutes, cinq autres à cause de troubles psychologiques, un pour un handicap physique et deux autres pour diverses raisons.

INTERVENTIONS Pendant les sessions thérapeutiques individuelles, les médecins ont appliqué le contrôle des stimuli. Dès le début de la thérapie, on a encouragé les patients qui prenaient des hypnotiques à réduire progressivement leur médication.

PRINCIPALES MESURES DES RÉSULTATS Le temps écoulé avant le début du sommeil (temps d'endormissement), la quantité d'hypnotiques utilisés et l'évaluation du traitement par le praticien.

RÉSULTATS Quinze patients ont complété le traitement ; 80 % d'entre eux ont réduit leur temps d'endormissement. Six des sept patients qui prenaient des hypnotiques au départ de l'étude ont réduit ou cessé leur médicament. Après trois mois et six mois, tous les gains thérapeutiques s'étaient maintenus. Les médecins ont confirmé l'applicabilité de la technique du contrôle des stimuli en pratique médicale tout en spécifiant son maximum d'utilité chez les patients fortement motivés.

CONCLUSION Les médecins de famille peuvent efficacement faire appel à la technique de contrôle des stimuli pour traiter les insomniaques chroniques. Cette approche non pharmacologique peut aider les patients motivés à réduire leur consommation d'hypnotiques.

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Insomnia is a frequent complaint in general practice. A German study conducted with 2512 consecutive patients consulting 10 general practitioners reported that 18.7% of patients suffered from severe, 12.2% from moderate, and 15% from mild insomnia.[1] Prescribed drugs are the treatment of choice for medical management of these patients, and half of them receive hypnotics.[2]

Current recommendations suggest limiting use of sleep medication to a few weeks.[3] Unfortunately, this guideline is rarely followed. Among hypnotic users, 19% said they had used a hypnotic on 120 days or more during the past year.[4] One reason for this could be that practitioners are unaware of effective nonpharmacologic treatments. Cognitive and behavioural treatments, such as relaxation,[5] sleep restriction,[6] stimulus-control treatment,[7,8] sleep education, and cognitive therapy,[9] have been shown to be effective for insomnia. A recent meta-analysis indicated that stimulus-control treatment was the most effective single therapy for both sleep-onset and maintenance insomnia.[10] Few physicians use behavioural techniques, however, probably because they are rarely taught during medical training.[11,12]

Our study evaluated the efficacy and applicability of stimulus-control treatment for chronic insomniac patients. Treatment was administered by general practitioners in a variety of clinical settings.

METHOD

Design

A single-case experimental design (multiple baseline across subjects) was used.[13,14] Contrary to standard group-comparison designs, this protocol needs fewer subjects to demonstrate the effectiveness of a therapeutic intervention, and patients serve as their own controls.

Treatment is applied in sequence across subjects, and control procedures are found for each subject's baseline period. A prerequisite to introducing the treatment is stability of the baseline level. Once this level is stable, treatment is applied to the next subject. Length of the baseline is increased as each succeeding subject enters the study, providing control data to compare with treatment outcomes.[13,14] Continuous assessment of the dependent variable before and during treatment allows researchers to verify whether change occurs when, and only when, the intervention is used.[15] Replications across three or four baselines is considered convincing.[13,14]

Dr Baillargeon *is a Clinical Teacher in the Family Medicine Department at Laval University and practises at the Unité de médecine familiale du Centre hospitalier universitaire de Québec (Pavillon CHUL) in Quebec City.*
Ms Demers *is an epidemiologist at the Ministère de la Santé et des services sociaux in Quebec City.*
Mr Ladouceur *is a Professor in the École de psychologie at Laval University.*

Settings

The treatment was used by six general practitioners in three primary care settings: two private offices, two offices in community health centres, and an office in a family medicine unit. Those settings are the most common for general practitioners working in the province of Quebec.

Participants

Physicians. Six general practitioners agreed to participate in the study: four men and two women. Their mean age was 35 years (range 30 to 40) and they had been practising for a mean of 8 years (range 4 to 14). They all practised full time and had never used stimulus-control treatment for insomnia before the study. They attended a 3-hour training session on stimulus-control treatment conducted by a behavioural and clinical psychologist with extensive experience in research and clinical therapy with insomniacs (R.L.). During the study, they had an additional 2-hour session to discuss problems with difficult cases.

Patients. Participants were recruited through media advertisements and from physicians' regular practices. They were selected according to the following criteria: between 25 and 65 years old, having sleep-onset insomnia (defined as mean sleep-onset latency longer than 30 minutes during a 2-week period), and suffering from insomnia for at least 1 year. Subjects were excluded if the insomnia was secondary to medical or psychological disorders or to other conditions such as possible sleep apnea or periodic leg movements during sleep; severe medical disorders that could be related to insomnia; major depression (a score higher than 29 on the Beck Depression Inventory [BDI]),[16] severe anxiety (a score higher than 29 on the Beck Anxiety Inventory [BAI]),[17] or other severe psychopathology ascertained during the clinical interview; regular use of alcohol, drugs, or medication that could cause insomnia; and shift work.

During an initial telephone interview, all potential subjects were given a brief description of the study and were screened for disqualifying criteria and motivation to participate. One practitioner evaluated 38 subjects who completed the BDI, the BAI, a sleep disturbance questionnaire,[18] and kept a sleep diary for 2 weeks before the interview. Of the initial 38 subjects screened, 14 were excluded: six for sleep-onset latency less than 30 minutes, five for psychological conditions, one for physical handicaps, and two for other reasons. The study was approved by the Centre hospitalier universitaire de Québec's Ethics Committee on Clinical Research.

Interventions

The stimulus-control treatment described by Bootzin and associates[19] was used. The goals of this intervention were to strengthen the bed as a cue for sleep, to weaken it as a cue for activities that might interfere with sleep, and to help insomniacs acquire a regular sleep pattern. Seven written instructions were given to patients at the first session (**Table 1**). During subsequent sessions, instructions incorrectly followed were clarified, and patients were encouraged to comply with the regimen. The first three individual therapeutic sessions were scheduled weekly; other sessions were given biweekly. Patients taking sleep medication were instructed to continue with their usual dosage until sleep improved and then commence a gradual withdrawal. Therapy stopped when a mean sleep-onset latency of 30 minutes or less was achieved for 4 consecutive weeks, or after 10 sessions.

Table 1. Stimulus-control instructions

Go to bed only when tired and drowsy.
Stop all strenuous physical and intellectual activity 1 hour before bedtime.
Use your bed for sleeping only: do not read, watch television, eat, or worry in bed (having sex in bed is the only exception to this rule).
Leave the bedroom if you waken for more than 20 minutes and return only when sleepy.
Repeat this step as often as necessary if still awake.
Set an alarm clock and get up at the same time every morning irrespective of how much sleep you got the night before. This will help you acquire a regular sleep pattern.
Do not nap during the day.

Measures

Patients collected data in daily sleep diaries. This method has been shown to have good reliability for ascertaining the time between sleep onset and the appearance of stage II sleep patterns on electroencephalogram.[20] Data included daily estimates of sleep-onset latency, number of awakenings during the night, whether patients felt refreshed on awakening, and use and dosage of hypnotics. Patients kept the sleep diaries during baseline and treatment periods and for 2 additional weeks at 3 and 6 months.

A research assistant conducted a semistructured interview with each practitioner, except the principal author (L.B.), after the study. Physicians gave their opinions on the suitability of stimulus-control treatment for various kinds of patients and its applicability in, and effect on, their clinical practice. The questionnaire used in these interviews is available upon request from the authors.

Analysis

Data were analyzed as five distinct single-case studies with each one including two to four patients. As recommended in the guidelines published by Hersen and Barlow[13] and by Kratochwill,[14] analysis was based on visual inspection of graphed data. In order to assess the clinical importance of the results, the proportion of patients who fell asleep in 30 minutes or less was reported. This endstate functioning criterion is the most widely accepted in the literature.[21]

Mean values of all outcome variables for four periods (2 weeks of baseline, 4 weeks at end of treatment, and 2 weeks at each follow up) were also compared.

RESULTS

Fifteen of the 24 participants completed the treatment. Characteristics of these patients and the nine who dropped out are presented in **Table 2**. Patients not taking sleep medication had on average 5.8 therapy sessions; those requiring withdrawal had 10.5.

Thirteen of 15 (87%) subjects reduced their sleep-onset latency, all during the first 4 weeks (**Figure 1**). Seven of these patients reached a sleep-onset latency of 30 minutes or less. To illustrate the evolution of therapeutic gains during treatment, **Figure 2** depicts one of the five single-case designs. The first patient decreased his sleep-onset latency by

Figure 1. Sleep-onset latency measures at baseline and posttreatment for 23 patients

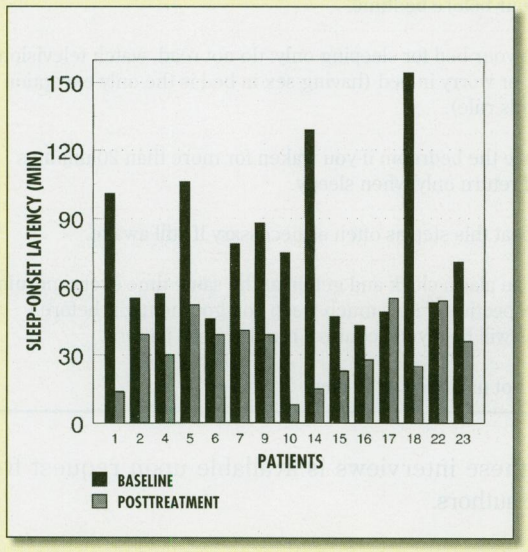

Table 2. Characteristics of patients who completed the study compared with patients who did not

CHARACTERISTIC	COMPLETED STUDY (N = 15)	DROPPED OUT (N = 9)
Sex		
• Men	5	1
• Women	10	8
Mean age	43.6	40.9
Years of education	15	14
Marital status		
• Married	8	4
• Single	7	2
• Divorced	0	2
• Widowed	0	1
Occupation		
• Working	13	7
• Unemployed	0	2
• Housekeeping	1	0
• Student	1	0
Had personal problems	6	7
Had health problems	7	3
Duration of insomnia (y)	9.5	10.8
Taking sleep medication	9	5

51%, but still could not fall asleep in less than 30 minutes after treatment. The second patient attained an 84% reduction, and latency was less than 30 minutes by the end of treatment. The third patient did not benefit from the intervention.

At the end of treatment, mean sleep-onset latency (33.2 ± 3.8 min/d) had decreased 57% compared with baseline (**Table 3**). The seven patients taking hypnotics at the beginning of the study reduced their mean daily dosage by 84%. Two patients completely stopped taking sleep medication, four took it less frequently, and one continued to take it as usual. Hence, the mean number of nights per week during which hypnotics were taken decreased by 62%, from 6.3 (±0.5) to 2.4 (±1.0) nights.

As shown in **Table 3**, therapeutic gains were maintained at 3 and 6 months. Also, average daily dosage and weekly intake of hypnotics were reduced even further than at end of treatment.

Physicians reported that stimulus-control treatment was easy to use. They indicated that the treatment is suitable for highly motivated patients. Two suggested that the number of therapeutic sessions could be reduced. Four were consulted by insomniacs after completion of the study: all used stimulus-control treatment. Regardless of clinical setting, physicians believed general practitioners could use this treatment.

DISCUSSION

This is the first study to demonstrate that stimulus-control treatment administered by general practitioners who received brief training produced clinically significant therapeutic gains in adult chronic insomniacs. A previous case series suggested that nurses could effectively use stimulus-control treatment, but this study suffered from serious methodologic flaws: absence of control measures and follow up for only 50% of the patients seriously limited the conclusions.[22] Our study, using stringent methodologic controls, demonstrates the efficacy of stimulus control. The magnitude of reductions in sleep-onset latency is similar to that reported by psychologists using similar treatment.[23-27]

Our results also showed that six of the seven patients using hypnotics at baseline reduced their use, an effect maintained at both follow ups. Very few studies have focused on long-term use of hypnotics after cognitive and behavioural treatment of insomnia. Morin and Azrin[27] observed a transient reduction in hypnotic intake in elderly insomniacs treated with

cognitive and behavioural approaches, but this effect was not maintained at 3 and 12 months. No withdrawal procedure was proposed to participants, however. Our results suggest that a withdrawal procedure combined with the stimulus-control treatment could help insomniacs improve their sleep and reduce use of hypnotics.

The efficacy of stimulus-control treatment is promising. Further research should be conducted on a larger sample of physicians and patients to generalize results.

Nine patients (38%) dropped out of the study, reflecting at first glance a higher drop-out rate than the 11% to 29% rate reported in other

Figure 2. Sleep-onset latency for three patients at baseline, during treatment, and at 3 and 6 months

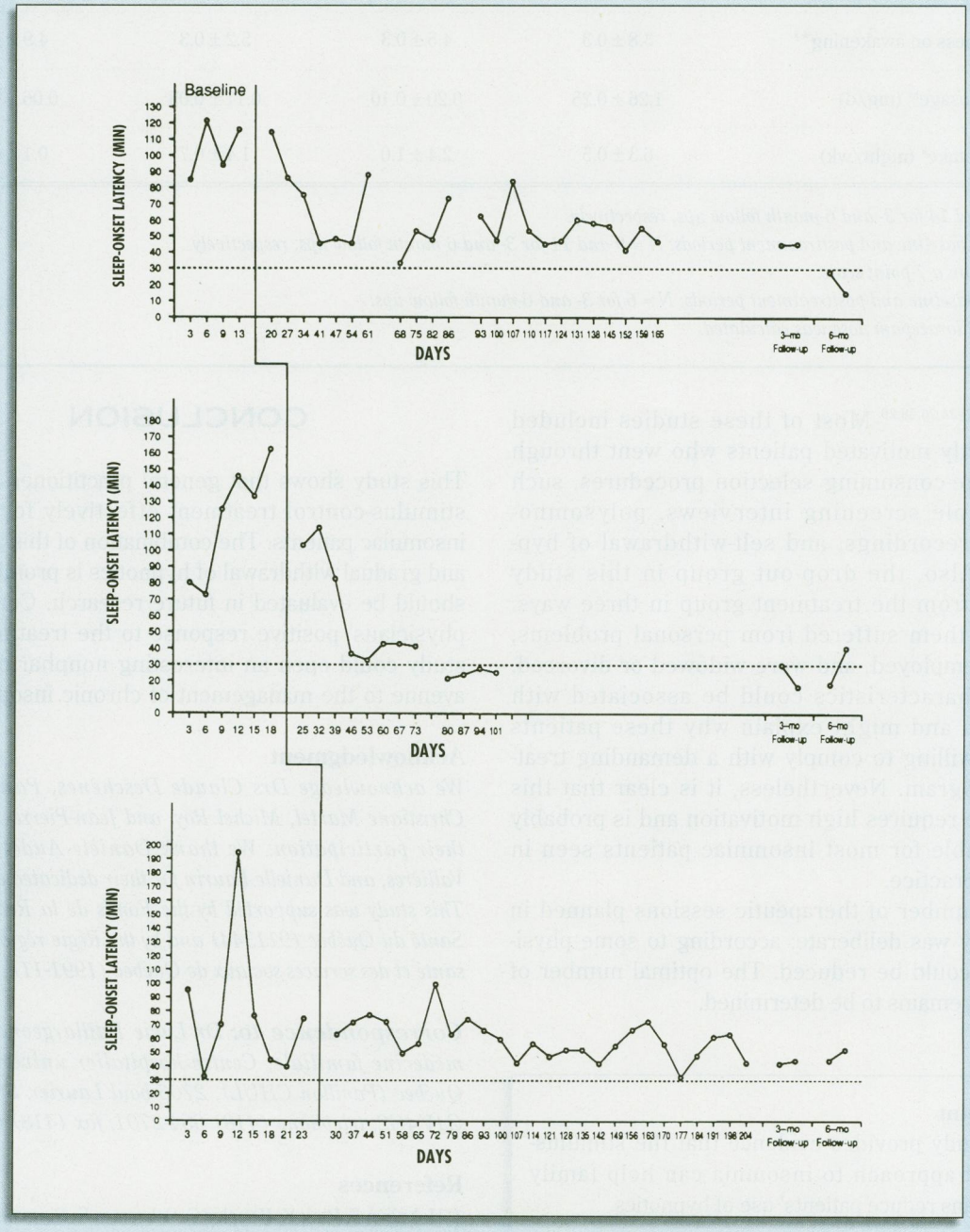

Table 3. Sleep parameters across experimental periods: *Mean values plus or minus standard deviations*

PARAMETERS	BASELINE	POSTTREATMENT	3-MONTH FOLLOW UP	6-MONTH FOLLOW UP
Sleep onset latency* (min/d)	76.9 ± 8.6	33.2 ± 3.8	33.1 ± 4.9	30.6 ± 3.2
Onset insomnia* (night/wk)	5.7 ± 0.4	1.8 ± 0.3	1.9 ± 0.4	1.7 ± 0.3
Intermittent insomnia† (night/wk)	3.8 ± 0.6	1.6 ± 0.5	1.5 ± 0.5	1.2 ± 0.5
Refreshedness on awakening*‡	3.8 ± 0.3	4.5 ± 0.3	5.2 ± 0.3	4.9 ± 0.3
Hypnotic dosage§‖ (mg/d)	1.26 ± 0.25	0.20 ± 0.10	0.11 ± 0.05	0.06 ± 0.03
Hypnotic intake§ (night/wk)	6.3 ± 0.5	2.4 ± 1.0	1.4 ± 0.7	0.1 ± 0.1

**N = 12 and 14 for 3- and 6-month follow ups, respectively.*
†N = 12 for baseline and posttreatment periods; N = 9 and 11 for 3- and 6-month follow ups, respectively.
‡Measured on a 7-point scale.
§N = 7 for baseline and posttreatment periods; N = 6 for 3- and 6-month follow ups.
‖Equivalent lorazepam dose was calculated.

studies.[22-24,26,28,29] Most of these studies included only highly motivated patients who went through long, time-consuming selection procedures, such as multiple screening interviews, polysomnographic recordings, and self-withdrawal of hypnotics. Also, the drop-out group in this study differed from the treatment group in three ways: more of them suffered from personal problems, were unemployed, and were widowed or divorced. These characteristics could be associated with insomnia and might explain why these patients were unwilling to comply with a demanding treatment program. Nevertheless, it is clear that this approach requires high motivation and is probably not suitable for most insomniac patients seen in general practice.

The number of therapeutic sessions planned in this study was deliberate; according to some physicians, it could be reduced. The optimal number of sessions remains to be determined.

Key Point
This study provides evidence that the stimulus-control approach to insomnia can help family physicians reduce patients' use of hypnotics.

CONCLUSION

This study shows that general practitioners can use stimulus-control treatment effectively for chronic insomniac patients. The combination of this approach and gradual withdrawal of hypnotics is promising and should be evaluated in future research. Considering physicians' positive response to the treatment, this study could open an interesting nonpharmacologic avenue to the management of chronic insomnia.

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Correspondence to: *Dr Lucie Baillargeon, Unité de médecine familiale, Centre hospitalier universitaire de Québec (Pavillon CHUL), 2705 boul Laurier, Ste-Foy, QC G1V4G2; telephone (418) 654-2701; fax (418) 654-2138.*

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