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Validation of the Insomnia Severity Index as an outcome measure for insomnia research

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Abstract

Background: Insomnia is a prevalent health complaint that is often difficult to evaluate reliably. There is an important need for brief and valid assessment tools to assist practitioners in the clinical evaluation of insomnia complaints.

Objective: This paper reports on the clinical validation of the Insomnia Severity Index (ISI) as a brief screening measure of insomnia and as an outcome measure in treatment research. The psychometric properties (internal consistency, concurrent validity, factor structure) of the ISI were evaluated in two samples of insomnia patients.

Methods: The first study examined the internal consistency and concurrent validity of the ISI in 145 patients evaluated for insomnia at a sleep disorders clinic. Data from the ISI were compared to those of a sleep diary measure. In the second study, the concurrent validity of the ISI was evaluated in a sample of 78 older patients who participated in a randomized-controlled trial of behavioral and pharmacological therapies for insomnia. Change scores on the ISI over time were compared with those obtained from sleep diaries and polysomnography. Comparisons were also made between ISI scores obtained from patients, significant others, and clinicians.

Results: The results of Study 1 showed that the ISI has adequate internal consistency and is a reliable self-report measure to evaluate perceived sleep difficulties. The results from Study 2 also indicated that the ISI is a valid and sensitive measure to detect changes in perceived sleep difficulties with treatment. In addition, there is a close convergence between scores obtained from the ISI patient's version and those from the clinician's and significant other's versions.

Conclusions: The present findings indicate that the ISI is a reliable and valid instrument to quantify perceived insomnia severity. The ISI is likely to be a clinically useful tool as a screening device or as an outcome measure in insomnia treatment research.

Keywords: Insomnia; Sleep; Assessment; Measure; Severity; Evaluation

1. Introduction

Insomnia is a frequent complaint brought to the physician's attention. Its prevalence in the general population ranges from 9% for persistent sleep disturbances to 27% for occasional insomnia [1,2]. Valid instruments are needed to assist health care practitioners in the assessment of insomnia complaints. Although polysomnography is the 'gold standard' for assessing sleep disorders such as sleep apnea, it is not recommended for routine use in the clinical assessment of insomnia [3]. Furthermore, it is not readily available to most clinicians. Structured and semi-structured clinical interviews [4,5] are excellent methods to obtain systematic information on the

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nature, history, and severity of sleep difficulties. Although they are essential for a thorough examination of insomnia, clinical interviews are time-consuming and may not be practical for routine clinical use. In addition, clinical interviews require excellent knowledge about sleep disorders, which is not always the case for all general health-care practitioners.

Brief and efficient clinical instruments are needed for assessing the severity of insomnia. Although numerous self-report measures have been developed for the evaluation of insomnia [6], very few have been validated specifically as screening or outcome measure for insomnia. The Pittsburgh Sleep Quality Index (PSQI) [7] is a reliable and valid instrument assessing sleep quality and disturbances over a 1-month time interval; although it discriminates well poor from good sleepers, and is an excellent general screening measure of sleep disturbances, this instrument was not specifically designed for the assessment of insomnia. Completion of a daily sleep diary has become a standard assessment procedure in insomnia treatment research; it is a very practical and cost-effective method for assessing insomnia when repeated measurements are needed [8]. Daily morning estimates of sleep parameters yield a reliable and valid index of insomnia even though they do not reflect absolute values obtained from polysomnography [9,10]. Although quite useful and easy to administer, neither of those instruments (PSQI and sleep diary) completely capture the diagnostic criteria for insomnia outlined in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) [11] or in the International Classification of Sleep Disorders (ICSD) [12]. Although these measures provide subjective estimates of sleep disturbances, they do not target the degree of impairment and emotional distress associated with insomnia.

The Insomnia Severity Index (ISI) (Fig. 1) [4], is a brief self-report instrument measuring the patient's perception of his or her insomnia (see description in the Section 2.1). The ISI targets the subjective symptoms and consequences of insomnia as well as the degree of concerns or distress caused by those difficulties. Its content corresponds in part to the diagnostic criteria of insomnia [11]. The ISI comprises seven items assessing the severity of sleep-onset and sleep maintenance difficulties (both nocturnal and early morning awakenings), satisfaction with current sleep pattern, interference with daily functioning, noticeability of impairment attributed to the sleep problem, and degree of distress or concern caused by the sleep problem. Each item is rated on a 0–4 scale and the total score ranges from 0 to 28. A higher score suggests more severe insomnia. The ISI takes less than 5 min to complete and can be scored in less than 1 min. Two parallel versions are available for completion by a clinician and by a significant other (usually a spouse).

Although the ISI has been used in our clinical research program for 15 years, there has been no systematic evaluation of its psychometric properties. Preliminary studies have shown that its concurrent validity with daily sleep diaries is adequate [13] and that it is also sensitive to detect changes related to insomnia treatment [14,15]. However, there have been no formal psychometric analyses of the reliability and validity of the ISI. The purpose of the present study was to document the psychometric properties of the ISI. In Study 1, the internal consistency and concurrent validity (with sleep diaries) were examined in a sample of patients evaluated at a sleep disorders centre. In Study 2, the concurrent and content validity were examined by comparing changes over time (with treatment) on the ISI measure with those obtained on daily sleep diaries and polysomongraphy, as well as with those obtained on a clinician's version of the ISI. A factor analysis was also conducted to examine the content validity of the ISI.

2. Study 1

2.1. Method

2.1.1. Participants

Data for Study 1 were compiled from an initial interview administered to 145 clinical patients presenting to a sleep disorder centre with a chief complaint of insomnia. The participants were 84 women and 61 men with a mean age of 41.4 years (SD = 13.1, range 17–82) and a mean education level of 14.7 years (SD = 3.3). They were community residents, and were predominantly single (44%) and employed (67%). Mean average insomnia duration was 10.0 years (SD = 11.6) with a mean age of insomnia onset of 31.5 years (SD = 15.9). The distribution

Name: _____ **Date:** _____

1. Please rate the current (i.e., last 2 weeks) **SEVERITY** of your insomnia problem(s).

	None	Mild	Moderate	Severe	Very
Difficulty falling asleep:	0	1	2	3	4
Difficulty staying asleep:	0	1	2	3	4
Problem waking up too early:	0	1	2	3	4

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

Very Satisfied				Very Dissatisfied
0	1	2	3	4

3. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.).

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

4. How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all Noticeable	Barely	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

5. How **WORRIED**/distressed are you about your current sleep problem?

Not at all	A Little	Somewhat	Much	Very Much
0	1	2	3	4

Guidelines for Scoring/Interpretation:

Add scores for all seven items (1a+1b+1c+ 2+3+4+5) = _____
Total score ranges from 0-28

0-7 = No clinically significant insomnia
8-14 = Subthreshold insomnia
15-21 = Clinical insomnia (moderate severity)
22-28 = Clinical insomnia (severe)

Fig. 1. Insomnia Severity Index (Copyright, Charles M. Morin, 1993).

of the different types of insomnia were as follows: onset (18.4%), maintenance (21.6%), mixed (58.4%), and other (1.6%). Information about insomnia diagnoses was available for 124 patients, including psychophysiological ($n = 45$), psychiatric ($n = 36$), idiopathic ($n = 8$), alcohol/substance abuse ($n = 6$), pain conditions ($n = 12$), and others ($n = 17$).

2.1.2. Measures

The Insomnia Severity Index (ISI), [4] see Fig. 1 is composed of seven items that evaluate: (a) the severity of sleep-onset (initial), (b) sleep maintenance (middle), (c) early morning awakening (terminal) problems, (d) satisfaction with current sleep pattern, (e) interference with daily functioning, (f) noticeability of impairment attributed to the sleep problem, and (g) level of distress caused by the sleep problem. Each of these items is rated on a five-point Likert scale ('0' = not at all, '4' = extremely) and the time interval is 'in the last 2 weeks'. Total scores range from 0 to 28, with high scores indicating greater insomnia severity. The ISI is available in three different versions: patient (self-administered), significant other (usually a spouse) and clinician. Preliminary findings (unpublished observations, Morin & Azrin, 1985) indicate that the ISI has adequate concurrent validity when compared to sleep diary data ($r = 0.65$).

The sleep diary [4] provides daily subjective estimates of sleep parameters including: daytime nap, sleep aids intake, bedtime, sleep onset latency, frequency of nocturnal awakenings, awakenings duration, wake-up time, arising time, feeling upon arising (five-point scale) and sleep quality (five-point scale). Measures derived from the sleep diary were sleep onset latency (SOL), defined as the time from initial lights-out to sleep-onset; wake after sleep onset (WASO), referred to as the amount of time awake from the initial sleep onset to the last awakening; early morning awakening (EMA), the time awake from the last awakening until actual rising time; time in bed (TIB), the total time elapsed from initial lights-out to final arising time; and total sleep time (TST). The variables upon which validation was assessed were SOL, WASO, EMA and sleep efficiency (ratio of TST to TIB multiplied by 100%). These data were based on a baseline monitoring period of 1–2 weeks.

2.1.3. Procedure

As part of a standard evaluation for insomnia, all participants were administered a clinical interview and were required to complete a daily sleep diary (during 1–2 weeks) and several sleep questionnaires, including the Insomnia Severity Index (ISI). Insomnia was the main presenting complaint for all participants. Thus, participants with primary insomnia or insomnia secondary to medical, psychiatric, or other sleep disorders were included as long as they completed the assessment instruments during evaluation. There were no exclusion criteria besides not complaining of insomnia.

2.2. Results

Means and standard deviations (in parentheses) for the Insomnia Severity Index and sleep diary measures are reported in Table 1. The ISI average total score was 19.7 (SD = 4.1). The average sleep efficiency, as computed from the sleep diary, was 67.7% (SD = 14.55). The internal consistency of the ISI was estimated with a Cronbach alpha coefficient and by the item-total correlations. Concurrent validity was estimated by correlating (a) severity ratings for the different subtypes of insomnia (initial, middle, terminal) obtained from the ISI with corresponding quantitative estimates of SOL, WASO and EMA obtained from the sleep diary, and (b) the total ISI score with the sleep efficiency variable of the sleep diary. The sleep efficiency variable was selected for comparison with the total ISI score because it is probably the best composite measure of overall sleep disturbances.

The internal consistency, (i.e. degree of consistency or homogeneity of the items within a scale) of the ISI was 0.74. The item-total correlations varied from a low of 0.36 (initial) to a high of 0.67 (interference) with an average of 0.54 (see Table 1). The correlation coefficients between the ISI individual items and the corresponding variables on the sleep diary were 0.38 (SOL), 0.35 (WASO) and 0.35 (EMA), while the correlation between the total ISI score and the sleep efficiency variable −0.19. All correlation coefficients were significant at the 0.01 level.

There was no significant difference on the total ISI

Table 1
Means (SD), item-total correlations, and reliability coefficients for the ISI and measures of concurrent validity between the ISI and the sleep diary[a]

ISI			Sleep diary			
Severity	Mean (SD)	Item-total *r*	SOL	WASO	EMA	SE
Initial	2.6 (1.3)	0.36*	$r = 0.38$*			
Middle	2.7 (1.1)	0.57*		$r = 0.35$*		
Terminal	2.1 (1.4)	0.52*			$r = 0.35$*	
Satisfaction	3.6 (0.8)	0.42*				
Interference	3.1 (0.9)	0.67*				
Noticeability	2.5 (1.2)	0.59*				
Distress	3.3 (0.8)	0.52*				
Total	19.7 (4.1)					$r = -0.19$*
			M (SD)			
			55.4 (45.8)	49.6 (47.3)	51.5 (58.7)	67.7 (14.6)

[a] *$P < 0.01$.

scores between the different insomnia subgroups: psychophysiological (19.5), psychiatric (21.0), idiopathic (19.7), alcohol/substance abuse (19.8), pain conditions (20.2), and others (19.5).

2.3. Summary

These preliminary results suggest that the Insomnia Severity Index is a reliable measure for the assessment of insomnia severity in a clinical population. Both the internal consistency and the item-total correlations are moderate in size. It is possible that a longer period of sleep diary monitoring for all participants might have increased the concurrent validity between this measure and the ISI. Nonetheless, the present findings suggest that the ISI is a reliable measure to quantify perceived insomnia severity.

3. Study 2

3.1. Method

3.1.1. Participants

In Study 2, data collection was part of a larger study comparing the efficacy of cognitive-behavior therapy and pharmacotherapy for late-life insomnia [14]. The participants were 78 insomnia patients with a mean age of 65 (SD = 6.7, range 55–84) and a mean education level of 14.4 years (SD = 2.4). They were predominantly women (64%), married (68%), and retired (47%). The average sleep efficiency was 68.4% (SD = 14.25). Mean average insomnia duration was 16.8 years (SD = 16.9) and mean age of insomnia onset of 48 years (SD = 16.9). The types of insomnia complaint were onset (11%), maintenance (27%), mixed (59%) and other (3%).

3.1.2. Measures

In addition to the instruments used in Study 1, a clinician's and a significant other's version of the ISI, as well as polysomnographic data, were used to validate the ISI. The main polysomnographic variables used for the present study were SOL, WASO, EMA and SE.

3.1.3. Procedure

After an initial screening interview, participants underwent a detailed evaluation including a clinical and sleep interview conducted by a board-certified sleep specialist, a physical examination, and a psychological screening evaluation. All participants met the DSM-III-R [15] and the International Classification of Sleep Disorders [12] criteria for primary insomnia. Exclusion criteria were the presence of major psychiatric disorders, (e.g. depression), a major medical disorder known to affect sleep, (e.g. diabetes), use of medications known to affect sleep, evidence of significant cognitive impairment, (e.g. dementia), and presence of another sleep disorder, (e.g. apnea, periodic limb movements). Polysomnographic evaluation

was conducted on 3 consecutive nights in the sleep laboratory before and after treatment.

Upon completion of the evaluation protocol, the final sample consisted of 78 participants. These individuals were randomly assigned to one of four conditions, including cognitive-behavior therapy, pharmacotherapy (temazepam), combined cognitive-behavior therapy and pharmacotherapy, and drug placebo (for more details about this study, see Morin et al. [14]. In addition to laboratory evaluations, all patients completed the ISI and a daily sleep diary for a 2-week period at baseline, post-treatment, and at 3-, 12- and 24-month follow-ups. A significant other's and a clinician's version of the ISI were also completed at pre and post-treatment. When completing the ISI, the clinician had access to diary data and information from the interview.

3.2. Results

Table 2 reports the means and standard deviations of the different variables of the ISI (patient's and clinician's versions), the sleep diary and polysomnography. The data from all four conditions were combined for those analyses. The ISI total score was significantly lower at post-treatment than at baseline on both the patient's (8.9 vs. 15.4) and clinician's versions (7.7 vs. 17.7). Those changes were paralleled by improvements on all sleep continuity and sleep efficiency variables obtained from the sleep diary and polysomnography. Those scores remained fairly stable from post-treatment through the 24-month follow-up evaluation.

3.2.1. Internal consistency

The internal consistency of the ISI was estimated with a Cronbach's coefficient alpha and with item-total correlation at the pre, post, and follow-up evaluations. Table 3 shows that item-total correlations ranged from 0.32 to 0.71, with a mean of 0.56 at pretreatment; 0.58–0.79, with a mean of 0.69 at

Table 2
Patients' and clinicians' means (SD) for the ISI, the sleep diary and polysomnography (PSG) at the different evaluation times[a]

Measures	Pre $n = 78$		Post $n = 71$		FU3 $n = 62$	FU12 $n = 59$	FU24 $n = 57$
	Patient, M (SD)	Clinician, M (SD)	Patient, M (SD)	Clinician, M (SD)	Patient, M (SD)	Patient, M (SD)	Patient, M (SD)
Insomnia severity index							
Initial	1.8 (1.3)	1.9 (1.4)	1.0 (1.0)	0.8 (1.0)	1.0 (1.1)	1.4 (1.2)	1.1 (1.1)
Middle	2.6 (0.9)	2.8 (1.2)	1.4 (0.9)	1.4 (1.2)	1.5 (1.1)	1.8 (1.0)	1.6 (1.2)
Terminal	2.0 (1.2)	1.9 (1.4)	1.4 (1.1)	0.7 (1.1)	1.4 (1.2)	1.9 (1.2)	1.4 (1.2)
Satisfaction	3.2 (1.0)	3.4 (0.9)	1.8 (1.1)	2.0 (1.4)	2.1 (1.1)	2.2 (1.1)	2.0 (1.3)
Interference	2.1 (1.0)	2.8 (1.1)	1.1 (0.9)	0.9 (1.2)	1.0 (0.9)	1.1 (0.9)	1.1 (1.0)
Noticeability	1.3 (1.0)	2.2 (1.2)	0.9 (0.9)	0.8 (1.1)	0.8 (0.8)	0.9 (0.8)	0.9 (0.9)
Distress	2.5 (1.1)	2.9 (0.8)	1.3 (1.2)	1.1 (1.3)	1.1 (1.1)	1.3 (1.3)	1.2 (1.2)
Total	15.4 (4.2)	17.7 (4.1)	8.9 (5.0)	7.7 (5.9)	8.9 (5.4)	10.6 (5.6)	9.2 (5.8)
Sleep diary							
Sleep-onset	44.6 (37.2)		25.6 (22.0)		26.6 (21.8)	30.9 (31.6)	25.8 (23.8)
Wake after sleep-onset	57.1 (42.8)		30.8 (22.9)		38.7 (30.6)	37.7 (28.6)	43.7 (38.6)
Early morning awakening	48.3 (44.8)		24.7 (25.0)		30.2 (36.0)	26.3 (33.4)	27.7 (30.7)
Sleep efficiency	68.4 (14.3)		81.7 (10.4)		78.8 (13.5)	78.7 (14.3)	78.6 (14.0)
Polysomnography							
Sleep-onset	21.3 (14.5)		16.2 (10.1)				
Wake after sleep-onset	68.1 (46.1)		41.1 (35.2)				
Early morning awakening	17.7 (22.1)		12.4 (13.2)				
Sleep efficiency	76.9 (10.7)		83.9 (8.8)				

[a] FU3, 3-month follow-up; FU12, 12-month follow-up, FU24, 24-month follow-up. Only the patient's ISI and sleep diary data are available at follow-ups. Sleep diary and polysomnographic measures are in min except for sleep efficiency which is expressed in percentage.

Table 3
Item-total correlations and reliability coefficients for the Insomnia Severity Index[a]

Items of the insomnia severity index	Pre *r*	Post *r*	FU3 *r*
Initial	0.32*	0.58*	0.62*
Middle	0.67*	0.76*	0.81*
Terminal	0.65*	0.64*	0.80*
Distress	0.71*	0.79*	0.90*
Interference	0.63*	0.71*	0.64*
Noticeability	0.53*	0.63*	0.46*
Satisfaction	0.38*	0.70*	0.82*
Reliability	0.76*	0.77*	0.78*

[a] FU3, 3-month follow-up. *$P < 0.01$.

post-treatment; and 0.46–0.90, with a mean of 0.72 at follow-up. The internal reliability coefficients remained very stable from 0.76 at baseline to 0.78 at follow-up.

3.2.2. Concurrent validity

The concurrent validity of the ISI, (i.e. extent to which a scale correlates to another scale at the same point in time) was assessed with Pearson's coefficients by correlating (a) severity ratings for the different types of insomnia (initial, middle, terminal) obtained from the ISI with the quantitative estimates of SOL, WASO and EMA obtained from the sleep diary and polysomnography, and (b) the total ISI score with the sleep efficiency variable obtained from the diary and polysomnography. These correlations were computed separately for the baseline and post-treatment periods. Similar correlations were also computed with corresponding items of the ISI clinician's version. Those data are summarized in Table 4.

The size of the correlations between ISI insomnia subtypes and the corresponding sleep diary variables ranged from 0.32 to 0.55 at baseline and from 0.50 to 0.91 at post-treatment (all *P*-values <0.05). Correlations for the same ISI variables with polysomnographic variables ranged from 0.07 to 0.45 at pretreatment, and from 0.23 to 0.45 at post-treatment. Only the correlation for SOL variable was significant at pretreatment, whereas all correlations, but one (EMA) were significant at post-treatment ($P < 0.05$). There was a stronger relationship between the ISI and both sleep diary and polysomnographic variables at post-treatment than at pretreatment assessment.

The correlations between the patient's and the clinician's versions of the ISI at the two assessment periods were all significant (*P*-values <0.01). Furthermore, the correlations between the patient's and the significant other's versions of the ISI were also significant at the two assessment periods (*P*-values <0.01). These results a significant correspondence between patient's insomnia severity ratings and collateral ratings from their significant others and from independent clinicians.

3.2.3. Sensitivity to changes

To estimate the ISI sensitivity to detect changes with treatment, correlations were computed between change scores (from baseline to post-treatment and from post-treatment to 3-month follow-up) for each dependent variable on the ISI and the corresponding variables on the sleep diary and polysomnography.

Table 4
Correlations between the patient's Insomnia Severity Index (ISI), the sleep diary, polysomnography, the clinician's and significant other's ISI at pre- and post-treatment[a]

Measures	Pre *r*	Post *r*
Sleep diary		
Sleep-onset	0.37*	0.66*
Wake after sleep-onset	0.55*	0.91*
Early morning awakening	0.32*	0.50*
Total score vs. sleep efficiency	−0.35*	−0.60*
Polysomnography		
Sleep onset	0.45*	0.39*
Wake after sleep onset	0.16	0.45*
Early morning awakening	0.07	0.23
Total score vs. sleep efficiency	−0.09	−0.35*
Clinician's ISI		
Initial	0.66**	0.64**
Middle	0.50**	0.55**
Terminal	0.58**	0.69**
Total score	0.57**	0.71**
Significant other's ISI		
Initial	0.44**	0.39**
Middle	0.34**	0.50**
Terminal	0.53**	0.49**
Total score	0.54**	0.47**

[a] *$P < 0.05$, **$P < 0.01$.

Total ISI scores were correlated with change scores on the sleep efficiency variable. The first three individual item of the ISI (severity of initial, middle, and terminal insomnia) were correlated with the corresponding variable (SOL, WASO, EMA) on the sleep diary and polysomnography. All correlations between the ISI and sleep diary measures were small but significant at both assessment periods (see Table 5). Correlations with polysomnographic measures at post-treatment were significant for the sleep-maintenance (WASO) and for the sleep efficiency/total ISI score variables.

3.2.4. Predictive validity

The predictive validity refers to the extent to which a scale can predict outcome in the future. A hierarchical (step-down) regression analysis was performed to assess which of the different measures from among the sleep diary, polysomnography, or the clinician version of the ISI would more accurately predict the patient's perception of his/her sleep difficulties. As shown in Table 6, the clinician's ratings predicted best the patient's ISI total score at baseline, relative to sleep diary and polysomnographic measures, whereas at post-treatment, both the clinician and the sleep diary data were reliable predictors of the patient's total ISI score.

3.2.5. Content validity

A principal component analysis, using varimax rotation, explored the ISI content validity, (i.e. relation of the items to the concept) and the extent to which its components corresponded to diagnostic criteria of insomnia. This analysis yielded three components that explained 72% of the total variance (see Table 7). A Kaiser measure of factorability (0.62) indicated that adding or deleting a component to the three-component solution would not change the total amount of explained variance. Thus, the factorial structure was easiest to interpret with three components. Component I included items related to interference with daily functioning, noticeability of impairment, and level of distress. This first component accounted for 26% of the total variance and was labeled 'Impact'. Component II was composed of the three items related to severity of sleep-onset, sleep maintenance and early morning awakening difficulties. This component accounted for 26% of the total variance and was labeled 'Severity'. Finally, three items had significant loading on Component III, including satisfaction with current sleep patterns, severity of initial insomnia, and level of distress. This component, labeled 'Satisfaction', accounted for 20% of the total variance.

Table 5
Correlations between change scores from the Insomnia Severity Index (ISI) with those on sleep diary and polysomnographic measures[a]

Variables	Pre–post r	Post-FU3 r
ISI and sleep diary		
Sleep-onset	0.27*	0.36*
Wake after sleep-onset	0.35*	0.35*
Early morning awakening	0.27*	0.34*
Total score vs. sleep efficiency	−0.37*	−0.30*
ISI and polysomnography		
Sleep-onset	0.20	
Wake after sleep onset	0.29*	
Early morning awakening	0.05	
Total score vs. sleep efficiency	−0.36**	

[a] Pre–post, change scores between pre- and post-treatment; post-FU3, change scores between post-treatment and 3-month follow-up. *$P < 0.05$. **$P < 0.01$.

3.3. Summary

The results regarding the ISI internal consistency and its concurrent validity with sleep diary measures replicate those from Study 1. The results also provide evidence that the ISI is sensitive to detect changes in the patient's perception of treatment outcome. In addition, there is an good degree of convergence between the patient and clinician's evaluation of insomnia severity. The relationships between change scores on the ISI and those on sleep diary and polysomnographic were modest but statistically significant. A component analysis yielded three factors, tentatively labeled impact, severity, and satisfaction. Despite some overlap among the items, these findings provide empirical support for the content validity of the ISI in that those components capture the main diagnostic criteria of insomnia [11,12].

4. Discussion

The Insomnia Severity Index is a brief instrument that was developed to assist in the clinical evaluation

Table 6
Summary of step-down regression analysis for variables predicting the patient's perception of the severity of insomnia at pre- and post-treatment ($n = 64$)[a]

Measures	Pre			Post		
	B	SE B	β	B	SE B	β
Clinician	0.56	0.11	0.52*	0.434	0.08	−0.52*
Sleep diary	−0.06	0.03	−0.19	−0.17	0.05	−0.34*
Polysomnography	−0.02	0.04	−0.06	−0.00	0.05	−0.09

[a] $R^2 = 0.37$ (*$P < 0.05$) at pretreatment; $R^2 = 0.61$ (*$P < 0.05$) at post-treatment.

of patients with insomnia complaints and to measure outcome in treatment research. The two studies reported in this paper provide initial empirical support regarding the psychometric properties of the scale in clinical samples of young and older adults. Specifically, the internal consistency of the ISI was adequate, its concurrent validity was documented by significant correlations with an equivalent clinician's version of the ISI and with sleep diary and polysomnographic measures. The content validity was also supported by a component analysis that yielded three components (impact, severity, satisfaction) which seemed to capture the diagnostic criteria of insomnia. Finally, the sensitivity of this scale for measuring treatment outcome was supported by its convergent changes over time observed with another subjective measure (sleep diary), with an objective laboratory measure (polysomnography), and with a clinician's parallel measure (ISI).

Although the correlations between the ISI and polysomnographic measures were fairly small, they were statistically significant, indicating adequate convergent validity. The strength of the relationship was greater for sleep-maintenance (WASO) than for sleep-onset measures. This result might be due to the fact that the sample in Study 2 was composed of older adults and that sleep-maintenance problems are much more prominent in this segment of the population [16]. Thus, it is possible that the variance was too small on the sleep-onset variable to yield significant correlations on this measure.

Table 7
Summary of the principal component analysis with varimax rotation at pre-treatment[a]

	I	II	III	Communalities
Initial		−0.48	0.64	0.68
Middle		0.80		0.76
Terminal		0.82		0.73
Satisfaction			0.77	0.72
Distress	0.52		0.53	0.66
Interference	0.75			0.63
Noticeability	0.87			0.82
Variance %	26	26	20	72

[a] Component I, impact component; component II, severity component and component III, satisfaction component.

The component analysis tended to support the content validity of the ISI; however, those findings must be interpreted cautiously because of the exploratory nature of this analysis and the small number of items on this scale. There was some overlap in the factor loading and it is possible that some refinement might be needed to enhance the factorial structure of this scale. For example, the addition of a few items assessing other insomnia complaints, (e.g. non-restorative sleep) or more specific subtypes of daytime impairments, (e.g. fatigue, attention and concentration problems) might improve the content validity of the ISI.

The degree of convergence between the ISI and other instruments increased over the assessment periods. Sleep difficulties were less severe over time and those improvements were reflected through lower ISI scores at post-treatment and at follow-up. This stronger convergence may indicate that patients have a better perception of time spent asleep and time spent awake with treatment, particularly following cognitive-behavior therapy.

The findings suggest that the ISI is a reliable and valid method to quantify perceived insomnia severity in samples of young and older patients and in primary and secondary insomniacs. In addition to presenting

adequate psychometric properties, the ISI is likely to be clinically useful for several reasons. It is brief and its format is easy to administer and to score and, most importantly, it provides relevant information for diagnosis and treatment planning. The information can be used to quantify insomnia severity and to provide cut-off score to determine the clinical significance of the subjective complaint. It is also useful to specify the nature (sleep onset vs. maintenance) of the sleep difficulties as well as the degree of interference and concern experienced by the patient. As such, it could be used to guide the clinician in deciding whether an insomnia complaint reaches clinical/diagnostic threshold. Finally, it can also be used to evaluate treatment outcome either in clinical practice or in research.

The ISI could be a particularly useful measure to examine the clinical significance of outcome with insomnia treatment. In a recent study [14], a cut-off score of 15 (the ISI items were rated on a scale of 1–5 rather than 0–4) was used to determine the proportion of patients who no longer met diagnostic criteria for insomnia. This cut-off score, which would be equivalent to a score of 10 on the current scale (0–4 ratings), was judged to reflect an insomnia complaint that was below clinical threshold, (i.e. minimal or no sleep difficulties, minimal impairment, and no or little distress). In the present study, the clinician's ISI version was used and the data obtained paralleled those obtained from the ISI patient's version as well as those obtained from daily sleep diary and polysomnographic measures. Additional research is needed to validate optimal cut-off scores to determine the clinical significance of treatment outcome.

Although the current study was based on fairly heterogeneous samples of clinical patients, it would be useful to replicate this study with patients presenting to primary care settings. It would also be interesting to compare clinician's ISI ratings obtained from general health-care practitioners with those from trained sleep clinicians. Additional research is needed to validate the ISI against a structured diagnostic interview for insomnia, which remains the 'gold-standard' for the evaluation and diagnosis of insomnia. Based on the present findings, the ISI could easily be incorporated to a structured clinical interview for insomnia in order to quantify insomnia severity and gauge its clinical significance. Finally, the ISI has four 'sleep-related' items and three 'wake-related' items. Given its brevity, one might consider adding a few more items to enhance its diagnostic specificity.

In conclusion, the Insomnia Severity Index appears to be a valuable clinical instrument for use as a screening tool with patients complaining of insomnia and as an outcome measure in treatment research. Additional studies are needed to further validate this instrument and to evaluate its diagnostic accuracy (sensitivity and specificity) as well as its ability to discriminate between poor and good sleepers and between primary insomnia (syndrome) and insomnia associated with medical or psychiatric disorders (symptom).

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