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Global perspectives on the Sleep Condition Indicator for DSM-5 insomnia disorder: a COSMIN and STARD systematic review of psychometric and diagnostic performance

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Abstract

Background A robust insomnia screening and measuring tool is essential for accurately assessing and diagnosing insomnia in research and clinical settings. The Sleep Condition Indicator (SCI) is an initial screening tool designed to assess insomnia complaints according to the DSM-5 criteria. This study aims to systematically evaluate item content, psychometric performance, diagnostic performance, and overall application of the SCI through a methodological quality assessment of original validation studies. These findings offer valuable information for optimizing insomnia diagnosis, assessment, and monitoring.

Methods A comprehensive search was conducted for finding studies published from 2012 to 2024, in PubMed, EMBASE, CINAHL, and MEDLINE electronic databases, and citation searching in PubMed, SCOPUS, Web of Science, and Google Scholar. Full-text articles focusing on the translation, validation, and application of the SCI were included. The psychometric studies were assessed regarding their measurement properties and methodological quality, using the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines. The diagnostic studies were assessed using the Standard for Reporting of Diagnostic Accuracy (STARD) guidelines. Finally, studies in which the SCI was used for assessment or screening purposes provided general information on the application of the scale.

Results We identified 285 studies with over 720,000 participants that used the SCI, and 13 language versions of the SCI were employed across at least 31 regions. The most commonly assessed measurement properties of the SCI within 19 studies were structural validity, internal consistency, criterion validity, and reliability, with findings supporting a stable two-factor structure and credible overall psychometric properties. The SCI demonstrated adequate sensitivity and specificity in 14 studies evaluating its diagnostic performance, and a cut-off value of 16 was recommended for screening insomnia. Finally, the studies showed that the SCI is widely used across clinical and non-clinical settings and provides valuable information for assessing insomnia risks.

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Conclusions The SCI includes items that align with the most current diagnostic criteria for insomnia disorder from the DSM-5. This tool demonstrates excellent psychometric performance and strong diagnostic performance. Overall, the SCI provides useful information for screening, diagnosing, and monitoring insomnia, making it a valuable tool in both research and clinical settings.

Highlights

- The DSM-5 criteria-based SCI can be used to screen for and diagnose insomnia.
- This systematic review was the first to examine the use of the SCI from a global perspective.
- The SCI is available in 13 languages and was evaluated in 285 studies in 31 regions.
- The SCI assessment adhered to rigorous the PRISMA-COSMIN and STARD guidelines.
- This review demonstrated strong psychometric and diagnostic performance of the SCI.

Keywords Sleep Condition Indicator, Insomnia, Screening tool, DSM-5, COSMIN, STARD

Background

Insomnia disorder (ID) is characterized by dissatisfaction with sleep quality or quantity associated with difficulty falling or staying asleep, and substantial distress or daytime impairments [1–4]. For ID diagnosis, these sleep disturbances must occur at least three times per week, persist for over 3 months, and cause daytime impairment [5]. The Prevalence of short-term insomnia symptoms in the general population ranges from 15 to 20% [6], while acute and chronic insomnia affect 3.9 to 22% of the population, depending on the definitions and diagnostic criteria used [7–9]. The high prevalence of insomnia has important individual and socioeconomic consequences, highlighting the urgent need to address this health concern [10–13].

Insomnia diagnoses can be made under three main systems: the Diagnostic and Statistical Manual of Mental Disorders (DSM, American Psychiatric Association; [1, 2]), the International Classification of Sleep Disorders (ICSD, American Academy of Sleep Medicine; [3]), and the International Classification of Diseases (ICD, World Health Organization; [4]). Each classification serves a distinct purpose within its respective domains of psychiatric disorders, sleep disorders, and classification of diseases [14–16]. Using different criteria and tools for diagnosing insomnia, including varying items and limitations, leads to inconsistent prevalence estimates of this disorder, making systematic comparisons and gathering research findings challenging [17–19]. Notably, following the removal of the distinction between primary and secondary insomnia in the DSM-5, the definitions of insomnia in both the ICSD-3 and ICD-11 have aligned accordingly [20–24]. Although cognitive behavioral therapy for insomnia (CBT-I) has proven effective in treating it, receiving an accurate diagnosis of ID is a crucial barrier to treatment [25, 26]. Professional diagnoses of ID are rare in clinical practice, and as a result, numerous patients cannot access early treatment for this disorder [27]. Hence, this reality underscores the imperative need for a quick and precise clinical screening and measuring tool.

Quantifying insomnia complaints and identifying its core symptoms through assessment tools can greatly benefit patients. The Sleep Condition Indicator (SCI) is an eight-item insomnia screening tool that encompasses two components: sleep pattern (items 1, 2, 3, 4, 8) and sleep-related impact (items 5, 6, 7) [28]. The SCI is aligned with the DSM-5 criteria for ID [1, 2] and assesses both nighttime and daytime symptoms, with lower scores indicating greater sleep difficulty [28]. Studies have consistently demonstrated that the SCI exhibits good measurement properties [28–31]. The SCI has established cut-off scores for ID and for identifying reliable Change with treatment, thus increasing the ease of use for the clinician. Specifically, the SCI recommends a cut-off value of 16 points for discriminating between those with and without insomnia, as per the DSM-5 criteria [28]. An ultra-brief two-item SCI form (SCI-2) has also been developed to preliminary flag insomnia symptoms [32], although only the full SCI form is typically used for diagnostic precision.

The SCI could be used to improve diagnostic ability access to treatment for patients with ID, and thus assist insomniacs to make better-informed decisions about health. However, although psychometric properties and clinical diagnostics of the SCI have been studied in various populations, no systematic review has yet been conducted to identify, evaluate, and synthesize its global performance as a clinical insomnia screening tool. Therefore, this systematic review aims to (i) comprehensively compare the SCI with current diagnostic systems for ID and assess how well the SCI reflects the

various features of insomnia; (ii) thoroughly evaluate key information on published reports of the SCI summarizing psychometric performance, diagnostic performance, and application; and (iii) serve as a clinical resource to guide the assessment and diagnosis of ID. By providing consolidated evidence on the SCI in quantifying insomnia and core symptoms for the DSM-5, this review offers key information to optimize insomnia screening, diagnosis, and monitoring [33]. These findings provide a robust basis for the comprehensive understanding and informed application of the SCI in clinical and non-clinical settings, facilitate management of insomnia in routine clinical practice, and enhance patient care and public health outcomes across the globe.

Methods

Scope of the review

The analytical framework of this review focuses on three primary goals related to the SCI, including validating its measurement properties, exploring recommendations for appropriate cut-off values, and examining the distribution of study populations, study types, and regional applications of this tool. Data extraction and rating were conducted following the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) [34, 35] and Standard for Reporting of Diagnostic Accuracy (STARD) [36] guidelines. The protocol for this study was registered in PROSPERO (CRD42024455607). This work did not rely on any large language models and artificial general intelligence—AI systems (e.g., DeepSeek and ChatGPT – OpenAI). All data analysis and chart-generation processes were performed using R, Microsoft Office, and Adobe. All the details are sorted in Additional files 1 and 2: electronic search strategies (Additional file 1: Table S1), COSMIN group (Additional file 1: Tables S2–S4 and Additional file 2: Tables S5–S7), STARD group (Additional file 1: Tables S8A and S8B), PRISMA checklist (Additional file 1: Table S9), general information on Application group (Additional file 2: Table S10), general information on COSMIN & STARD groups (Additional file 2: Table S11), and exclusion list (Additional file 2: Table S12), as shown in a logical order. The overview information for the work is summarized in Table 1 and Figs. 1, 2, 3, and 4.

Search strategy and selection criteria

The review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines and incorporated COSMIN-recommended filters [37–39]. A latest comprehensive electronic search for eligible studies was performed across PubMed, EMBASE, CINAHL, and MEDLINE [40] databases, covering articles published between January 1, 2012 (marking the initial release of the SCI in [29, 31]) and December 31, 2024. No language restrictions were applied to the search, and search terms were guided by the construct, instrument, and measurement properties filters. The search terms were adapted for each database, but the main terms included "insomnia", "sleep initiation and maintenance disorders", "sleep assessment", "insomnia screening", "Sleep Condition Indicator", "the SCI", with the search terms for measurement properties provided by the COSMIN guidelines (Additional file 1: Table S1).

A rigorous citation search was undertaken to enhance the results of the electronic search; this involved compiling articles referencing the original/English SCI study [28] identified from PubMed, SCOPUS, Web of Science, and Google Scholar [41]. Expert consultation was also sought from the authors and co-authors of published works on the SCI across various languages. This comprehensive approach aimed to capture all original studies focusing on developing, validating, or translating observational or self-reported SCI measures within the review period.

The selection criteria aimed to identify articles using partial or full forms of the SCI and having the full texts. No restrictions were placed on the population, study design, or publication language of the identified studies. However, literature reviews, meta-analyses, methodological articles, case reports, letters, commentaries, conference abstracts/posters, study protocols, guidelines, and books were excluded. Following the elimination of duplicates through cross-referencing, two reviewers (MH and NY) independently screened the titles and abstracts, examined the full texts, and classified the identified articles into three groups: (i) COSMIN group, focused on the translation of the SCI into various languages or validation of its measurement properties across different linguistic contexts; (ii) STARD group, comprising investigations assessing or comparing the diagnostic precision of the SCI; and (iii) Application group, focused on employing the SCI to identify individuals exhibiting insomnia characteristics or to evaluate sleep conditions.

Data extraction and quality assessment

Two reviewers (MH and NY) extracted information on psychometric and diagnostic performance in accordance with COSMIN and STARD instructions, and conducted the initial eligibility checks and ratings (e.g., study quality, eligibility criteria) for all three groups. In cases of disagreement (e.g., the eligibility of a certain study for inclusion, the rating of the study on the basis of PRISMA-COSMIN and STARD guidelines), consensus was reached with the assistance of another reviewer (RM). A PRISMA 2020 checklist is provided in Additional file 1:

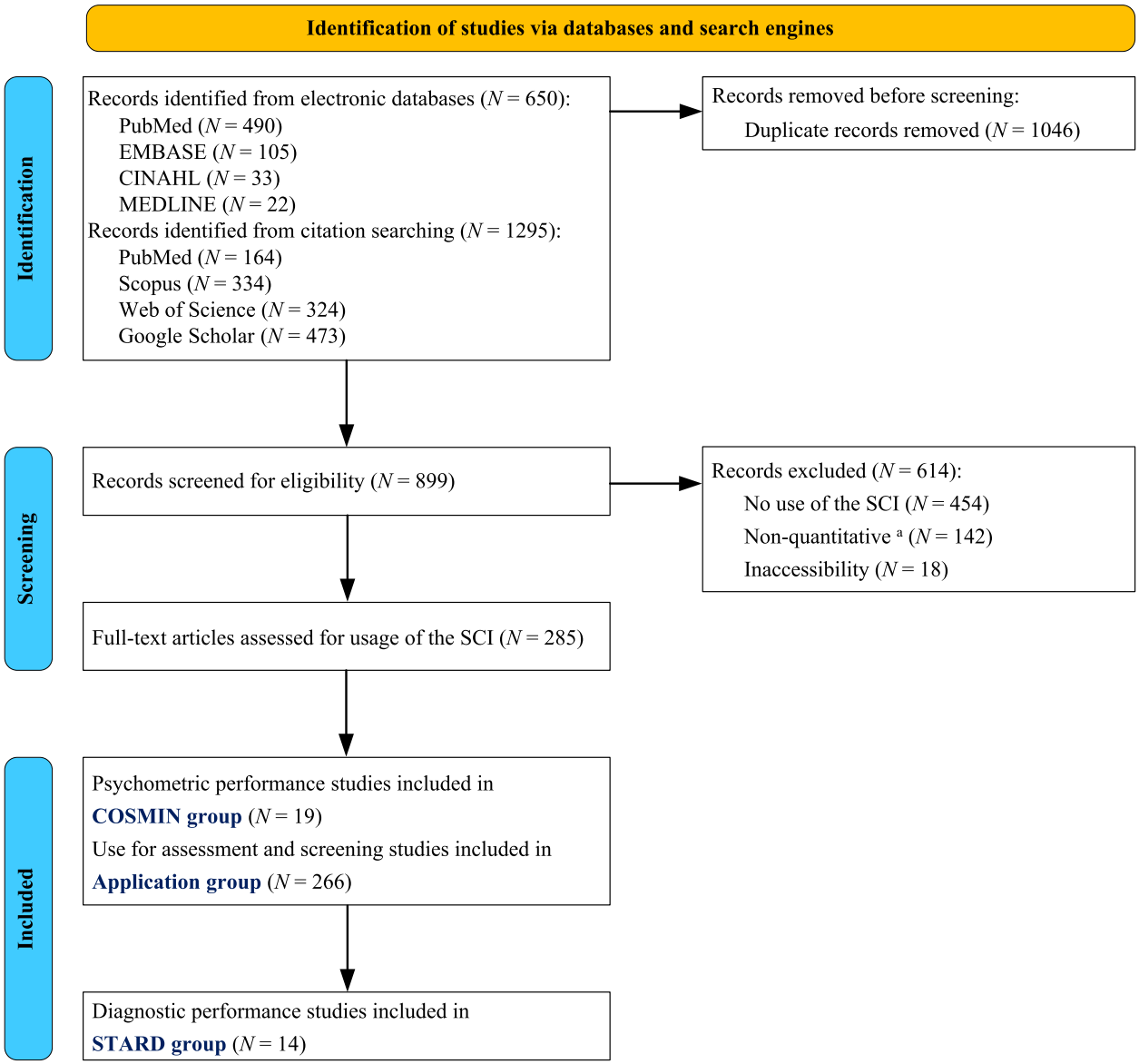

Fig. 1 Flowchart of literature search and study selection. Note: [a]literature reviews, meta-analyses, methodological articles, case reports, letters, commentaries, conference abstracts, conference posters, study protocols, guidelines, and books. Abbreviations: SCI, Sleep Condition Indicator; COSMIN, Consensus-based Standards for the Selection of Health Measurement Instruments; STARD, Standard for Reporting of Diagnostic Accuracy

Table S9. Two other reviewers (LF and YJ) performed the initial data extraction for the Application group and COSMIN and STARD groups; detailed information, respectively, is listed in Additional file 2: Table S10 and Table S11. Additionally, two groups of four reviewers (YYing and JZ, EC and YYe) independently screened a list of the references, identified the reasons for exclusion, and then cross-checked these records in study eligibility criteria (Additional file 2: Table S12). Information for the articles not in English was confirmed by the original authors or native speakers of the relevant languages. All records were finally compared and cross-checked, and any discrepancies were resolved by consensus of all nine reviewers (RM, MH, NY, LF, YJ, YYing, JZ, EC, and YYe).

Group I: COSMIN

The methodology for systematic reviews of COSMIN Patient-Reported Outcome Measures (PROMs) was used to guide the comprehensive review of measurement properties of the SCI [42]. The results were extracted using standardized tables for three categories of measurement properties: construct validity (structural

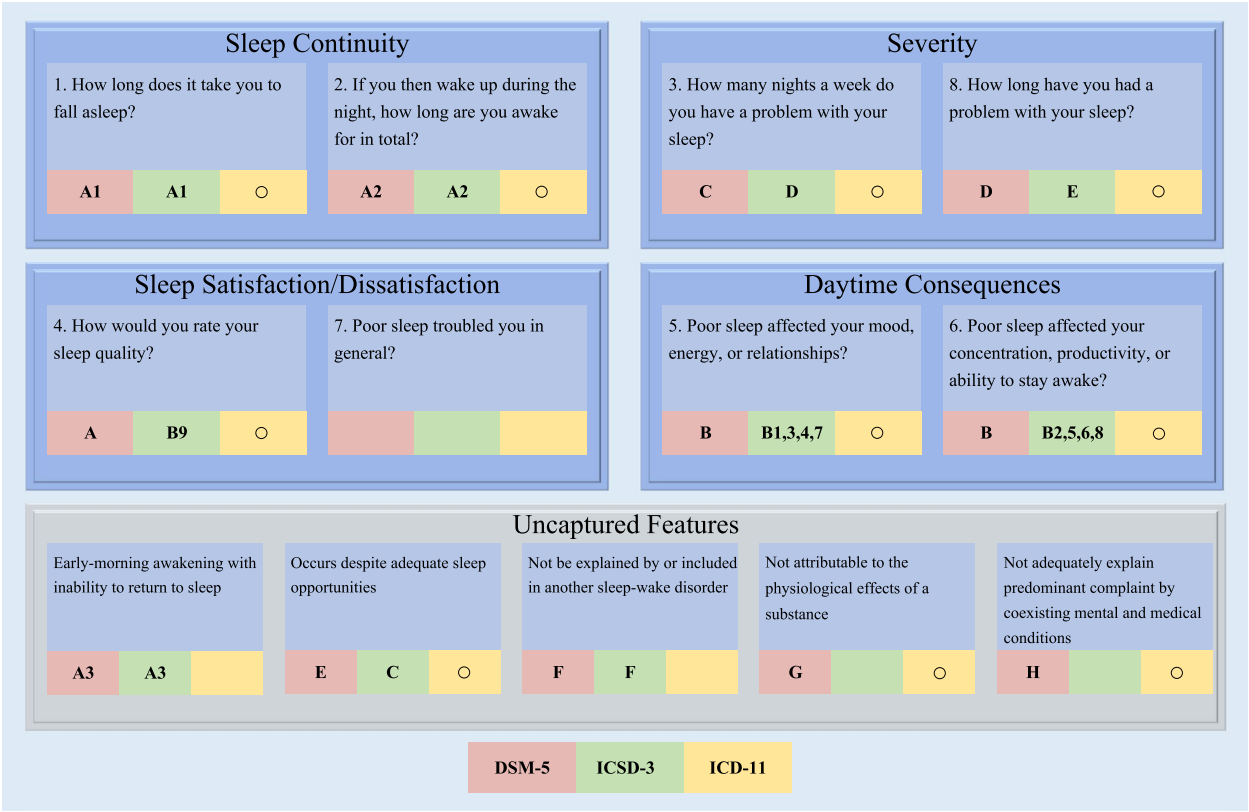

Fig. 2 Insomnia item content measured with the SCI under DSM-5, ICSD-3, and ICD-11. Abbreviations: SCI, Sleep Condition Indicator; DSM-5, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition; ICSD-3, International Classification of Sleep Disorders-Third Edition; ICD-11, International Classification of Disease-Eleventh Edition; A-H and ○, overlap with item content of three diagnostic systems

validity, cross-cultural validity, and hypotheses-testing), criterion validity and responsiveness, and reliability (reliability, internal consistency, and measurement error). The quality of the included studies was assessed using the COSMIN Risk of Bias checklist, which covers the PROM development standards and nine measurement properties. The ratings were synthesized as "sufficient", "insufficient", or "indeterminate" based on all the findings from each language version using the COSMIN criteria for adequate measurement properties.

Group II: STARD

The STARD guidelines were used to assess the quality of the selected studies exploring the diagnostic accuracy of the SCI [36]. The STARD checklist, consisting of 30 items, was used to assess the accuracy, completeness, potential bias, and generalizability of the diagnostic accuracy studies. Each study was examined for its scientific and clinical background, eligibility criteria, reference standard, and index test descriptions, with attention to the handling of indeterminate items and the results of diagnostic accuracy measures. The overall quality of each language version was rated as "poor" (< 50%), "moderate" (50–75%), or "good" (> 75%) based on the number of STARD criteria met.

Group III: Application

This group included all studies that utilized either the partial or full forms of the SCI for evaluating insomnia or sleep conditions. General information was extracted from all these studies to provide an overview of SCI applications across three dimensions: populations, study types, and global distributions.

Results

Study selection and general summary

The initial electronic search yielded 1945 potentially relevant studies. After removing 1046 duplicates and excluding 614 studies that did not meet the inclusion criteria—based on a thorough review of titles, abstracts, and full texts—or did not have the full text available, we included 285 studies (Fig. 1). The reasons for the exclusion list are described in Additional file 2: Table S12, including three main categories: no use of the SCI, non-quantitative research, and inaccessibility.

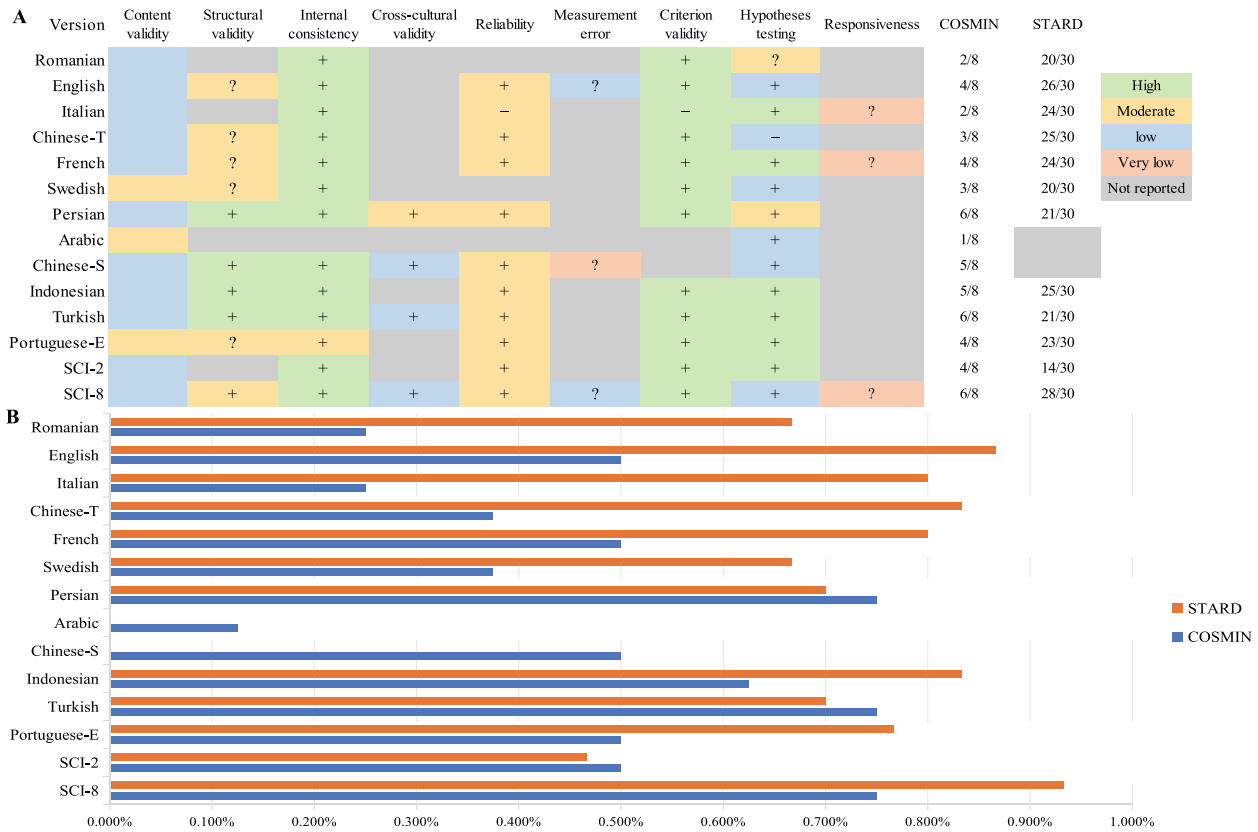

Fig. 3 Measurement properties and methodological quality evaluation based on COSMIN and quality assessment based on STARD checklist; **A** COSMIN ratings for each language version; **B** COSMIN and STARD compliance rates for each language version. Note: Percentage represents the compliance rate of items meeting the COSMIN and STARD checklists in **B**. Abbreviations: SCI, Sleep Condition Indicator; +, sufficient; -, insufficient;?, indeterminate; Chinese-T, traditional Chinese; Chinese-S, simplified Chinese; Portuguese-E, European Portuguese; COSMIN, Consensus-based Standards for the Selection of Health Measurement Instruments; STARD, Standard for Reporting of Diagnostic Accuracy

Of these, 19 studies were clustered in the COSMIN group (Group I), including 12 different language versions of the SCI [28, 30, 43–58] and one study on the two-item form [32] of the SCI. One study in Korean was excluded from the COSMIN group because of the unavailability of information on the SCI translation and the absence of assessment of measurement properties of the SCI [59]. The STARD group (Group II) comprised 14 studies from 10 languages and involving eight populations, including clinical patients, healthy people, community residents, nationally representative samples, general population, pregnant women, adults, and students [28, 32, 43–47, 49, 51, 53–55, 57, 58]. On the other hand, the Application group (Group III) comprised 266 studies applying the SCI, primarily to assess sleep condition or insomnia severity, using SCI scores.

Adherence to the DSM-5 framework

The SCI aligned with most insomnia symptoms in the DSM-5, ICSD-3, and ICD-11 (Fig. 2). A key feature of ID is dissatisfaction with sleep quantity or quality, which is evaluated in the SCI through qualitative questions. In line with the DSM-5 criteria, the SCI includes two quantitative questions to assess sleep-onset insomnia (i.e., latency to sleep > 30 min) and sleep maintenance insomnia (i.e., wakefulness > 30 min after sleep onset). The SCI also qualitatively assesses daytime complaints and symptoms associated with insomnia, including fatigue, decreased energy, mood disturbances, and perceived daytime functional impairment. Additionally, the SCI presents questions and options that align with the DSM-5 criteria for the frequency (at least three times per week) and duration (symptoms present for ≥ 3 months) of sleep difficulties.

General information on the COSMIN and STARD groups

Measurement properties of the SCI were evaluated in 19 studies covering 12 different language versions (Table 1), including Romanian ($n = 1$; [43]), English ($n = 3$; [28, 30, 58]), Italian ($n = 1$; [44]), traditional Chinese ($n = 2$; [45, 55]), French ($n = 2$; [46, 51]), Swedish ($n = 1$; [47]), Persian ($n = 2$; [48, 49]), Arabic ($n = 1$; [50]), simplified Chinese

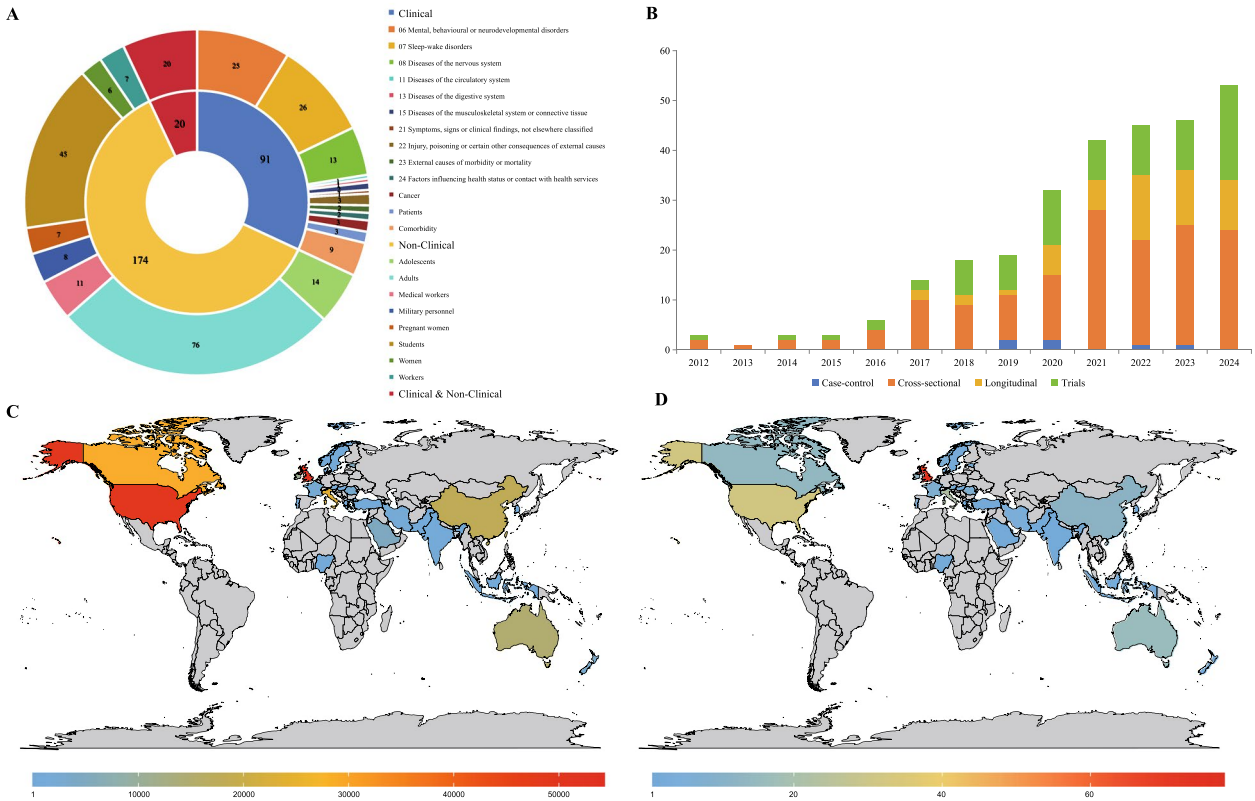

Fig. 4 Overview of distribution maps on the SCI application across the globe; **A** population-based clinical and non-clinical distribution; **B** time-based study types distribution; **C** sample size-based global distribution; **D** study size-based global distribution. Note: Map **A** as the numbers of study based on target clinical or nonclinical populations, map **B** as the numbers of study based on four study types yearly, map **C** based on the global distribution of sample sizes across regions, map **D** based on the global distribution of study sizes across regions, gray color in maps **C** and **D** indicates that no data are available

($n=2$; [52, 56]), Indonesian ($n=1$; [53]), Turkish ($n=1$; [54]), and European Portuguese ($n=1$; [57]). An additional article concentrated on the English SCI-2 [32]. All the included studies were observational and used varying sample sizes ($N=65\sim200{,}000$). Eight studies conducted follow-ups [30, 32, 44–46, 49, 53, 56], with follow-up periods ranging from 12 h to 2 months. The translation processes involved forward and backward translation for nine languages: Italian [44], traditional Chinese (Hong Kong and Taiwan, China) [45, 55], French [46], Swedish [47], Persian [48], Arabic [50], Indonesian [53], Turkish [54], European Portuguese [57]. However, the translation method for Romanian was not reported [43], and the simplified Chinese version was adapted from traditional Chinese [52, 56].

Group I: COSMIN Risk of Bias and measurement properties assessment

The COSMIN Risk of Bias assessment checklist was employed to evaluate the risk of bias in the outcomes of the included studies. The specific results for construct validity, criterion validity, responsiveness, and reliability for the studies in the COSMIN group are detailed in Additional file 1: Tables S2–S4. Detailed ratings of measurement properties of the SCI are outlined in Additional file 2: Tables S5–S7. Figure 3A presents a visualization of the overall COSMIN ratings for each language version of the SCI.

Previous studies validated the Swedish [47], Arabic [50], and European Portuguese [57] versions using in-depth interviews with both patients and experts, providing high-quality evidence for content validity. In addition to the original/English version, the remaining language versions [43–46, 48, 49, 51–56] generally adhered to the recommendations of at least either one expert or one patient group. Concerning reliability, all the SCI studies showed robust internal consistency, with values of Cronbach alpha for the full SCI form exceeding 0.70 in nearly all COSMIN studies, corresponding to a "very good" rating. Test–retest reliability, assessed using the intraclass correlation coefficient (ICC), was deemed "adequate" for the SCI studies except for the Italian full form [44] and

Table 1 Characteristics summary of the 19 studies included in the systematic review with COSMIN and STARD groups

Reference, year	Language (region)	Sample size (*N*)	Participants		Translation process	Interval	Matching instrument(s)	ROC		SCI scores
			Population	Age (Mean ± SD)				Cut-off value	AUC (Sen, Spe)	
1. Voinescu, et al., 2013 [43]	Romanian (Romania)	588	Undergraduate, master students, community adults	29.49 ± 11.82	NR	/	SDQ	SDQ: 16[a]	0.83 (82%, 79%)	19.74[a] ± 2.22
2. Espie, et al., 2014 [28]	English (UK)	30,941	GBSS: *N* = 12,628 GBSS + : *N* = 11,017 TV: *N* = 6876 GSC: *N* = 256 RCT: *N* = 164	GBSS: 38.7 ± 14.5 GBSS + : 42.3 ± 16.5 TV: 36.4 ± 13.3 GSC: 40.3 ± 14.9 RCT: 48.9 ± 13.7	/	/	PSQI, ISI, HADS, DASS	ISI: 16[b]	NR	PPS: 8.56 ± 4.93 No PPS: 15.6 ± 7.80 Probable ID: 10.7 ± 5.3 No ID: 22.9 ± 6.2
3. Palagini, et al., 2015 [44]	Italian (Italy)	171	T1 ID: *N* = 88 OSAS: *N* = 43 Healthy: *N* = 40 T2 ID: *N* = 65	T1 ID: 49.9 ± 15.1 OSAS: 50.2 ± 9.1 Healthy: 49.3 ± 13 T2 ID: 49.6 ± 16.7	Forward and backward translation	2 months	PSQI, ISI	ISI: ID, 17 Healthy, 18 OSAS, 17	ID: NR (100%, 97.6%) Healthy: NR (99%, 100%) OSAS: NR (100%, 95%)	T1 ID: 10.7 ± 3.7 Healthy: 29.5 ± 3.4 OSAS: 22.3 ± 3.1 T2 ID: 10.9 ± 4.0
4. Wong, et al., 2017 [45]	Traditional Chinese (Hong Kong, China)	158	Full-time students	20.1 ± 1.6	Forward and backward translation	7–14 days	CI (DSM-5, ICSD-3), ISI, BIQ, DASS, WHOQOL-BV, Actigraph-watch, Sleep diary	DSM-5 and ICSD-3: SCI, 21 SCI-2, 5 ISI, 8	SCI DSM-5: 0.887 (83%, 80%) ICSD-3: 0.884 (86%, 77%) SCI-2 DSM-5: 0.877 (80%, 81%) ICSD-3: 0.856 (83%, 77%) ISI DSM-5: 0.855 (73%, 89%) ICSD-3: 0.852 (73%, 86%)	T1: 23.5 ± 5.4 T2: 23.2 ± 5.4
5. Bayard, et al., 2017 [46]	French (France)	366	Community-dwelling adults	50.7 ± 16.7	Forward and backward translation	1 month	DSM-5, ISI, BDI-II	DSM-5: ISI, 16	0.93 (95%, 75%)	T1: 23.83 ± 7.4 T2: 24.19 ± 6.8
6. Espie, et al., 2018 [30]	English (UK)	200,000	Adults	31 ± 13	/	12 h to 7 days	NR	/	/	Total: 14.97 ± 5.93 F: 14.29 ± 5.83 M: 15.90 ± 5.94
7. Luik, et al., 2019 [32]	English[c] (UK)	190,000	Adults	40.24 ± 14.31	/	12 h to 7 days	NR	SCI: SCI-2, 2[b]	NR (80%, 81%)	Total: 2.60 ± 2.23 F: 2.39 ± 2.17 M: 2.88 ± 2.28
8. Hellström, et al., 2019 [47]	Swedish (Sweden)	634	Undergraduate students	26.9 ± 7.4	Forward and backward translation	/	ISI, PSQI, PSS	ISI: 16	0.94 (86%, 90%)	Median (Q1, Q3): 23 (15, 28)

Table 1 (continued)

Reference, year	Language (region)	Sample size (*N*)	Participants		Translation process	Interval	Matching instrument(s)	ROC		SCI scores
			Population	Age (Mean ± SD)				Cut-off value	AUC (Sen, Spe)	
9. Ranjkesh, et al., 2019 [48]	Persian (Iran)	300	Pregnant women	27.92 ± 6.13	Forward and backward translation	/	NR	/	/	NR
10.Lin, et al., 2020 [49]	Persian (Iran)	859	Patients with cancer at stage III or IV	67.4 ± 7.5	/	2 weeks	DSM-5, ISI, PSQI, ESS, HADS, GHQ, ESAS, KPS, Wrist actigraphy	DSM-5: 20 ISI: 17	DSM-5: 0.92 (83%, 87%) ISI: 0.98 (97%, 98%)	NR
11. Khaled, et al., 2021 [50]	Arabic or English (Qatar)	1611	Community-dwelling adults	NR	Forward and backward translation	/	PHQ-9, GAD-2	/	/	NR
12. Bayard, et al., 2021 [51]	French (France)	65	Parkinson's disease patients	63.8 ± 7.9	/	/	DSM-5, ISI, MoCA, IRLSSG, LEDD, RBD1Q, BDI-II, PAS	DSM-5: ISI, 16	0.86 (86%, 87%)	18.05 ± 8.3
13. Meng, et al., 2022 [52]	Simplified Chinese (China)	751	Community residents	Median (IQR): 28 (22.500)	Adapted from the traditional Chinese SCI	/	SQQ	/	/	24.162 ± 5.783
14. Hasan, et al., 2023 [53]	Indonesian (Indonesia)	160	Adults with a diagnosis of stroke for more than 3 months	Median (range): 58.5 (25–92)	Forward and backward translation	7 days	CCI, DSM-5, ISI, PHQ-9, GAD-7	DSM-5: 23	0.98 (94%, 97%)	25.14 ± 7.46
15. Uygur, et al., 2024 [54]	Turkish (Turkey)	834	General population	36.15 ± 9.64	Forward and backward translation	1 month	PSQI, ISI	ISI: 15	0.963 (90.3%, 91.8%)	22.23 ± 6.84
16. Chang, et al., 2024 [55]	Traditional Chinese (Taiwan, China)	200	Hemodialysis patients	65.56 ± 13.08	Forward and backward translation	/	ISI, PHQ-9, GAD-7, EQ-VAS, EQ-5D	DSM-5: 16	0.91 (88.2%, 84.7%)	19.62 ± 9.59
17. Meng, et al., 2024 [56]	Simplified Chinese (China)	343	Healthcare students	19.650 ± 1.414	/	7 days + 2 h	RU_SATED scale, PHQ-4	/	/	Baseline: 24.834 ± 4.762 Follow-up: 25.052 ± 4.754
18.Marques, et al., 2024 [57]	European Portuguese (Portugal)	537	Higher education students	26.6 ± 9.8	Forward and backward translation	/	ISI, FIRST, ESS, DSPS-4	ISI: 16 ISI: 18	NR (86.3%, 80.1%) 0.91 (76.6%, 91.2%)	19.3 ± 6.9

Table 1 (continued)

Reference, year	Language (region)	Sample size (*N*)	Participants		Translation process	Interval	Matching instrument(s)	ROC		SCI scores
			Population	Age (Mean ± SD)				Cut-off value	AUC (Sen, Spe)	
19.Declan, et al., 2024 [58]	English (UK)	180	Community-based adult (≥ 18 years), stroke survivors	Total: 49.61 ± 12.41 ID: 49.24 ± 12.04 IS: 51.82 ± 11.56 NI: 48.99 ± 13.18	/	/	ISI, PHQ-9, GAD-7, SIS-SF	SCI: DSM-5 ID: 13 DSM-5 IS: 14 SCI-2: DSM-5 ID: 2 DSM-5 IS: 3	SCI: DSM-5 ID: 0.859 (88.00%, 71.43%) DSM-5 IS: 0.854 (81.48%, 76.39%) SCI-2: DSM-5 ID: 0.79 (76.00%, 68.57%) DSM-5 IS: NR (81.48%, 68.06%)	Total: 13.74 ± 7.51 ID: 8.47 ± 4.60 IS: 13.52 ± 5.33 NI: 19.35 ± 6.79

AUC, Area Under the Curve; BDI, Beck Depression Inventory; BIQ, Brief Insomnia Questionnaire; CCI, Charlson Comorbidity Index, CI, clinical interview; DASS, Depression Anxiety Stress Scale; DSM-5, Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition; DSPS, Daytime Sleepiness Perception Scale; EQ-VAS, EuroQol Visual Analogue Scale; EQ-5D, EuroQol Five Dimensions Questionnaire; ESAS, Edmonton Symptom Assessment System/Scale; ESS, Epworth Sleepiness Scale; F, female; FIRST, Ford Insomnia Response to Stress Test; GAD, Generalized Anxiety Disorder; GBSS, Great British Sleep Survey; GBSS+, a revision of the GBSS; GSC, Glasgow Science Centre; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; ICSD-3, International Classification of Sleep Disorder, Third Edition; ID, insomnia disorder; IQR, interquartile range; IRLSSG, International Restless Legs Syndrome Study Group criteria; IS, Insomnia Symptoms; ISI, Insomnia Severity Index; LEDD, levodopa equivalent daily dose; KPS, Karnofsky Performance Scale; M, male; MoCA, Montreal Cognitive Assessment; MCTQ, Munich Chronotype Questionnaire; NI, No Insomnia; NR and/, not reported; OSAS, obstructive sleep apnea syndrome; PAS, Parkinson's Anxiety Scale; PHQ, Patient Health Questionnaire; PPS, prescription sleeping pills; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale; RBD1Q, Rapid eye movement sleep Behavior Disorder Single-Question Screen; ROC, receiver operating characteristic; RCT, randomized controlled trial; RU_SATED, Regularity, Satisfaction, Alertness, Timing, Efficiency, Duration; SCI, Sleep Condition Indicator; SD, standard deviation; SDQ, Sleep Disorder Questionnaire; Sen, sensitivities; SIS-SF, Stroke Impact Scale Short Form; Spe, specificity; SQQ, Sleep Quality Questionnaire; T1, first assessment; T2, second assessment; WHOQOL-BV, World Health Organization Quality of Life Scale-Brief Version.

Note: [a], original report had a cutoff value of 5 (on a 10-point scale), which was converted to a 32-point scale; [b], no ROC validation; [c], SCI-2

the English short form [32]. However, the evidence for reliability was considered of moderate quality because of the absence of data on symptom stability between tool administrations. Moreover, evidence of measurement error with the SCI is currently limited.

Admittedly, there is ample evidence supporting criterion validity for the SCI, but due to different research objectives and practice points, variations exist in the gold standard tests used to assess criterion validity for the SCI across studies, including the DSM-5 or ICSD-3 clinical interviews [45, 46, 49, 51, 53], Insomnia Severity Index (ISI) [28, 44, 45, 47, 49, 54, 55, 57, 58], and Sleep Disorders Questionnaire (SDQ) [43]. There was moderate support for the structural validity of the SCI, with all factor analyses suggesting that the SCI has a stable two-factor structure except in Swedish [47] and European Portuguese [57] (unidimensionality); however, only seven studies (Persian, simplified Chinese, Indonesian, Turkish, traditional Chinese) performed confirmatory factor analysis (CFA) [48, 49, 52–56], and these provided an "indeterminate" rating for structural validity. Hypothesis testing for structural validity suffered from inadequate subgroup details and was rated as having moderate quality. Three language versions of the SCI—Persian [48, 49], simplified Chinese [52, 56], and Turkish [54]—were examined concerning cross-cultural validity, but this validation was limited to specific subpopulations, such as cancer patients, community residents, and the general population. Finally, no clear evidence exists regarding the responsiveness of the SCI scores to treatment.

Group II: STARD diagnostic performance results assessment

Overall, 14 studies [28, 32, 43–47, 49, 51, 53–55, 57, 58] were included in the assessment of diagnostic performance of the SCI. None of these studies fully adhered to all 30 criteria in the STARD checklist (Additional file 1: Tables S8A and S8B). Of these 14 studies, nine studies (six language versions) (original/English [28, 58]: 26/30; Italian [44]: 24/30; traditional Chinese [45, 55]: 25/30; French [46, 51]: 24/30; Indonesian [53]: 25/30; European Portuguese [57]: 23/30) were rated as "good", one study (SCI-2 [32]: 14/30) was rated as "poor", and the remaining studies were rated as "moderate". Fig. 3B shows the COSMIN and STARD compliance rates for each language version of the SCI, with higher compliance rates indtter validation and more complete diagnostic reports. The Indonesian [53], Persian [49], and Turkish [54] versions of the SCI achieved high compliance rates for both ratings simultaneously, with the top three in cumulative rating.

The initial diagnostic cut-off value of 16 points for the SCI was not empirically derived but based on DSM-5 quantitative recommendations set by the development team the SCI [28]. The diagnostic performance of six language versions (English [28], Italian [44], French [46, 51], Swedish [47], Turkish [54], and European Portuguese [57]) was evaluated against the ISI (Table 1). The English [28] version determined the cut-off values based on correlations between the SCI and ISI, and the accuracy of insomnia case classification. The Swedish [47] and French [46, 51] versions also employed a cut-off score of 16. In studies referencing the DSM-5 criteria, the cut-off values were higher: 21 for traditional Chinese (Hong Kong, China) [45], 20 for Persian [49], and 23 for Indonesian [53]. Confusingly, however, the DSM-5 cut-off values in stroke survivors were even lower, 13 for insomnia disorder and 14 for insomnia symptoms, respectively [58]. All 14 studies (ten language versions: English [28, 32, 58], Romanian [43], Italian [44], traditional Chinese (Hong Kong and Taiwan, China) [45, 55], French [46, 51], Persian [49], Indonesian [53], Swedish [47], Turkish [54], and European Portuguese [57]) reported sensitivity values ranging from 0.76 to 1.00 and specificity values ranging from 0.71 to 1.00. Ten studies (eight language versions: Romanian [43], traditional Chinese (Hong Kong and Taiwan, China) [45, 55], French [46, 51], Persian [49], Indonesian [53], Swedish [47], Turkish [54], and European Portuguese [57]) reported areas under the curve ranging from 0.83 to 0.98.

Group III: temporal, spatial, and population distribution of SCI applications

In addition to the 19 studies previously discussed, we included 285 studies that employed the SCI (Additional file 2: Tables S10 and S11) as a general measurement tool for insomnia. Figure 4 provides an overview of the utilization of the SCI across populations (Fig. 4A), study types (Fig. 4B), and global distributions on sample sizes (Fig. 4C) and study sizes (Fig. 4D) over the 13 years from 2012 to 2024 since the creation of the SCI. In particular, utilization of the SCI has steadily increased each year across both clinical populations (classified under ICD-11 disease categories) and non-clinical populations (classification: adults, students, adolescents, medical workers, workers, military personnel, pregnant women, and women). Four types of study design were employed: cross-sectional ($k=149$), longitudinal ($k=51$), case–control ($k=6$), and trials ($k=79$). The SCI had been used at least in 31 regions, with the largest sample and study sizes observed in the UK, USA, and Italy. Overall, the sample sizes of these SCI studies ranged from 2 to 290,000, with a cumulative total of more than 720,000 participants ($N=722,253$). Of these, 20 were online studies and the source of the sample was treated to be the same as the original place of the first or corresponding

author. Notably, 74 large-scale surveys had sample sizes greater than 1000 participants each. Most studies used validated versions of the SCI in each language, except for one Korean study [59]. Studies ($k=48$) used different cut-off values of the SCI, studies ($k=269$) that used the SCI for evaluation purposes calculated a total score to assess insomnia or sleep condition, and a few studies ($k=2$) simply used items from the SCI.

Discussion

This systematic review comprehensively examined items content, measurement properties, diagnostic performance, and applications of the SCI, thus providing clear and detailed evidence of its utility in clinical practice and research. The overall evidence supports the use of the SCI as a psychometrically reliable, diagnostically useful, and widely accepted instrument, which can aid clinicians in identifying patients who may require a more comprehensive clinical assessment of their sleep patterns and the daytime impact of any sleep difficulties they are experiencing.

Consistency between diagnostic frameworks and the SCI for insomnia disorders

The SCI comprehensively encompasses the key insomnia symptoms outlined in the DSM-5 [1, 2], ICSD-3 [3], and ICD-11 [4]. The SCI includes DSM-5-recommended quantitative criteria, such as sleep latency exceeding 30 min or wake time exceeding 30 min after sleep onset, occurring at least three times per week for a minimal duration of 3 months. Therefore, the SCI closely aligns with these diagnostic criteria, making it a relevant tool for assessing suspected ID. Furthermore, as definitions and diagnostic criteria for insomnia continue to evolve [14, 21], the SCI could serve as a valuable clinical tool, providing researchers and clinicians with an easy-to-use tool for assessing the prevalence of various insomnia symptoms and conditions across populations. The SCI complements subjective assessments with objective measures, facilitating a comprehensive evaluation of sleep status and comorbidities [60]. The qualitative scores in the SCI support a further evaluation of sleep quality, daytime functioning, and overall disturbance, offering a comprehensive assessment of the impact of insomnia on an individual. This approach can complement existing insomnia measurement tools, enabling researchers and clinicians to intuitively visualize the distribution of subjects across sleep conditions.

Nonetheless, the SCI also has limitations as it assumes that the respondents' insomnia is not attributable to external factors such as sleep deprivation, other psychiatric conditions, sleep–wake disturbances, or substance use. This assumption highlights the challenges of self-reported psychometric tools in capturing the influence of external factors and underscores the need for clinical discretion. Another limitation of the original/English SCI is that it does not contain specific questions related to early morning awakenings (EMA), a core feature of insomnia. However, a nine-item form of the SCI has been developed and can be used to understand EMA [61, 62]; this form asks the following question: "If your final wake-up time occurs before you intend to wake up, how much earlier is this?".

COSMIN criteria for measurement properties of the SCI

Content validity is considered a key component of instrument validity [35]. Content validity of the SCI is supported by the development process of this tool, which incorporated key diagnostic criteria for ID [28] and involved interviews with patients and clinical caregivers. In its various language versions, the SCI has demonstrated a stable two-factor structure along with excellent specificity and sensitivity, high internal consistency, and outstanding test–retest reliability. Specifically, multidimensionality through two-factor solutions of the SCI may be closer to the essence of insomnia due to theory-driven (i.e., CFA) and is therefore supported by most of the other versions (i.e., four language versions, seven studies) [48, 49, 52–56]. For factor structure in Swedish [47] and European Portuguese [57], admittedly, given the ordinal nature of the SCI item data, a unidimensional structure seems more appropriate based on rigorous statistical criteria. However, additional evidence of the SCI is needed regarding cross-cultural validity, measurement error, and responsiveness to treatment. In particular, assessing responsiveness is crucial for determining whether patients have improved with treatment in clinical trials or routine care [34].

STARD ratings and optimal cut-off values for the SCI

Determining the cut-off values is critical from a clinical perspective to distinguish between different severity levels of insomnia. These cut-off values are also crucial for assessing an intervention's effectiveness [63]. While the studies in the STARD group consistently reported adequate sensitivity and specificity for insomnia screening, the reported cut-off values used were inconsistent. This discrepancy may stem from the broad set of the DSM-5 symptoms, including EMA, sleep opportunity, or daytime dysfunction, which the SCI does not cover adequately. The three studies comparing the SCI to the DSM-5 were conducted with selected, small samples. In particular, the Persian and Indonesian studies were limited to cancer and stroke patients, respectively [49, 53]. Given that the cut-off value of 16 for the SCI is derived from the quantitative reflection of the DSM-5 diagnostic

criteria, this score remains the most recommended cut-off value for insomnia screening.

Clinical diagnosis and care relevance

The importance of impaired daytime functioning in diagnostic criteria for insomnia is increasingly being emphasized, but detecting such dysfunction in the early stages of insomnia can be challenging [64]. Moreover, because chronic ID is associated with increased medical risk [65], psychiatric disorder rates [66], multimorbidity [10, 67], and mortality [68], early detection and intervention may improve the prognosis and management of these patients [69]. Diagnosing insomnia in the acute phase before chronic insomnia develops may help reduce the long-term consequences of insomnia [70, 71]. The SCI encompasses two dimensions—sleep patterns and daytime-related impact—that provide a comprehensive picture of insomnia, thus supporting the identification of insomnia in clinical settings. Moreover, the SCI also stands out among other screening tools because of its ease of use, availability of quantitative criteria, and efficient administration time, making it particularly well suited for primary care settings.

CBT-I, which is recognized as the first-line treatment option for insomnia [14, 21, 72, 73], has notable effects on sleep and insomnia complaints and positive effects on somatic and psychiatric comorbidity as well as quality of life, and is preferred by patients, especially using digital cognitive behavioral therapy and brief behavioral treatment for insomnia [60, 74–77]. The SCI has been used in several studies to evaluate the treatment effects of CBT-I; for instance, one study suggested that a seven-point change in SCI scores represents a reliable improvement in insomnia, implying that the SCI is suitable for demonstrating therapeutic effects [30]. Effective insomnia treatments may not only target insomnia symptoms but also have the potential to reduce subclinical and clinical psychopathological symptoms and prevent mental disorders and physical diseases [78]. Nevertheless, targeted and immediate means of assessment (e.g., applying the SCI or its subscale) are necessary to realize these benefits. The SCI can be used for detecting from mild to severe insomnia symptoms and assisting in transforming from sleep disorder to sleep health among insomniacs [79, 80].

Recommendations

Although a cut-off value of 16 on the SCI is recommended for screening purposes [28], the selection of cut-off values should be carefully considered because the cut-off value is not universal when using the SCI, based on various factors (e.g., the pretest probability of insomnia and the costs incurred by misdiagnosis) related to a certain region and target population [63, 81]. Furthermore, to avoid reporting misleading information because of the absence of certain diagnostic symptoms, it is recommended to include additional items related to EMA [28]. These additions would help account for potential performance bias in different subtypes of ID [82, 83]. Individuals with a certain subtype of ID may perform more poorly on the SCI. Moreover, considering that the SCI [28] and the ISI [84] explore four-fifths of clinical manifestations with content analysis and are the most suitable tools for addressing clinical issues [85], therefore, there is a need to ensure an appropriate toolset (i.e., SCI and ISI) is communicated to patients and clinicians as a front line of care for insomnia management in the future [14, 76, 86]. This review would make it possible to select the most appropriate tool based on the issue to be addressed. Suggestions are made regarding the development of the updated form SCI to better screen insomnia symptoms and distinguish different phenotypes of ID.

Future research agenda should focus on the following: (i) examining relationships between sleep disorder and health outcomes, including a comprehensive insomnia disorder assessment (i.e., insomnia symptoms as predictors when feasible); (ii) continuing to assess the psychometric and diagnostic performance of the SCI adhering to rigorous PRISMA-COSMIN and STARD guidelines; (iii) addressing discrepancies in the definitions and assessment of insomnia disorder characteristics, both subjective (i.e., self-reported) and objective (i.e., device-measured), based on DSM, ICSD, and ICD; and (iv) including insomnia assessment and management in public health agendas to promote health equity.

Clinical practice points

Insomnia is highly prevalent in clinical practice. The lack of an updated, standardized screening, diagnosing, and monitoring tool contributed to delayed or even absence of treatments, resulting in increased costs to healthcare systems and societies at large, on top of the immeasurable sufferings and burdens in patients and families. The SCI, both full and short forms, can be used for detection and management of insomnia at different levels of interventions. This review provides an overview of each identified language version of the SCI against methodological quality assessment criteria from the robust COSMIN and STARD guidelines, hence consolidating the knowledge base for a brief, user-friendly, and cross-culturally validated self-report measure for both clinicians and researchers to advance sleep science and clinical care. In particular, given that the SCI aligns with the DSM-5 criteria and offers clear cut-off values with superior measurement properties, the current review further equips researchers and clinicians with a simple yet cogent tool to screen for core features of insomnia, identify its nature

and severity, and provide valuable quantitative information for monitoring treatment progress in routine clinical care as well as assessing efficacies of insomnia interventions in clinical trials.

Strengths and limitations

This study used a rigorous, pre-registered systematic review approach to gather meta-information on the psychometric characteristics, diagnostic performance, and applications of the SCI, and provide a comprehensive quality assessment of this tool. Admittedly, the SCI is a commonly-used self-report instrument to assess insomnia symptomatology against updated knowledge of the DSM-5 criteria. To our knowledge, there has been no SCI systematic review prior to this work across the globe. All the included studies strictly adhered to at least one of the specified guidelines (i.e., COSMIN and/or STARD), such that clinicians and researchers seeking a suitable instrument to use in health systems and scholarly contexts should find this review informative.

Despite these promising results regarding key information of the SCI, first, this review is limited by the heterogeneity in the designs of the included studies that prevents calculating a standardized prevalence estimate of insomnia. Second, as this review merely provided a descriptive review on psychometric and diagnostic performance of the SCI without conducting a quantitative analysis (i.e., meta-analysis), it was unable to calculate effect size analysis (e.g., subgroup analysis, meta-regression) on heterogeneity and perform sensitivity analyses. Finally, using differential cut-off values for the SCI across languages and settings has led to discrepancies in findings related to screening, diagnosis, and treatment progress for insomnia.

Conclusions

The 13 language versions of the SCI have been rigorously validated and demonstrate a stable two-factor structure and high credibility, making the SCI a brief, valid, reliable, and versatile instrument for assessing insomnia disorder. The SCI effectively captures a range of insomnia symptoms and demonstrates strong structural validity, criterion validity, internal consistency, and reliability. The 16-point cut-off score for the SCI may hold instructive significance for insomnia screening purposes, and changes in scores may also provide valuable information for assessing the efficacy of therapeutic interventions for insomnia.

Abbreviations

CBT-I	Cognitive-behavioral therapy for insomnia
CFA	Confirmatory factor analysis
COSMIN	Consensus-based Standards for the Selection of Health Measurement Instruments
DSM	Diagnostic and Statistical Manual of Mental Disorders
EMA	Early morning awakenings
ICC	Intraclass correlation coefficient
ICD	International Classification of Diseases
ICSD	International Classification of Sleep Disorders
ID	Insomnia disorder
ISI	Insomnia Severity Index
SCI	Sleep Condition Indicator
SDQ	Sleep Disorders Questionnaire
STARD	Standard for Reporting of Diagnostic Accuracy
PRISMA	Preferred Reporting Items of Systematic Reviews and Meta-analyses

Supplementary Information

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Additional file 1. Table S1. Electronic search strategies with COSMIN search filters for finding studies. Table S2. Construct Validity: Detailed measurement properties of 19 included studies on the SCI. Table S3. Criterion Validity & Responsiveness: Detailed measurement properties of 19 included studies on the SCI. Table S4. Reliability: Detailed measurement properties of 19 included studies on the SCI. Table S8A. STARD checklist for quality assessment of STARD group studies. Table S8B. STARD checklist for the reporting of studies of diagnostic accuracy. Table S9. PRISMA 2020 checklist.

Additional file 2. Table S5. COSMIN box 1 Standards for evaluating the quality of PROM development. Table S6. COSMIN box 2 Standards for evaluating the quality of content validity studies of PROMs. Table S7. COSMIN boxes 3–10 Risk of Bias checklist. Table S10. General information on Application group. Table S11. General information on COSMIN & STARD groups. Table S12. Exclusion list.

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Author contributions

RM: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing-original draft, Writing-review & editing. MH: Data curation, Formal analysis, Investigation, Methodology, Software, Validation, Visualization, Writing-original draft, Writing-review & editing. CBM: Investigation, Methodology, Resources, Validation, Writing-original draft, Writing-review & editing. DYTF: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. AMG: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. AHP: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. JMD: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. ALH: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. BlV: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. NY: Data curation, Investigation, Methodology, Validation, Writing-review & editing. HM: Resources, Validation, Writing-review & editing. YL: Resources, Validation, Writing-review & editing. EYYL: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. KS: Investigation, Methodology, Validation, Writing-original draft, Writing-review & editing. CAE: Conceptualization, Methodology, Resources, Validation, Writing-original draft, Writing-review & editing. All authors read and approved the final manuscript.

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Data Availability
Data is provided within the manuscript or supplementary information files. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
Dr. Meng reports grants from the Health Commission of Zhejiang Province and Hangzhou Normal University during the conduct of the study. Prof. Espie reports being a cofounder, chief scientist, and shareholder of and receiving salary from Big Health Ltd. Drs. Miller and Henry report being a director and a senior manager, respectively, and receiving salary from Big Health Ltd. The views expressed are those of the authors and not necessarily those of the National Institute for Health and Care Research (NIHR) or the Department of Health and Social Care. The contents do not represent the views of the National Sleep Foundation. The funding agencies had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. No other disclosures were reported.

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