The Effects of Medication and Cognitive Behavior Therapy on Insomnia

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This study on the treatment of insomnia compares medication (Flummoxide), cognitive behavior therapy, and a wait-list control group. The patients in each group kept a sleep diary for 4 weeks of treatment and 4 weeks of follow-up. Results showed that both the medication group (89%) and the psychotherapy group (75%) had higher rates of improvement than the wait-list controls (47%).

In one form or another, insomnia affects virtually everyone at some time. More often than not, difficulty falling asleep or maintaining sleep is a transient episode associated with particular life events or physical states (Kittle, 1986). Even when it is chronic, some people are able to function effectively and appear to get along on less sleep than most people require. For others, insomnia is a persistent pattern that leaves them fatigued the following day and interferes with work and other activities. Insomnia can take several forms: difficulty in falling asleep, awakening during the night and having trouble getting back to sleep, or awakening prematurely in the morning and not being able to doze off again. These are not necessarily exclusive categories—they may be found in combination in the same individual.

The particular form of the disorder that is the focus of this research is sleep onset. The first resource for individuals with this disorder is usually the drugstore that carries any number of patent medicines that claim to promote sleep or the health food store that sells herbal and other substances whose very names, such as Sleepy Time and Peaceful, are intended to make people yawn as they sort through the bottles of available nostrums. Some people with insomnia are attracted to the sedative use of alcohol. If none of these remedies brings relief, they usually go to a general practitioner, who generally suggests that they cut down on the use of stimulants or relinquish them entirely, exercise more, avoid dietary indiscretion, and take a prescription drug that is a more potent sedative than anything that can be bought off the shelf. If this regimen fails, individuals may be referred to a mental health professional for appraisal and amelioration of psychological factors or to a sleep clinic that specializes in sleep disorders. Practitioners of alternative approaches are earnestly waiting in the wings for all of this to be of no avail. If nothing works, people with insomnia have no choice but to be stoic and to spend their days fighting off the onset of that blissful state of somnolence that so inconsiderately remains out of reach when they are tossing and turning in bed at night.

Insomnia is classified in the *Diagnostic and Statistical Manual of Mental Disorders* (3rd ed.; American Psychiatric Association, 1980) as (a) primary, (b) related to another mental disorder, or (c) related to a known organic factor. Primary insomnia is present when the individual has trouble falling asleep or remaining asleep, has had this difficulty at least three times a week for a month or more, and experiences fatigue or impaired functioning during the daytime. The acceptable range is to fall asleep within 30 min of trying to initiate sleep and to remain asleep for 4–10 hr.

The present investigation compares and contrasts the relative efficacy of a newly available prescription drug and a relatively new form of short-term cognitive–behavioral approach. Both are used with individuals having primary insom-

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NOTE: This is a fictional article to be used solely for purposes of research education.

nia of the sleep-onset variety. The medication, Flummoxide, is orally administered in the form of a tablet; is alleged to act rapidly; does not cause stomach upset; can be safely taken by pregnant women, people with respiratory disorders, and men with benign enlargement of the prostate; and is not followed by fatigue and lethargy the following morning. It is meant to be used exclusively at bedtime, and it is not to be used before operating machinery or driving a motor vehicle. Developed and used with reported success in the Czech Republic (Švejk, 1990), it has not yet been widely used in the United States.

The Seldrick (1992) manual for the behavioral treatment of insomnia is reported to have been used effectively at the Garbrand Sleep Clinic, but the data are largely anecdotal in nature (Ingraham, 1993). We have used it along with other treatments at our clinic since 1991. Clinical results appear to be favorable, but there remains a need to establish its value scientifically and to determine how it compares to medication. Our intention, then, is to appraise these two contemporary approaches side-by-side in a naturalistic field setting and to compare participants with an untreated control group.

Method

Participants

Participants were all those who responded to a newspaper advertisement for people who were interested in receiving free treatment for difficulty in falling asleep. A total of 135 individuals applied. Each applicant filled out a detailed health history form and was interviewed by a specialist at the Bainbridge Sleep Center to screen for any coexisting physical or mental disorder and to judge whether the claimed insomnia fell within the established criteria for the disorder. We excluded anyone who was currently being treated for insomnia elsewhere, taking medications that might contaminate the results, or admitted to having a substance abuse or alcohol problem. Where there were any doubts, the applicant was interviewed by an internist, a neurologist, or a psychologist as appropriate. All participants were at least 21 years old.

In order to keep the research as naturalistic as possible, all of the participants were asked to choose whether they would receive medication or psychotherapy. In real-life situations the patient has that choice. Giving participants that choice in research equalizes the expectancy factor, which can be crucial in the outcome of treatment. In addition, the medication was not administered in a double-blind design because it is not possible for the patients receiving psychotherapy (or for their therapists) to be blind to what they were doing. Just as there was no placebo therapy, there was no placebo drug. As soon as 25 participants had elected one of these treatments, the quota for that treatment was considered to be filled. After 25 people had been placed in each of the two treatment groups, all who expressed a preference for these groups were placed on a waiting list and were promised that they would receive the treatment of their choice in 8–10 weeks. Assignment continued in this fashion until there were 25 in the waiting-list group. They were told that they would be expected to keep a record of their sleep experiences while waiting. Demographic characteristics of the three groups of 25 participants each are shown in Table 1.

Treatment Conditions

Medication. Participants who were assigned to the medication group were given a 1-week supply of Flummoxide on their second visit, with instructions to swallow one 5-mg tablet each night ½ hr before bedtime. They were required to come to the Sleep Center once a week to check for any side effects and to receive a renewal of their medication. They were also to bring in their sleep diary (described below). This regimen was continued for the 4 weeks of the treatment phase and 4 weeks of a follow-up phase. participants who failed to come in on a scheduled date and who could not be reached by phone to schedule a make-up visit were dropped from the program.

Psychotherapy. Patients who were assigned to the psychotherapy group were required to come to the Sleep Center twice a week for 4 weeks

Table 1
Demographic Summary of the Three Groups

Characteristic	Medication	Psychotherapy	Wait List
Mean age (years)	28.6	52.8	41.4
Gender (%)			
Male	62	32	44
Female	38	58	56
Marital Status (%)			
Single	28	30	29
Married	44	42	40
Divorced or Widowed	13	16	15
Cohabiting	15	12	16
Occupation (%)			
Professional/ management	25	48	26
Clerical/sales	36	25	32
Skilled	28	15	29
Semiskilled	10	11	10
Unskilled	1	1	2
Education (%)			
High School Graduation	37	22	38
Some College	28	32	28
College Graduation	29	35	26
Graduate School	6	11	8

beginning with their second visit. At this time they participated in individual 45-min sessions. Sessions were conducted by three experienced Sleep Center professionals who were instructed to follow Seldrick's (1992) manual. Sessions were spot-checked by a supervisor who sat in on random sessions. Participants were expected to bring in their updated sleep diary at every session. Attendance of at least six out of the eight sessions was required for continuance in the program.

Waiting List. Patients on the waiting list were supplied with prepaid envelopes and were asked to mail in their sleep diaries on a specific day once a week.

Sleep Diary

All participants were given printed forms on which to keep a daily log of their sleep patterns. They were told to enter their most accurate estimate of the time it took for them to fall asleep the night before; this was to be done each morning, as soon as they woke up. The estimate was to be from the time that they set out to initiate sleep to the time that they actually fell asleep. Time estimates were to be made in minutes. They were also to note whether they felt rested or overly fatigued on awakening. The pretest was the recording of the first night before any medication had been taken or other treatment received. The estimate on the first night for those on the waiting list was also used as the pretest.

Results

Of the 75 original participants, 18 either dropped out, had to be excluded because of incomplete data (failure to properly maintain sleep diary), or failed to meet the attendance requirements. These losses were spread fairly evenly among the three groups, so that 18 remained in the groups that received medication, 20 in the psychotherapy group, and 19 in the group that was on the waiting list.

Participants were rated as either improved or unimproved on the basis of a comparison of their pretest and posttest sleep-onset estimates. The posttest estimate was derived from the average of estimates made over the 4-week follow-up period. The data were analyzed in a 2×3 chi-square analysis. The result of this overall analysis yielded $\chi^2(2, N = 57) = 9.70, p < .01$. Frequencies for this analysis are shown in Table 2. Here it can be seen that 89% of the medication group improved in comparison to 75% of the psychotherapy group and 47% of the waiting-list group. A second analysis omitted the waiting-list group and isolated the medication and psychotherapy groups for comparison. The advantage of the medication group is not statistically significant, $\chi^2(1, N = 38) = 1.22, p > .30$.

Table 2
Chi-Square Analysis of Improvement for the Three Groups

Status	Medication	Psychotherapy	Wait List
Improved	16	15	9
Unimproved	2	5	10
Total	18	20	19

Discussion

The results of this research clearly demonstrate the benefits of Flummoxide and the Seldrick approach to the behavioral treatment of insomnia of the sleep-onset variety. Both of these treatments resulted in significantly more improvement than was shown by a wait-list control group. Although the percentage of those who showed improvement was slightly higher for the medicated patients than for those who received psychotherapy, the difference was not statistically significant. These results should encourage more widespread clinical application. It would be of interest to determine whether a group that receives both the medication and the psychotherapy combined would show even better results than those receiving either treatment alone. Furthermore, a longer follow-up period would help to determine the durability of these favorable results. It would also be of value to see whether results would be comparable with other forms of insomnia.

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