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Psychometric properties of Indonesian version of sleep condition indicator for screening poststroke insomnia

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PSYCHIATRICS • ORIGINAL ARTICLE



Psychometric properties of Indonesian version of sleep condition indicator for screening poststroke insomnia

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Abstract

Background No study has examined the psychometric properties of the sleep condition indicator (SCI) for screening poststroke insomnia in the Indonesian population. We aimed to develop the Indonesian version of the sleep condition indicator (ISCI) and to examine its psychometric properties for screening adult patients in late sub-acute and chronic periods after stroke.

Methods This was a cross-sectional study with two stages. In the first stage, the English version of the SCI was translated into the ISCI using standard procedures. The psychometric properties of the ISCI were tested in the second stage. Internal consistency and test-retest reliability of ISCI were used to evaluate reliability. A confirmatory factor analysis (CFA) was performed to test construct validity. To test concurrent and convergent validity, the Indonesian version of the insomnia severity **5** dex (ISI-INA), generalized anxiety disorder questionnaire (IGAD-7), and patient health questionnaire (IPHQ-9) were used. A receiver operating characteristic (ROC) analysis was conducted to calculate the optimal cutoff score of the ISCI on the basis of the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) diagnostic criteria for insomnia. **Results** A total of 160 adults with a diagnosis of stroke for more than 3 months were included (median age of 58.5 years, 31% met the DSM-5 criteria for insomnia). The ISCI had a satisfactory Cronbach's alpha of 0.89 and test–retest reliability of 0.78. The CFA revealed that the ISCI exhibited a satisfactory model fit and was associated with the ISI-INA, IGAD-7, and IPHQ-9 (r = -0.81, -0.32, and -0.52, respectively; all P < .001). The ROC test revealed that the optimal cutoff point of ≤ 23 yielded the highest sensitivity (94%) and specificity (97%).

Conclusion The study results revealed that the 8-item ISCI is a reliable and valid screening tool for detecting insomnia symptoms according to the DSM-5 criteria in the chronic period after stroke.

Keywords Poststroke insomnia · SCI · Sleep condition indicator · Psychometric testing · Stroke · Insomnia

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Introduction

Insomnia is a highly prevalent complaint reported by patients with stroke; its prevalence ranges between 35% and 43% depending on the stroke phase [1, 2]. Insomnia is defined by having difficulties initiating or maintaining sleep, or waking up too early for at least 3 days a week, and experiencing such symptoms for 3 months or longer [3]. Poststroke insomnia is associated with poor rehabilitation outcomes [4], impaired cognitive function [5], and reduced health-related quality of life [6]. Impaired psychological health (e.g., depression and anxiety) and functional status have been linked with the development of disrupted sleep after stroke [7–9].

Several insomnia screening tools are widely used in various research fields and clinical settings [10], such as the Athens Insomnia Scale [11], Pittsburg Sleep Quality Index (PSQI) [12], and Insomnia Severity Index (ISI) [13]. These screening tools have comparable sensitivity and specificity for detecting insomnia symptoms [14]. However, because the definition of insomnia has been updated over time, these insomnia screening tools may be not suitable for use in clinical settings because they have not incorporated the updated criteria.

The Sleep Condition Indicator (SCI), which was developed based on the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), is a self-administered screening tool for assessing insomnia symptoms [15]. The SCI comprises 8 items and is widely used in clinical settings [16, 17]. It exhibits excellent sensitivity and specificity by applying a cutoff point of ≤ 16 (95.4%) and 76.8%, respectively) [18]. Thus far, the SCI has been translated into various languages for various populations, for example, the Italian version for outpatient populations at sleep centers [19], the French version for communitydwelling adults and patients with Parkinson's disease [20, 21], the Hong Kong version for university students [22], and the Swedish version for undergraduate student populations [23], all of which exhibit satisfactory validity and reliability. However, no study has examined the properties of the SCI in the context of the Indonesian population. Furthermore, even though satisfactory psychometric results were obtained for various populations, its cultural equivalence for patients with stroke has not yet been tested.

To facilitate the early detection of poststroke insomnia and the implementation of appropriate interventions in clinical settings, adopting a useful and accurate screening tool is a clinical necessity. The present study aimed to develop the Indonesian version of the SCI (ISCI) for patients in the late subacute and chronic periods after stroke and to evaluate its psychometric properties.

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Methods

Study design

This was a cross-sectional study with two stages: translation procedure and psychometric testing. The study was approved by the Taipei Medical University Jointed Institutional Review Board (N202106016) and Medical and Health Research Ethic Committee Dr. Sardjito General Hospital (KE/FK/0810/EC/2021). The study was performed in accordance with the principles of the Declaration of Helsinki.

Stage 1: Translation of SCI content into the Indonesian language

Before the SCI was translated, we informed its original developer (Prof. Espie) and obtained his permission to do so. The forward–backward translation method was applied to translate the SCI from English to Indonesian [24].

First, the English version of the SCI was translated into Indonesian by two independent Indonesian bilingual experts. The two Indonesian versions were compared, and discussions among the co-authors were held until a consensus was reached. Two health professionals who were fluent in both Indonesian and English independently back-translated the 2 donesian version into English with cultural adaptations. The translated and back-translated versions were examined and compared by an expert panel. Expert validation was conducted to evaluate each item with regard to its explicit construct definition and to examine its semantic, idiomatic, experiential, and conceptual equivalence. A consensus was reached through panel discussions to establish the final version of the ISCI. All individuals who used the final ISCI did not encounter difficulties completing it. The supplementary Table 1 presents the version of ISCI.

Stage 2: Psychometric properties testing

Participants and study settings Participants were recruited from stroke rehabilitation outpatient clinics in Indonesia from July 2021 until March 2022. Outpatients were included if they (1) were 18 years or older, (2) were diagnosed with stroke for more than 3 months, (3) were speaking the Indonesian language, (4) and had sufficient cognitive function to complete the tasks required for the present study (Montreal Cognitive Assessment [MoCA] score \geq 27). Outpatients who were performing shift work, were diagnosed with psychiatric and sleep disorders (e.g., sleep apnea), were pregnant or breast feeding, were engaged in drug or alcohol abuse, or were in a severe or unstable medical condition prior to the study were excluded. Eligible outpatients with stroke were

Sleep and Breathing

recruited on the basis of the calculated sample size (i.e., subject-to-item ratio of 20:1) [22, 25].

Measurements

An information sheet was used to collect demographic data, including age, gender, body mass index, education level, marital status, monthly family income, stroke severity, stroke type, and comorbidities. The Charlson Comorbidity Index (CCI) was used to assess comorbidities, which are various health conditions associated with mortality. The absence and presence of a comorbid disease was coded as 0 and 1, respectively [26]. In addition, we included three open questions related to sleep: "Do you have a sleeping problem?" "When you experience poor sleep, do you go visit a physician for a check-up?" and "Do you use sleeping pills?".

The 8-item SCI was developed in accordance with the DSM-5 criteria for clinically assessing and screening for the presence of insomnia over the preceding month. Two domains of the SCI are as follows: sleep pattern (5 items) and sleep-related impact (three items). Each item is scored from 0 to 4. The total score of the SCI is between 0 and 32, with a higher score indicating superior sleep quality. The cutoff score of ≤ 16 is used to screen for the risk of insomnia in the general population. The original version achieved satisfactory reliability ($\alpha \geq 0.86$) and favorable validity against the PSQI (r = -0.734) [15].

The ISI was developed in accordance with the DSM-4 criteria [13]. The 7-item self-reported questionnaire is used to evaluate individuals who experience sleeping difficulties within the preceding month. Each item is evaluated from 0 to 4 (0 = no problem is reported, 4 = a severe problem is reported), with a higher score indicating a more severe condition. The total score of the ISI ranges from 0 and 28, and the cutoff score of ≥ 8 indicates the presence of insomnia, which is the standard applied in the original version [27]. A study reported that the Indonesian version of the ISI (ISI-INA) exhibited favorable reliability and validity [28].

The Patient Health Questionnaire-9 (PHQ-9) is used to measure depression in the preceding 2 weeks [29–31]. Each item is scored from 0 to 3; the total score of the questionnaire ranges from 0 to 27, and a higher score indicates a poorer condition. The cutoff point of ≥ 10 indicates the presence of depression [32]. The Indonesian version of the PHQ-9 (IPHQ-9) exhibited favorable reliability and validity [33].

The Generalized Anxiety Disorder 7-item (GAD-7) is a self-reported questionnaire for measuring anxiety [34, 35]. Each question of the GAD-7 is scored from 0 to 3, and its total score is from 0 to 21. The cutoff score of ≥ 8 indicates the presence of anxiety. A study reported that the Indonesian version of the GAD-7 (IGAD-7) exhibited satisfactory reliability and validity [33].

Study process

After the participants provided written informed consent, a trained research assistant who was unaware of the findings of the DSM-5 diagnosis of insomnia required participants to complete the battery of the aforementioned questionnaires. The participants were then examined by a board-certified neurologist with sleep expertise who was not aware of the results of the questionnaire. The participant's sociodemographic, medical history, psychiatric medication usage, and insomnia were all evaluated during this face-to-face clinical interview. Current cases of insomnia, mood, and anxiety disorders were diagnosed using DSM-5 criteria. To evaluate the test–retest reliability of the ISCI, 50 patients with stroke were randomly selected from the study population and asked to again complete the ISCI after an interval of 7 days.

Data analyses

All data were analyzed using SPSS version 23 (IBM, Armonk, NY, USA) and R version 3.6.1 [36]. Data were checked for normality, the presence of outliers, and missing values. Continuous data are presented as means and standard deviations, and categorical data are presented as numbers and percentages. The Mann–Whitney U test and a chi-square analysis were performed to compare the demographic and disease characteristics of the groups with and without insomnia. A two-tailed α significance level of P < .052 yas regarded as statistically significant.

The internal consistency of each item and the overall scale of the ISCI was assessed using Cronbach's α . Cronbach's α between 0.7 and 0.9 was regarded as acceptable, and a value between 0.9 and 0.95 was regarded as desirable [37]. The test–retest reliability of the scale was evaluated within an interval of 7 days in 50 randomly selected participants by using intraclass correlation coefficients (ICCs) calculated through a two-way mixed model [38]. An ICC of 0.4–0.75 indicates fair-to-good reliability, and an ICC of >0.75 indicates satisfactory reliability [39].

The *lavaan* package in R was used to perform a confirmatory factor analysis (CFA), and the *semPlot* package was used to draw a CFA plot [40]. The CFA was conducted to examine the factor structures of the ISCI through the application of a two-factor model of insomnia symptoms, which reflects the sleep pattern and sleep-related impact dimensions of insomnia disorder in accordance with the DSM-5 standards and original version of SCI [15]. The model's fit was evaluated using the goodness-of-fit index (GFI) [41] and the χ^2 value/degree of freedom (CMIN/DF); a GFI value of >0.8 and a CMIN/DF value between 1 and 3 indicates an acceptable fit [42]. A Tucker–Lewis index (TLI) value of \geq 0.90, a root mean square error of approximation (RMSEA) value between 0.05 and 0.08 [42], and a standardized root

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mean square residual (SRMR) value of <0.09 indicate a favorable model fit [43, 44].

Concurrent validity of ISCI and ISI-INA scores was evaluated using Spearman's correlation. To establish convergent validity, a Spearman's correlation analysis was conducted to compare ISCI scores with IPHQ5 and IGAD-7 scores.

To test sensitivity and specificity, a receiver operating characteristic (ROC) analysis was performed to determine the optimal cutoff score of the ISCI in accordance with the DSM-5 diagnostic criteria for insomnia. The area under the receiver operating characteristic curve (AUC) of the ISCI was calculated to distinguish participants with insomnia from those without insomnia. A higher AUC value indicates a more accurate prediction, and a value of ≥ 0.8 indicates favorable discr 7 ination [45]. Finally, to determine the optimal cutoff point, Youden's index (J = sensitivity + specificity - 1) was adopted [46].

Results

Participant characteristics

A total of 160 participants (93 men) with stroke were included (Supplementary Figure 1). Median age was 58.5 years (range from 25 to 92). The mean time to stroke was 6.2 months, and most participants were diagnosed with ischemic stroke (87%). Among them, 31% (n = 49) were diagnosed with insomnia in accordance with the DSM-5 criteria. The participants with both stroke and insomnia were predominantly female and obtained higher scores on the ISI-INA, IGAD-7, and IPHQ-9 relative to those with stroke but without insomnia (all differences were significant with P <.05). Among the participants with stroke who were diagnosed with insomnia (n = 49), 86% of them self-reported experiencing sleeping problems, 27% visited a physician when they experienced poor sleep, and 25% used sleeping pills. Table 1 presents information on the participants' characteristics.

Psychometric properties of ISCI

Internal consistency and test-retest reliability

Supplementary Table 2 indicates that the ISI-INA had a high Cronbach's α value (0.89) for its total score; for each item of the ISI-ING, Cronbach's α ranged from 0.86 to 0.89, indicating favorable internal consistency. For test–retest reliability, the ICC analysis of the two-time ISCI total scores yielded a value of 0.78 (95% confidence interval: 0.65 to 0.87), suggesting that the first and second total scores were significantly associated, and that the ISCI exhibited favorable temporal stability over time.

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Testing of construct validity using CFA

The results of the CFA of the ISCI suggested a two-factor structure, reflecting the sleep pattern domain (items 1, 2, 3, 4, and 8) and daytime impact domain (items 5, 6, and 7) for the symptoms of insomnia. The standardized factor loading of the ISCI is illustrated in Fig. 1. The $\chi 2$ value of the ISCI was 47.39 with 19 degrees of freedom (CMIN/DF = 2.50); the GFI of the ISCI was 0.93, indicating the acceptable fit of the model. A TLI value of 0.95, RMSEA of 0.02, and SRMR of 0.05 indicated a satisfactory model fit.

Concurrent and convergent validity

The ISCI was highly and negatively associated with the ISI-INA (r = -0.81, P < .001). In addition, the ISCI was significantly associated with the IGAD-7 (anxiety; r = -0.32, P < .001), and IPHQ-9 (depression; r = -0.52, P < .001).

ROC analyses

The results of ROC analyses are presented in Fig. 2. The total score of the ISCI had the highest predictive value for insomnia (94% sensitivity and 97% specificity) when the optimal cutoff point of \leq 23 was applied. On the basis of a DSM-5 diagnosis, the AUC of the ISCI was 0.98 (Table 2).

Discussion

This is the first study to validate the SCI among patients with a diagnosis of stroke for more than 3 months. Our findings suggest that the ISCI exhibited high internal consistency and test-retest reliability when it was applied to a stroke population. In addition, our study is the first to reveal the factor structure of the ISCI on the basis of the CFA, and we discovered that the two-factor ISCI yielded a satisfactory goodness-of-fit. Crucially, we identified the optimal cutoff point of \leq 23 for the ISCI, which yielded the best-fit sensitivity and specificity with the highest diagnostic accuracy for detecting insomnia in accordance with the DSM-5 criteria. Because the present study used a sufficient sample size and applied robust methodology, our findings have a high level of credibility.

In contrast to the original development of the SCI [15] and other validation studies that have conducted exploratory factor analysis (EFA) to detect the structure of the SCI [19–23], we verified that the ISCI exhibits a two-factor structure (i.e., sleep pattern and sleep-related impact) by performing CFA on the basis of theoretical variables and the underlying latent construct relationship [15]. CFA is a research tool used to reduce the overall number of observed variables into latent factors on the basis of data similarity [47]. In contrast to EFA, CFA reduces measurement error and enables the comparison of alternatively

Sleep and Breathing

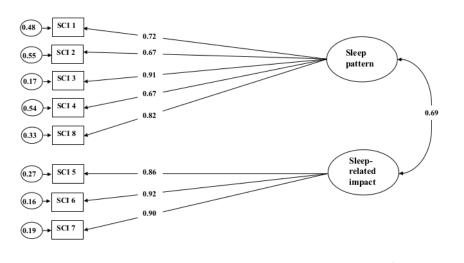
 Table 1 Demographic and disease characteristics of the included participants

Variables	Total (<i>n</i> = 160)		Insomnia (n= 49)		Non-insomnia (n= 111)		p-value
	Mean	(SD)	Mean	(SD)	Mean	(SD)	
Age, median (range)	58.5	(25-92)	58	(25-81)	59	(25-92)	0.39
BMI	24.2	(4.1)	25.3	(4.2)	23.8	(4.0)	0.08
Male, n (%)	93	(58)	22	(45)	71	(64)	0.02
Education level above college, n (%)	76	(48)	19	(39)	57	(51)	< 0.01
Married, n (%)	138	(86)	41	(84)	97	(87)	0.71
Monthly income > 348 (USD), n (%)	37	(23)	10	(20)	27	(24)	0.86
Time to stroke, mean month (SD)	6.2	(4.0)	6.4	(4.5)	6.1	(3.7)	0.95
Stroke Type- n (%)							0.43
Ischemic	139	(87)	41	(84)	98	(86)	
Hemorrhagic	21	(13)	8	(16)	13	(12)	
MoCA	27.7	(0.9)	27.5	(0.7)	27.8	(0.9)	0.10
NHISS Score in outpatient clinics	2.4	(2.2)	2.7	(2.2)	2.3	(2.2)	0.17
CCI	4.86	(2.55)	5.71	(3.14)	4.48	(2.15)	0.03
ISCI	25.14	(7.46)	15.16	(5.37)	29.55	(1.96)	< 0.001
ISI-INA	4.82	(5.45)	11.73	(4.78)	1.77	(1.51)	< 0.001
IGAD-7	3.51	(4.87)	5.78	(5.8)	2.5	(4.03)	$<\!0.001$
IPHQ-9	4.07	(4.53)	7.71	(5.48)	2.46	(2.82)	< 0.001
Do you have a sleeping problem, n (%)							< 0.001*
Yes	46	(29)	42	(86)	4	(4)	
No	114	(71)	7	(14)	107	(96)	
If you experience poor sleep, do you go to doctors for a check-up, n (%)							<0.001*
Yes	15	(9)	13	(27)	2	(2)	
No	145	(91)	36	(74)	109	(98)	
Do you use sleeping pills, n (%)							< 0.001*
Yes	14	(9)	12	(25)	2	(2)	
No	146	(91)	37	(76)	109	(98)	

CCI Charlson Comorbidity Index; *n* number of participants; *SD* standard deviation; *BMI* body mass index; *MoCA* Montreal cognitive assessment; *USD* United State dollar; *ISCI* Indonesian version sleep condition indicator; *ISI-INA* Indonesian version insomnia severity index; *IGAD-7* Indonesian version general anxiety disorder-7; *IPHQ-9* Indonesian version patient health questionnaire-9

The continuous data were analyzed using Mann-Whitney U Test and categorical data were analyzed using Chi-Square Test or *Fisher's Exact Test

Fig. 1 Two-Factor Model of Confirmatory Factor Analysis of the Indonesian version of the Sleep Condition Indicator among patients diagnosed with a stroke for more than 3 months. Goodness-of-fit indices: the comparative fit index was 0.97, goodness-of-fit indice was 0.93, and Tucker–Lewis index value was ≥0.95, indicating favorable model fit



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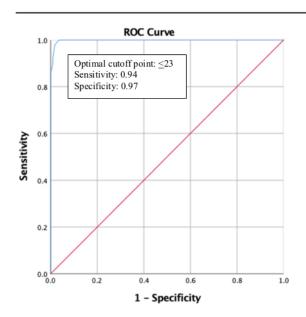


Fig. 2 Receiver operating characteristics curves for detecting Insomnia condition using the Indonesian version of Sleep Condition Indicator based on the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM- 5)

 Table 14
 The optimal cutoff value, sensitivity, specificity, area under curve of Indonesian version of sleep condition indicator for detecting insomnia according to the DSM-5

Cutoff value	Sensitivity (%)	Specificity (%)	AUC (95% CI)
22	0.91	0.97	0.98 (0.94 to 1.00)
23	0.94	0.97	
24	0.94	0.97	
25	0.95	0.94	

DSM-5 diagnostic and statistical manual c^{5} mental disorders, 5^{th} edition; The optimal cutoff value determined based on Youden's index (J = sensitivity + specificity—1) is in bold

proposed a priori models at the latent factor level [48]. The application of CFA to investigate the construct validity of hypothesis-based testing instruments increases statistical precision [47, 49]. Sample size is a critical consideration when conducting a CFA. After considering power value and errors based on Wolf et al. study, a two-factor model involving 3 to 6 indicators per factor with factor loading between 0.65 to 0.80 requires reasonable sample sizes of 130 for conducting a CFA [50]. The current SCI validation study including 160 stroke survivors yielded a two-factor structure with factor loading from 0.67 to 0.92. Taken together, our sample size might be sufficient to produce the reasonable findings of CFA. In general, the construct validity of the ISCI is established through a CFA model, which increases our knowledge of the application of the ISCI in patients with a diagnosis of stroke for more than 3 months.

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Our study examined cutoff scores ranging from ≤ 16 to ≤ 25 to identify the optimal point for distinguishing patients with insomnia from those without insomnia. Compared with other studies [15, 20, 21] that have applied the original model's cutoff point of ≤ 16 to obtain the highest level of predictive accuracy for screening insomnia, we discovered that the optimal cutoff point of the ISCI is ≤ 23 , which yielded the highest sensitivity (94%) and specificity (97%). Similarly, a recent validation of the Chinese version of the SCI in a university student population also yielded the cutoff point of ≤ 21 with 83% sensitivity and 80% specificity [22]. In this situation, the variations in cutoff points may be influenced by sample size variances and cultural differences [27, 51–53]. Therefore, further studies are required to test the reliability and validity of the SCI in various populations and racial groups.

Our findings revealed that the participants with both stroke and an insomnia diagnosis exhibited a substantially lower ISCI score compared with those with stroke but without an insomnia diagnosis (15.16 vs. 29.55), and that the ISCI exhibited satisfactory diagnostic accuracy (92% sensitivity and 99% specificity), suggesting that the ISCI is an alternative screening tool for detecting insomnia in stroke populations. Notably, 42 (86%) participants diagnosed with insomnia reported experiencing sleep problems, whereas the remaining 7 (14%) patients did not recognize their sleep problem, that is, approximately 15% of the participants with poststroke insomnia underestimated their insomnia problem. This may be due to a lack of sleep-related knowledge, which further suggests the necessity of giving sleep education and the clinical importance of early poststroke insomnia detection through a valid and reliable screening tool such as the ISCI instead of the single-item questionnaire.

In this study, the prevalence of poststroke insomnia in the 7 ronic phase (average time to stroke of 6.2 months) was 31% according to the DSM-5 diagnostic criteria, which is consistent with the findings of a recent meta-analysis (37%) of the chronic phase following stroke [1]. Previous studies have suggested that the prevalence of insomnia decreases from the acute phase to the chronic phase after stroke [1, 54], implying that poststroke insomnia resolves over time. After stroke, neuronal regeneration and functional recovery may help a patient to maintain sleep consistency [55], resulting in relief from insomnia. However, the prevalence of insomnia (diagnosed on the basis of standard references) after stroke in the chronic phase is still substantially higher than the prevalence of insomnia in the general population (31% vs. 5–7%) [56–58], highlighting the urgent need to identify patients with poststroke insomnia.

Limitation

2

The present study has several limitations. First, we only recruited patients with stroke in the chronic phase; therefore, our findings may not be generalizable to stroke populations in

Sleep and Breathing

the acute and subacute phases. Second, because the participants' NIHSS scores at emergency room admission could not be accessed, the effects of stroke severity on tool validation could not be measured; this could have affected the internal validity of our findings. The aforementioned data could not be obtained because all the participants were recruited from outpatient clinics for stroke rehabilitation, and most of them experienced their first stroke at other hospitals. Third, we could not assess other sleep disorders such as sleep disordered breathing which may be confounders in this population.

Conclusion

The findings of the study show that the ISCI is a reliable and valid screening tool for detecting insomnia symptoms in the poststroke period population according to the DSM-5 criteria. We also demonstrated that the two-factor ISCI exhibits satisfactory prediction accuracy when the cutoff score of ≤ 23 is applied to detect poststroke insomnia. Several challenges in clinical settings (e.g., lack of sleep specialists) contribute to the low rates of insomnia assessment, which may in turn lead to the underestimation of poststroke insomnia. This problem may be addressed by employing a quickly completed and accurate insomnia assessment tool that helps health-care providers to identify stroke survivors with poststroke insomnia. The 8-item ISCI is suitable for addressing clinical issues because it is straightforward to administer and can be completed in less than 5 min. We therefore recommend the incorporation of poststroke insomnia assessments such as the ISCI into daily routine care.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11325-023-02797-1.

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Author contribution Conceptualization: HYC and FH; methodology: HYC and FH; investigation: ANF, HYC and FH; software: FH and HYC; formal analysis: HYC and FH; data curation: HYC, FH, and LTY; validation: HYC, FH, and LTY; resources: HYC, FH, DSR, and OFDM; writing- original draft: HYC and FH; writing—review and editing: HYC, FH, ANF, PST, HSL, and DW; supervision: HYC, FH, ANF, PST, HSL, and DW; funding acquisition: HYC.

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Data availability The data was available on reasonable request.

Declarations

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the Taipei Medical University Jointed Institutional Review Board (N202106016) and Medical and Health Research Ethic Committee Dr. Sardjito General Hospital (KE/FK/0810/EC/2021).

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflicts of interest The authors declare no potential conflicts of interest regarding the authorship and publication of this article.

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