

# The Consensus Sleep Diary: Quantitative Criteria for Primary Insomnia Diagnosis

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## ABSTRACT

**Objective:** The aim of the study was to put forward quantitative criteria for the Consensus Sleep Diary, to differentiate insomniacs from normal sleepers.

**Methods:** In this retrospective study, we analyzed 295 sleep diaries of patients with primary insomnia (43% were male, ages ranging between 17 and 76 years) collected in two clinical centers for insomnia and 536 sleep diaries of normal sleepers (47% were male, ages ranging between 15 and 82 years). We considered the following sleep parameters: time in bed, sleep onset latency, total sleep time, wake after sleep onset, sleep efficiency, number of awakenings, terminal wakefulness, and subjective feeling of rest. Using the Youden index, we calculated the quantitative criteria that performed best for each sleep parameter. Finally, we created receiver operating characteristic curves to test the accuracy of each identified criterion.

**Results:** Individuals with insomnia significantly differed from controls on all sleep indices ( $p < .001$ ). Differentiation between individuals with insomnia from controls was optimal for terminal wakefulness (>15 minutes, area under the curve [AUC] = 0.83), wake after sleep onset (cutoff >20 minutes, AUC = 0.81), total sleep time (<390 minutes, AUC = 0.80), and particularly sleep efficiency (<87.5%, AUC = 0.92, sensitivity = 0.80, specificity = 0.90). Time in bed was the least differentiating variable (<500 minutes, AUC = 0.57).

**Conclusions:** The quantitative criteria of the sleep diary in this study agree with the few available data in the literature. This confirms that the sleep diary could be a useful screening tool for assessing patients with primary insomnia.

**Key words:** sleep diary, insomnia, normal sleepers, ROC analyses, sleep efficiency.

## INTRODUCTION

Epidemiological studies agree that insomnia is the most common sleep complaint throughout the world.<sup>1,2</sup> Insomnia is clearly defined as a subjective report of difficulty with sleep initiation, difficulty in maintaining sleep, or nonrestorative sleep, which occurs despite adequate opportunity for sleep and which results in some form of daytime impairment.<sup>3,4</sup> Insomnia can be primary or comorbid; that is, it may also be the first symptom of mental or physical illness.<sup>3,5</sup> Insomnia should be diagnosed because of the way it affects the life of the patients and its social and economic impact: increased hospitalizations, absenteeism at work, and impaired quality of life.<sup>6,7</sup>

Shared recommendations on routine clinical evaluation of a patient with insomnia complaints include the use of specific questionnaires such as sleep diaries, as well as careful collection of patient's sleep history, clinical and psychiatric interview, and physical examination.<sup>8,9</sup> The use of a

sleep diary is indeed considered as a “first-level” mandatory tool to assess sleep habits and sleep disorders. A sleep diary allows clinicians to evaluate the timing and variability of sleep schedules on several nights, can help to identify targets for cognitive behavioral therapy, and allows for comparison between pretreatment and posttreatment sleep quantity, quality, and regularity.<sup>8,10</sup> Because of their prospective use, sleep diaries may be considered as less influenced by recall biases in comparison to sleep questionnaires.<sup>8–10</sup>

Despite widespread agreement about the usefulness of sleep diaries in insomnia assessment, strangely there has been a lack of standardization.<sup>11</sup> For a long period, different versions of the sleep diary have been used: these differences

AUC = area under the curve, CSD = Consensus Sleep Diary, NWAK = number of awakenings, SE = sleep efficiency, SOL = sleep onset latency, TIB = time in bed, TST = total sleep time, TWAK = terminal wakefulness, WASO = wake after sleep onset

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concerned the question format (with open-ended or closed-ended questions) and the sleep indexes used (i.e., including or excluding the terminal wake time in the calculation of sleep efficiency [SE]). To solve this lack of standardization, in 2005, a workgroup was created to develop a standardized sleep diary which has been published recently: the Consensus Sleep Diary (CSD).<sup>12</sup> Three versions of the final CSD have been put forward, based on input from a large group of insomnia experts, and on focus groups of individuals with and without sleep disorders: the core CSD, the expanded CSD for morning, the expanded CSD for evening. The last two versions contained the same items as the CSD but also a number of optional items that should be completed in the morning or in the evening. The core CSD consists of nine questions: “1) the time of getting into bed; 2) the time at which the individual attempts to fall asleep; 3) sleep onset latency (SOL); 4) number of awakenings (NWAK); 5) duration of awakenings; 6) time of final awakening; 7) final rise time; 8) perceived sleep quality (rated via Likert scale); and 9) an additional space for open-ended comments from the respondent.”<sup>12</sup> One of the most obvious and relevant advantages of using a shared format of sleep diary is the possibility of comparing results across studies.

Despite the consensus efforts made by the experts to define a common format for the CSD, the group did not take any position on any “cutoff values” to differentiate participants with insomnia from good sleepers.

Previously, Lichstein et al.<sup>13</sup> attempted to define sleep diary quantitative criteria for insomnia. Reviewing 61 studies on insomnia (Study 1) they identified 30 minutes as an optimal cutoff value for both SOL and wake after sleep onset (WASO) and successfully tested these criteria on 214 patients with insomnia (study 2). Afterward, Lineberger et al.<sup>14</sup> asked 72 participants with insomnia and 88 good sleepers (based on polysomnography criteria) to complete a sleep diary for 14 consecutive days. They proposed 20 minutes as the best “cutoff” for both SOL and WASO, to distinguish between insomniacs and good sleepers. More recently, Levenson et al.<sup>15</sup> compared sleep diaries and actigraphic records of 77 insomniacs with those of 40 normal sleepers in older adults (age > 60 years), confirming 20 minutes as a cutoff value for WASO and proposing 17.7 minutes for SOL. The authors highlighted that sleep diary parameters differentiate individuals with insomnia from good sleepers more accurately than actigraphic sleep parameters do.

To date, the quantitative criteria for sleep diaries can be considered as still provisional because these criteria were derived from few studies, with possible methodological limits concerning, in particular, the different sleep diary format administered,<sup>13</sup> the size of the sample,<sup>14,15</sup> and the specific age considered.<sup>15</sup> Therefore, these quantitative criteria have to be replicated in a larger sample with a wider age range.

The aim of our retrospective study was to identify the best sleep diary cutoff values to differentiate insomniacs from normal sleepers.

## METHODS

### Sample

We performed a retrospective study using sleep diary data from two anonymous databases. Informed consent was obtained for each database before original data collection. The study was approved by the Ethics Committee of the Department of Psychology of the University of Bologna and by the Ethic Committee CPP Ile de France for French data, and complied with the tenets of the Declaration of Helsinki.

### Insomnia Group

Sleep diaries of patients with insomnia came from the Centre du Sommeil et de la Vigilance, Hôtel-Dieu de Paris, and from the Service for Diagnosis and Treatment of Insomnia at the Department of Psychology, University of Bologna. At the time of assessment, all participants filled in the sleep diary for at least seven consecutive days.

In this study, we only included patients with a diagnosis of primary insomnia according to the qualitative criteria of the International Classification of Sleep Disorders (ICSD-2)<sup>3</sup> and the Research Diagnostic Criteria for Primary Insomnia<sup>16</sup> based on subjective complaints and clinical interviews in accordance with the published *Recommendations for a Standard Research Assessment of Insomnia*.<sup>8</sup> The diagnosis of primary insomnia was confirmed under the supervision of accredited sleep specialists using semistructured interviews in the two participating clinical centers.

Based on ICSD-2 and Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition definitions,<sup>3,4</sup> patients with other sleep diagnoses or suspected sleep diagnoses, such as narcolepsy, sleep apnea, restless leg syndrome, or periodic limb movement disorder, were excluded from this study.

Patients with psychiatric disorders or using psychoactive medications (including hypnotics) or other drugs that can affect sleep (e.g., corticosteroids and  $\beta$ -blockers) were also excluded from the study.

During clinical assessments, patients were systematically screened for significant symptoms of depression or anxiety in the last month using the Beck Depression Inventory<sup>17</sup> and State-Trait Anxiety Inventory.<sup>18</sup> Patients with a Beck Depression Inventory score of 20 or more, or a State-Trait Anxiety Inventory score of 40 or more were not considered as having primary insomnia. Moreover, none of the selected patients worked flexi-time or night shifts.

The final sample consisted of 295 patients with primary insomnia aged 44.02 (13.74) years (range, 17–76 years) years. There were 127 men (43.05%) and 168 women (56.95%).

### Control Group

Database of the control group was created at the Laboratory of Applied Chronopsychology at the Department of Psychology, University of Bologna, using a series of previous studies.<sup>19,20</sup> We retrospectively included 536 participants aged 35.58 (14.61) years (range, 15–82 years). There were 252 men (47.01%) and 284 women (52.99%). None of the participants worked

flexi-time or night shifts, and none had complained of sleep disturbance or daytime symptoms because of unsatisfactory sleep. The exclusion criteria were the presence of sleep disorders, mental disorders, serious or acute illness, the use of psychoactive medication, and the presence of disabilities interfering with or restricting mobility.<sup>8</sup> The participants had to complete the General Health Questionnaire (GHQ-12),<sup>21</sup> the Sleep Disorders Questionnaire (SDQ),<sup>22</sup> and the Profile of Mood States<sup>23</sup>; participants who did not complain of any sleep disorder in the Sleep Disorders Questionnaire were included in those studies if they had a General Health Questionnaire score of 4 or less and a Profile of Mood States score of 250 or less.

**Sleep Diary**

We used a sleep diary like the core CSD, with only one added question (total self-reported sleep time; see Table 1). The layout of the sleep diary we used allowed a week to be recorded on a single page.

**Recordings**

All participants were requested to fill in the sleep diary every day in the morning within 30 minutes after getting out of bed for at least seven consecutive nights.

**Scoring**

Data were inserted into an electronic worksheet by an expert scorer. For each participant, we considered the weekly average of each sleep parameter.

**Sleep Measures**

The considered sleep parameters are summarized at the bottom of Table 1: time in bed (TIB), the time expressed in minutes, between bed time and get up time; SOL (in minutes); the NWAK; the minutes of wake between sleep onset and last awakening in the morning (WASO); and the terminal wakefulness (TWAK), the amount of wake time, in minutes, between the last awakening and the get up time.

Total sleep time (TST), both reported (TSTr; i.e., indicated by the participant) and calculated (TSTc; i.e., obtained by subtracting the sum of SOL + WASO + TWAK from the TIB), was considered.

Having two different TST values, calculated and reported, we obtained two measures of SE: SEc, based on the ratio of the TSTc to the TIB multiplied by 100, and SEr, based on the ratio of the TSTr to the TIB multiplied by 100. Moreover, according to Levenson and coauthors,<sup>15</sup> we calculated another measure of SE: SEa (awake),

**TABLE 1.** Items of the Sleep Diary Used in the Present Study With Relative Response Format (at the Top) and Considered Sleep Parameters With Relative Scoring Method (at the Bottom)

Sleep Diary Item	Response Format
Item 1: What time did you get into bed?	Hours and minutes
Item 2: What time did you try to go to sleep?	Hours and minutes
Item 3: How long did it take you to fall asleep?	In minutes
Item 4: How many times did you wake up, not counting your final awakening?	Number
Item 5: In total how long did these awakenings last?	In minutes
Item 6: What time was your final awakening?	Hours and minutes
Item 7: What time did you get out of bed for the day?	Hours and minutes
Item 8: How would you rate the restorative quality of your sleep?	Likert scale ranging from 0 (no restorative) to 5 (very restorative)
Item 9: Comments (if applicable)	(for example: I had a heavy dinner)
Item 10: In total how long did you sleep?	In hours and minutes
Sleep Diary Parameters	Scoring
TIB	(Item 7 – Item 2) + 24
SOL	Item 3
NWAK	Item 4
WASO	Item 5
TWAK	Item 7 – Item 6
TSTr	Item 10
TSTc	TIB – (SOL + WASO + TWAK)
SEr	(TSTr/TIB) * 100
SEc	(TSTc/TIB) * 100
SEa	(TSTc/(TSTc + WASO)) * 100
Restorative quality of sleep	Item 8

TIB = time in bed; SOL = sleep onset latency; NWAK = number of awakenings; WASO = wake after sleep onset; TWAK = terminal awakening; TSTr = total sleep time referred; TSTc = total sleep time calculated; SEr = sleep efficiency referred; SEc = sleep efficiency calculated; SEa = sleep efficiency awake.

which is based on the ratio of the time between sleep onset and final morning awakening to the TIB multiplied by 100.

The restorative quality of sleep was assessed using a 6-point Likert-type item (with a very simple answer format: 0 = nonrestorative and 5 = very restorative) referring to each single sleep night.

### Statistical Analyses

Sex distribution was similar across the two samples ( $\chi^2 = 1.20$ ,  $p = .27$ ). In contrast, the mean age was different ( $F = 42.34$ ,  $p < .0001$ ). Therefore, we systematically inserted age as a covariate in the analyses. For each sleep measure, independent analyses of covariance (age as covariate) were performed to compare the insomnia group to the control group. Because multiple comparisons were performed, the Bonferroni correction was applied, considering a  $p$  value less than .0001 as significant. Cohen  $d$  index was calculated as a measure of the extent of effect.

The sleep parameters that were significantly different between the insomnia and control groups were further analyzed. Various cutoff values for each parameter were tested with regard to sensitivity and specificity. Sensitivity was the proportion of accurately classified individuals who reported insomnia. Specificity was the proportion of accurately classified individuals who reported having no sleep disorders. The Youden index (i.e., the highest value obtained when calculating sensitivity + specificity - 1) was used to determine optimal cutoff values.<sup>24</sup> For each quantitative criterion, we generated a receiver operating characteristic curve.<sup>25</sup> Values for the area under the receiver operating characteristic curve (AUC), which graphically depicts the relation between sensitivity and specificity, were used as figures of merit. A common guide for classifying the accuracy of a diagnostic test is as follows: 0.90–1, excellent; 0.80–0.90, good; 0.70–0.80, fair; 0.60–0.70, poor; and <0.60, fail.

For each quantitative criterion, the positive (the probability that someone who tested positive with the sleep diary really had insomnia) and negative (the probability that someone who tested

negative with the sleep diary was really a normal sleeper) predictive values were also computed.

All statistical analyses were carried out using SPSS 18.0 (SPSS, Inc, Chicago, IL).

### RESULTS

The insomnia patients completed the CSD for an average of 7.10 (0.47) days (range, 7–days), whereas the control group did the same for an average of 7.05 (0.31) days (range, 7–9 days).

The sleep measures for the two groups are shown in Table 2. Patients with insomnia reported staying in bed (TIB) significantly longer (16 minutes longer) than the control group. The insomnia group had significantly higher values for SOL, NWAK, WASO, TWAK, and a lower SE than the control group.

The insomnia group reported less TST in comparison to the control group, both for TSTc (79 minute less) and TSTr (68 minutes less).

According to the Youden index, the following cutoff values should be optimal: SOL, 16 minutes; NWAK, 1.2; WASO, 20 minutes; TWAK, 15 minutes; SE, 87.5%; and TST, 390 minutes.

The performance varied across the sleep parameters with the AUC ranging from 0.57 to 0.92. TST, WASO, SE, and TWAK had AUCs greater than 0.80 (good accuracy). The parameter that seemed to perform best was the SE, with a better ratio both for sensitivity/specificity and for negative/positive predictive value (Table 3).

### DISCUSSION

The aim of our work was to identify which quantitative sleep diary criteria would best differentiate participants with

**TABLE 2.** Sleep Measures for the Insomnia and Control Groups

	Control Group ( <i>n</i> = 536)	Insomnia Group ( <i>n</i> = 295)	<i>F</i>	<i>p</i>	Cohen <i>d</i>
TIB	460.71 (45.71)	476.98 (75.61)	31.10	<.00001	0.26
SOL	10.54 (8.59)	28.85 (26.29)	195.01	<.00001	0.94
NWAK	.85 (0.82)	1.90 (1.37)	157.99	<.00001	0.93
WASO	7.41 (9.81)	48.35 (52.80)	234.53	<.00001	1.08
TWAK	12.85 (13.76)	49.09 (51.95)	197.11	<.00001	0.95
TSTc	429.95 (45.67)	350.42 (103.92)	166.03	<.00001	0.99
TSTr	436.40 (44.32)	368.62 (72.77)	199.42	<.00001	1.12
SEc	93.35 (4.19)	73.50 (17.57)	508.69	<.00001	1.55
SEr	94.88 (5.12)	78.04 (14.59)	445.98	<.00001	1.54
SEa	98.27 (2.23)	87.21 (15.06)	212.49	<.00001	1.03
Restorative quality of sleep	3.33 (0.74)	2.74 (0.91)	123.53	<.00001	0.71

Data are reported as means and standard deviations. Statistics and Cohen  $d$  values are also shown. TIB = time in bed (in minutes); SOL = sleep onset latency (in minutes); NWAK = number of awakenings; WASO = wake after sleep onset (in minutes); TWAK = the time (in minutes) between sleep end and get up time; TSTc = total sleep time calculated (in minutes); TSTr = total sleep time referred (in minutes); SE = sleep efficiency in percentage (SEc based on TSTc; SEr based on TSTr; SEa considering TWAK); restorative quality of sleep = subjective evaluation about restorative quality of sleep, Likert scale ranging from 0 (no restorative) to 5 (very restorative).

**TABLE 3.** Accuracy of Diary-Based Sleep Items as Related to Insomnia Status

	Cutoff Value	Area Under the ROC Curve	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
TIB	500	0.57	0.31	0.83	0.54	0.65
SOL	16	0.76	0.62	0.84	0.72	0.77
NWAK	1.2	0.76	0.66	0.74	0.62	0.77
WASO	20	0.81	0.61	0.92	0.82	0.79
TWAK	15	0.83	0.81	0.72	0.65	0.86
SEc	87.5%	0.92	0.80	0.90	0.83	0.88
SEr	87%	0.88	0.71	0.92	0.86	0.83
SEa	95%	0.84	0.63	0.92	0.84	0.80
TSTc	390	0.81	0.70	0.83	0.72	0.81
TSTr	390	0.80	0.63	0.86	0.75	0.78
Restorative quality of sleep	3.1	0.70	0.65	0.67	0.56	0.75

ROC = receiver operating characteristic; TIB = time in bed (in minutes); SOL = sleep onset latency (in minutes); NWAK = number of awakenings; WASO = wake after sleep onset (in minutes); TWAK = the time (in minutes) between sleep end and get up time; TSTc = total sleep time calculated (in minutes); TSTr = total sleep time referred (in minutes); SE = sleep efficiency in percentage (SEc based on TSTc; SEr based on TSTr; SEa considering TWAK); restorative quality of sleep = subjective evaluation about restorative quality of sleep, Likert scale ranging from 0 (no restorative) to 5 (very restorative).

For each sleep parameter, the following values are reported: the cutoff value, the value of the area under the ROC curve, the sensitivity, the specificity, the positive predictive value, and the negative predictive value.

primary insomnia from participants with normal sleep, using a large sample group. The results first allowed us to confirm that the sleep diary was a satisfactory tool for distinguishing patients with primary insomnia from normal sleepers.

On the one hand, cutoff values identified in our study agreed overall with those recently suggested: 16 minutes for SOL versus 17.7 minutes proposed by Levenson et al.,<sup>15</sup> 20 minutes for WASO versus 20.7 minutes proposed by Levenson et al.,<sup>15</sup> and 20 minutes proposed by Lineberger et al.<sup>14</sup> Starting from these shared results, it seemed possible that these quantitative cutoff criteria could be used in clinical and primary care settings.

On the other hand, our results showed that not only SOL and WASO but also other parameters such as SE, TWAK, and NWAK could discriminate between groups. These results show the wide range of information that can be obtained from a sleep diary.

It is worth noting the use of both TSTc and TSTr. The CSD considers only TSTc, that is, the TST indirectly calculated by participant's answers.<sup>8-12</sup> Results confirmed that the TSTc performed better than TSTr.

In connection with the previous point, SEc was a more accurate parameter than SEr. Moreover, the measure of SEc performed better than SEa in differentiating the two groups. Therefore, we suggest using only SEc in future. This kind of measure offers another relevant advantage because it is calculated in the same way as usually the SE measured by the actigraph, giving more sense to a possible comparison between the two kinds of sleep assessment.

This way of measuring SE provides another important advantage in that it is easier to compare results with the SE usually obtained from the actigraph, seeing as they are calculated in the same way.

Interestingly, Item 8 (which asked for a subjective evaluation regarding the restorative quality of the participant's sleep) was not a reliable parameter for assessing insomnia. This result confirms the well-known difficulty of insomnia patients in evaluating their own sleep and provides some doubts about the usefulness of such an item.

Despite the large sample size studied, this work has some methodological limitations. First, we acknowledged that insomnia was only diagnosed by interview; polysomnography, which is the gold standard in evaluating sleep disorders, was not systematically performed to include the patients. However, participants were carefully interviewed by sleep specialists and specific exclusion criteria were adopted. Second, although the age range was similar between the two samples, the control group was significantly younger. We attempted to control this difference by introducing age as covariate in the analyses. However, this aspect should also be studied in depth in future studies. Third, insomnia data were derived from two different clinical centers; however, the definition of insomnia used was the same, based on ICSD-2 criteria. Moreover, the use of data from different countries should also be considered as a potential strength of the study. Finally, this study was only conducted on primary insomnia. It would certainly have been useful to have sleep diaries data of other and less frequently considered kinds of comorbid insomnia. We think that it would

be important in the future to replicate the same kind of study in large groups of participants with other specific sleep disorders.

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