The Sleep Condition Indicator: a clinical screening tool to evaluate DSM-5 Insomnia Disorder

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Key words: insomnia, assessment, patient outcomes, DSM-5, psychometric, scale

ABSTRACT

Objective: Describe the development and psychometric validation of a brief scale [The Sleep Condition Indicator (SCI)] to evaluate DSM-5-defined Insomnia Disorder in everyday clinical practice.

Design: The SCI was evaluated across five studies, including large scale surveys and a placebo-controlled trial of Cognitive Behavioural Therapy (CBT) for insomnia. Content validity, internal consistency, sensitivity and specificity, concurrent validity, and responsiveness to change were investigated.

Participants: 30,941 individuals (71% female) completed the SCI along with other descriptive demographic and clinical information.

Setting: Data acquired on dedicated web-sites.

Results: The 8-item SCI (concerns about getting to sleep, remaining asleep, sleep quality, daytime personal functioning, daytime performance, duration of sleep problem, nights per week having a sleep problem, and extent troubled by poor sleep) had robust internal consistency (α ≥0.86), and 92% sensitivity (SCI score ≤ 4.6) / 87% specificity (SCI score >4.6) for Insomnia Disorder. Sensitivity to treatment outcome using CBT (relative) to placebo was demonstrated in a randomised trial (d=0.95). A 2-item short-form (SCI-02: nights per week having a sleep problem, extent troubled by poor sleep), derived using logistic regression modelling, correlated strongly with the SCI total score (r=.90).

Conclusions: The SCI has potential as a clinical screening tool for appraising insomnia complaints against DSM-5 criteria.

STRENGTHS AND LIMITATIONS

- Existing instruments used to evaluate insomnia lack specificity or do not permit assessment against the latest diagnostic criteria. This study describes the development and validation of a new instrument (the sleep condition indicator) for use in everyday clinical practice. The SCI is valid, reliable and sensitive to change in insomnia severity. Its brevity and appealing visual format permit rapid assessment and interpretation of poor sleep, against contemporary clinical diagnostic criteria (DSM-5).
- While we have used large surveys and treatment evaluation to assess SCI properties, more work is required to assess predictive validity with reference to independent clinical evaluation of Insomnia Disorder.

INTRODUCTION

Although insomnia is the most common of all mental health complaints,[1] it is seldom adequately assessed and treatment is often poor.[2,3] This perhaps reflects the perspective that insomnia is usually a symptom,[4] coupled with minimal medical education on sleep and its disorders.[5] However, there are three reasons why this perspective must now change. First, insomnia is not merely a symptom. The DSM-5 Workgroup has recognised that the dichotomy of primary versus secondary insomnia is simply not evidence-based.[6] Accordingly, DSM-5 (due May 2013), is set to recommend that Insomnia Disorder should be coded "*whenever diagnostic criteria are met whether or not there is a co-existing physical, mental or sleep disorder*".[7] Moreover, insomnia is not necessarily transient or benign. Once established, insomnia is remarkably persistent,[8,9] and constitutes a risk factor for the development of physical and mental health problems, notably depression,[10-12] as well as adverse effects upon quality of life.[13] Third, insomnia is treatable. There is a substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),[14,15] although the latter are very seldom available.[3,16]

Insomnia is ubiquitous[17] so it is important that clinicians, GPs in particular, have a reliable, valid, and brief, screening tool. Such instruments are now a standard part of patient-centred care[18] for depression,[19] anxiety[20] and alcohol problems.[21] Two potential scales are the Pittsburgh Sleep Quality Index (PSQI)[22] and the Insomnia Severity Index (ISI).[23] The PSQI is widely used in research, and has a cut-off score indicative of sleep disturbance. However, it lacks specificity for insomnia. The ISI is sound psychometrically, and is more specific; but based on DSM-IV criteria for insomnia. It is used to select people for clinical trials and as an outcome measure.

In this paper, we present a new measure (the Sleep Condition Indicator: SCI) offering possible advantages. The SCI is based on DSM-5 insomnia criteria coupled with research diagnostic criteria[24] and recommended quantitative parameters for sleep disturbance.[25] In keeping with DSM-5, the SCI also evaluates associated

daytime factors, which are important drivers of clinical complaint[17] and should be incorporated in insomnia measurement.[13,26] In terms of utility, the SCI is brief but versatile. It yields a) a dimensional perspective on sleep quality: on an intuitive, global 0-10 scale where higher scores represent better sleep; b) a visual profile of night-time and daytime symptoms that the clinician can use in consultations; and c) cut-off points for clinical Insomnia Disorder. This paper summarises the development and psychometric evaluation of the SCI across several studies.

METHODS

Sample characteristics

Data are reported from five validation studies (total n=30,941; 71% Female) in which SCI items were administered. The Great British Sleep Survey (GBSS) was an open access, web-based survey completed by adults (18+yr.) with a UK postcode yielding data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between February 2010 and August 2011.[27] The GBSS+ was a revision of the GBSS, extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017; 68% Female; 42.3yr (16.5)]. The TV sample was obtained in response to a network programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice (n=6,876; 76% F, 36.4yr (13.3)]. Glasgow Science Centre data (n=256; 56% Female, 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the relationship between salivary alpha-amylase, sleep pressure and diurnal preference.[28] Finally, an RCT sample comprised 164 participants (72% F, 48.9yr (13.7)] recruited in February 2011 into a placebo-controlled evaluation of CBT for insomnia.[29]

Across our combined largest samples (GBSS, GBSS+, TV), women were slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs; $t(27638) = 7.94$, $p<.0001$] and the great majority was in average or better physical health (86%) and mental health (82%) [5-point scale: 0 ‘very good’, 1 ‘good’, 2 ‘average’, 3 ‘poor’, 4 ‘very

poor']. Around 57% screened positive for possible DSM-5 Insomnia Disorder.[27] These are not prevalence data as we did not adopt a formal population sampling approach. Nevertheless, the inevitable bias of these open access surveys towards those with sleep concerns does permit us a) to profile many respondents, against criteria;[27] b) to conduct powerful analyses of the properties of the SCI; and c) to make comparisons with sizeable cohorts of good sleepers. Respondents who made some use of prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr, $t(20813) = 19.6$, $p < .0001$]. A higher proportion took over-the-counter sleep aids (OTCs; 18.1%), and more than one-third of those taking sleeping pills also used OTCs.

Design and Measurement

This is a psychometric scale development study. Standard approaches to the appraisal of validity, reliability and sensitivity were applied, making appropriate selection amongst the available datasets. These methods and datasets will be introduced in an integrated way in subsequent sections, so that the research process can be more clearly expressed and understood.

RESULTS

Development of the Sleep Condition Indicator (SCI)

Content Validity

An 8-item scale was developed (see Appendix) based strictly upon DSM-5 recommendations.[6,7] The SCI comprised 2 quantitative items on sleep continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two quantitative items on severity [item 3: nights per week; item 8: duration of problem], and two qualitative items on attributed daytime consequences of poor sleep [item 5:

effects on mood, energy, or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)].

Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall asleep) served as responses for sleep continuity items 1 and 2.[7,24,25] Items 5 and 6 on daytime effects were derived by Principal Components Analysis (PCA; Varimax rotation) of six individual proposed DSM-5 impact areas, using combined datasets (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-Olkin (KMO=0.874) and Bartlett (p<.0001) statistics. Iteration converged after 3 rotations. A two component model explained 75.8% of variance. Component 1 (Eigenvalue=3.83; 63.8% of variance) comprised 'mood' (loading = .812) 'energy' (.651) and 'relationships' (.859), and was subsequently named 'personal functioning'. Component 2 (Eigenvalue=0.72; 12.0% of variance) comprised 'concentration' (.719), 'get through work' (.724), and 'stay awake' (.875) may be regarded as 'daytime performance'. PCA offered a relatively pure solution, although 'energy' also loaded significantly on component 2 (.519).

We then investigated the inter-relationships of our 8 SCI items. PCA with Varimax Rotation (KMO=0.888; Bartlett, p<.0001) yielded a two component solution (66.4% explained variance). Component 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2, 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616) and 'sleep-related impact' components (0.576).

Response format

Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range, reflecting threshold criteria for DSM-5 Insomnia Disorder (shaded area: see Appendix). The clinician can then see at a glance the profile of possible concerns. Possible total score ranges from 0 – 32, with higher values indicative of better sleep. However, scores can be readily transformed into a more intuitive 0 - 10 SCI range, either by dividing the total by 3.2, or by using an online version with automated scoring, which will shortly be available free of charge.

Concurrent Validity and association with related domains

Data from the Science Centre sample demonstrated that the SCI correlates inversely with the PSQI (r=-.734) and the ISI (r=-.793), suggesting measurement properties consistent with these related measures. In the GBSS and GBSS+ samples, the SCI of those taking prescribed sleeping pills or OTCs was lower (by 2.2 and 1.6 points respectively: equivalent to approximately 1.0 SD). There was also a small but significant association of sleep condition with self-rated physical health (r =.222), and an association also with mental health (r=.335). Using more specific measures, in the Science Centre sample, correlation of the SCI with symptoms of depression (r=-.426) and anxiety (r=-.400) on the Hospital Anxiety and Depression Scale[30] was modest, and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale[31]: depression (r=-.267), anxiety (r=-.236) and stress (r=-.263)].

Sensitivity/ Specificity of SCI

The GBSS dataset was used to investigate discriminant validity. Applying cut-offs of SCI ≤ 15 (on the 0-32 scaled version) and SCI ≤ 4.6 (on the 0–10 scaled version) correctly identified 92% of people scoring positive for minimal DSM-5 ID criteria (sensitivity),[27] whereas SCI > 16 and SCI > 4.6, respectively, correctly identified 87% of individuals who did not meet criteria.

Internal consistency

Cronbach's *α* for the GBSS sample was strong at 0.857 (range of *α-if-item-deleted* 0.822-0.860). Replication of these internal consistency data was obtained from the GBSS+ sample (*α*=0.865). Mean corrected item-total correlation was moderate (*r*=0.620) indicating substantial unique variance per item (shared variance = 38%).

Sensitivity to change

We evaluated sensitivity in our RCT.[29] Mean baseline to post-treatment change on the SCI was 3.24 (CI 2.64 to 3.83), and to 8-week post-treatment follow-up was 3.53 (CI 2.91 to 4.13), reflecting standardised ES of *d*=1.20 and *d*=1.11 in favour of CBT relative to TAU, and *d*=0.95 and *d*=0.77 relative to placebo.

Short-form version of the SCI

Although the SCI is brief, in clinical practice ultra short-form scales are often helpful (e.g. GAD-2).[32] Accordingly, we conducted a logistic regression analysis to determine which subset of items explained the greatest proportion of variance in the SCI total score. A two-item (SCI-02), comprising item 3 '…how many nights' (standardized ß = .515) and item 8 '… troubled you in general' (ß = .491) together predicted 82% of variance (Adjusted R^2 = .820) in the full scale SCI [R^2 change = .672 + .148; F(2,27637) = 62770, p < .0001]. The SCI-02 also correlated strongly with the SCI score total (*r* = .904). Applying ROC analyses, SCI-02 ≤ 3 (on the 0-8 scaled version) correctly identified 87% of people scoring positive for ID (sensitivity), whereas SCI-02 > 3 correctly identified 91% of individuals who did not meet DSM-5 criteria.

DISCUSSION

Neither patients nor physicians quite know what to do about insomnia.[33] It is a common subjective complaint, difficult to evaluate, and with no clear pathway for its management.[3,16,17] Despite the majority being unsure whether or not to mention it to their doctor,[34] twelve million prescriptions are written annually in the UK,[35] to doubtful benefit.[36-38] If insomnia were simply a transient blemish then all this might not matter. However, consistent with the fact that sleep, like oxygen, water and food, is crucial to effective functioning,[39] there is mounting evidence that poor sleep often becomes persistent,[8,9] and that persistent insomnia is detrimental to health and wellbeing.[10-13]

Pre-requisite to improved care is the availability, and regular use, of reliable and valid insomnia assessment. Only then can a clinical problem be recognised as distinct from normal variation, and a persistent problem be differentiated from a transient one. We have reported here the development and validation of the SCI; a DSM-5 compliant, brief screening measure that may be fit for such purposes. Importantly, the SCI items reflect the underlying complaint of insomnia; that is, concerns about sleep pattern and concerns about the impact of poor sleep, both of which need to be addressed in clinical practice. The SCI, at 8 items, is simple and quick to complete and, based on several sizable studies, it has very promising psychometric characteristics. The derived 2-item short-form version focuses upon the severity of the presenting complaint coupled with frequency of the sleep problem, so we would suggest that these might be the lead questions for a clinician to use in the context of their consulting room practice.

Of course, further work is required, particularly real world studies of how the SCI might be used in population screening and in the evaluation of outcome following an episode of care. Studies of predictive validity with reference to independent clinical evaluation of Insomnia Disorder would be welcome. Finally, it should be noted that the SCI does not contain specific questions relating to early morning awakenings

(EMA; premature awakening with inability to return to sleep) – a symptom which has recently been incorporated into DSM-5 criteria. However, to our knowledge, quantitative values for EMA are yet to be defined. To some extent, SCI item 2 on wakefulness during the night may capture this complaint, but we recommend that the clinician follows-up a 'positive' answer to locate the nature and temporal position of wakefulness during the sleep period.

Contributorship Statement

All authors engaged in the following study tasks:

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content; and

3) final approval of the version to be published.

Competing Interests

All authors have completed the ICMJE uniform disclosure form and declare: CE is Clinical and Scientific Director of Sleepio Ltd. and PH is co-founder, shareholder and board member of Sleepio Ltd. SK has acted as a consultant for Sleepio Ltd.

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Appendix: The Sleep Condition Indicator

	Score				
Item	4	3	2	1	0
Thinking about a typical night in the last month … 1. … how long does it take you to fall asleep?	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
2. … if you then wake up during the night … how long are you awake for in total? (add all the wakenings up)	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
3. … how many nights a week do you have a problem with your sleep?	0 - 1	2	3	4	5 - 7
4. … how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month, to what extent has poor sleep … 5. … affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6. … affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
7. … troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally … 8. … how long have you had a problem with your sleep?	I don't have a problem / < 1 mo	1 – 2 mo	3 – 6 mo	7 – 12 mo	> 1 yr

Scoring instructions:

a. Add the item scores to obtain the SCI total (minimum 0, maximum 32)
b. A higher score means better sleep
c. Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
d. Item scores in grey area represent threshold criteria for DSM-5 Insomnia Disorder

A free online version, with built-in score convertor, will shortly be available

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ABSTRACT

Objective: Describe the development and psychometric validation of a brief scale [The Sleep Condition Indicator (SCI)] to evaluate Insomnia Disorder in everyday clinical practice.

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Participants: 30,941 individuals (71% female) completed the SCI along with other descriptive demographic and clinical information.

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Results: The 8-item SCI (concerns about getting to sleep, remaining asleep, sleep quality, daytime personal functioning, daytime performance, duration of sleep problem, nights per week having a sleep problem, and extent troubled by poor sleep) had robust internal consistency (α ≥0.86) and showed convergent validity with the Pittsburgh Sleep Quality Index and Insomnia Severity Index.. Sensitivity to treatment outcome using CBT (relative) to placebo was demonstrated in a randomised trial (d=0.95). A 2-item short-form (SCI-02: nights per week having a sleep problem, extent troubled by poor sleep), derived using linear regression modelling, correlated strongly with the SCI total score (r=.90).

Conclusions: The SCI has potential as a clinical screening tool for appraising insomnia complaints against DSM-5 criteria.

STRENGTHS AND LIMITATIONS

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- While we have used large surveys and treatment evaluation to assess SCI properties, more work is required to assess predictive validity with reference to independent clinical evaluation of Insomnia Disorder.

INTRODUCTION

Although insomnia is the most common of all mental health complaints,[1] it is seldom adequately assessed and treatment services are often poor.[2,3] This perhaps reflects the perspective that insomnia is usually a symptom,[4] coupled with minimal medical education on sleep and its disorders.[5] However, there are three reasons why this perspective must now change. First, insomnia is not merely a symptom. It has for some time been proposed as a genuine diagnosis (see Harvey review),[6] and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.[7,8] Accordingly, DSM-5 now recommends that 'Insomnia Disorder' should be coded "*whenever diagnostic criteria are met whether or not there is a co-existing physical, mental or sleep disorder*".[9] Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,[10,11] constituting a risk factor for the development of physical and mental health problems, notably depression,[12-14] as well as adverse effects upon quality of life.[15] Chronic insomnia is also associated with high societal cost,[16] and is, for example, a robust predictor of work disability.[17] Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),[18,19] although the latter are very seldom available.[3,20]

Insomnia is ubiquitous[21] so it is important that clinicians, GPs in particular, have a reliable, valid, and brief, screening tool. A wide range of such instruments is a standard part of patient-centred care,[22] for example, for depression,[23] anxiety[24] and alcohol problems.[25] In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)[26] and the Insomnia Severity Index (ISI).[27] The PSQI is a an established research tool, which has a cut-off score indicative of sleep disturbance. However, it lacks specificity for insomnia. The ISI is very sound psychometrically, and is more specific and based on DSM-IV criteria for insomnia. It is used in the main to select people for clinical trials and as an outcome measure.

In this paper, we present a further measure (the Sleep Condition Indicator: SCI) that may have some useful features. The SCI is informed by the development phase for DSM-5 insomnia disorder,[7,8] coupled with published research diagnostic criteria[28] and recommended quantitative parameters for sleep disturbance.[29] In keeping with DSM-5, the SCI also evaluates associated daytime factors, which are important drivers of clinical complaint[21] and should be incorporated in insomnia measurement.[15,30] In terms of utility, the SCI is brief but versatile. It yields a) a dimensional perspective on sleep quality: on an intuitive, global scale where higher scores represent better sleep; b) a visual profile of night-time and daytime symptoms that the clinician can use in consultations; and c) indicative cut-off points for clinically-significant Insomnia. This paper summarises the development and evaluation of the SCI across several studies, and in doing so addresses two major questions. First, does the SCI have adequate psychometric properties?; and second, is it possible to derive an even briefer, short-form, SCI that has similar psychometric characteristics?

METHODS

Sample characteristics

Data are reported from five validation studies (total n=30,941; 71% Female) in which SCI items were administered. The Great British Sleep Survey (GBSS) was an open access, web-based survey completed by adults (18+yr.) with a UK postcode yielding data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between February 2010 and August 2011.[27] The GBSS+ was a revision of the GBSS, extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017; 68% Female; 42.3yr (16.5)]. The TV sample was obtained in response to a network programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice (n=6,876; 76% F, 36.4yr (13.3)]. Glasgow Science Centre data (n=256; 56% Female, 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the relationship between salivary alpha-amylase, sleep pressure and diurnal

preference.[28] Finally, an RCT sample comprised 164 participants (72% F, 48.9yr (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.[29] Ethical agreement concerning the latter two studies are provided in the source manuscripts. For the open access web surveys participation was covered by the site terms.

Across our combined largest samples (GBSS, GBSS+, TV), women were slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs; t(27638) = 7.94, p<.0001] and the great majority was in average or better physical health (86%) and mental health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very poor']. Around 57% screened positive for possible Insomnia Disorder.[31] These are not prevalence data as we did not adopt a formal population sampling approach. Nevertheless, the inevitable bias of these open access surveys towards those with sleep concerns does permit us a) to profile many respondents, against criteria; b) to conduct powerful analyses of the properties of the SCI; and c) to make comparisons with sizeable cohorts of good sleepers. Respondents who made some use of prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr, t(20813) = 19.6, p<.0001] and had a substantially poorer SCI score [8.56 (4.93) vs 15.6 (7.80), t(20813) = 38.8, p<.0001]. Of the total sample, 18.1% took over-the-counter sleep aids (OTCs), and more than one-third of those taking sleeping pills also used OTCs.

Design and Measurement

This is a psychometric scale development study. Standard approaches to the appraisal of validity, reliability and sensitivity were applied, making appropriate selection amongst the available datasets. These methods and datasets will be introduced in an integrated way in subsequent sections, so that the research process can be more clearly expressed and understood.

RESULTS

Development of the Sleep Condition Indicator (SCI)

Content Validity

An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft criteria that were available at the time (in 2010).[7,8] At that stage, a consultation process was underway and draft information was posted on the APA website. Consequently, the SCI items generated comprised 2 quantitative items on sleep continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two quantitative items on severity [item 3: nights per week; item 8: duration of problem], and two qualitative items on attributed daytime consequences of poor sleep [item 5: effects on mood, energy, or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)].

Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall asleep) served as responses for sleep continuity items 1 and 2.[8,28,29] Items 5 and 6 on daytime effects were derived by Principal Components Analysis (PCA; Varimax rotation) of six individual proposed DSM-5 impact areas, using combined datasets (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-Olkin (KMO=0.874) and Bartlett ($p<.0001$) statistics. Iteration converged after 3 rotations. A two component model (derived from inspection of the scree plot and a criterion for associated variance ≥ 10%) explained 75.8% of total variance, with item loadings ≥ .60. Component 1 (Eigenvalue=3.83; 63.8% of variance) comprised 'mood' (loading = .812) 'energy' (.651) and 'relationships' (.859), and was subsequently named 'personal functioning'. Component 2 (Eigenvalue=0.72; 12.0% of variance) comprised 'concentration' (.719), 'get through work' (.724), and 'stay awake' (.875) may be regarded as 'daytime performance'. PCA offered a relatively pure solution, although 'energy' also loaded significantly on component 2 (.519).

We then investigated the inter-relationships of our 8 SCI items using the same methodology, but applying this time a minimum item loading of 0.40, to permit incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett, p<.0001) yielded a two component solution (66.4% explained variance). Component 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2, 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616) and 'sleep-related impact' components (0.576).

Response format

Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range, reflecting threshold criteria for Insomnia Disorder (shaded area: see Appendix). The clinician can then see at a glance the profile of possible concerns. Possible total score ranges from 0–32, with higher values indicative of better sleep. However, scores can be readily transformed into a more intuitive 0-10 SCI range, either by dividing the total by 3.2, or by using an online version with automated scoring, which is available free of charge (www.sleepio.com/clinic/).

Concurrent Validity and association with related domains

Data from the Science Centre sample demonstrated that the SCI correlates inversely with the PSQI (r=-.734) and the ISI (r=-.793), suggesting measurement properties consistent with these related measures. There was also a small but significant association of sleep condition with self-rated physical health (r =.222), and an association also with mental health (r=.335). Using more specific measures, in the Science Centre sample, correlation of the SCI with symptoms of depression (r=-.426) and anxiety (r=-.400) on the Hospital Anxiety and Depression Scale[34] was modest,

and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale[35]: depression (*r*=-.267), anxiety (*r*=-.236) and stress (*r*=-.263)].

We have not at this stage tested the discriminant validity of the SCI against clinical diagnosis of insomnia disorder. As a first step, however, using our Science Centre sample, we were able to compare the discriminant ability of SCI score ≤16, reflecting minimum criteria for putative Insomnia Disorder (see appendix), with published ISI cut-off scores. We first categorized our sample according to ISI ranges (ISI score=0-14, reflecting "absence of insomnia" or "sub-threshold insomnia" [n=228] versus "moderate or severe insomnia" ISI score=15-28, n=27])[36] and conducted an independent *t*-test on SCI total score. Mean SCI values for the probable insomnia disorder category were 10.7 (SD=5.3) versus 22.9 (SD=6.2) for no insomnia disorder (*t*=9.86, *p*<.0001). Applying SCI cut-off ≤16, 89% of the sample were correctly identified as having probable insomnia disorder (ISI scores of ≥15), while SCI score of >16 correctly identified 82% of those with no insomnia disorder. These findings therefore suggest good discriminant validity for the SCI and help to confirm that a score of ≤16 on the SCI seems reasonable to detect possible insomnia disorder.

Internal consistency

Cronbach's *α* for the GBSS sample was strong at 0.857 (range of *α-if-item-deleted* 0.822-0.860). Replication of these internal consistency data was obtained from the GBSS+ sample (*α*=0.865). Mean corrected item-total correlation was moderate (*r*=0.620) indicating substantial unique variance per item (shared variance = 38%).

Sensitivity to change

We have previously reported that the SCI is sensitive as a measure of treatment outcome.[33]

Short-form version of the SCI

Although the SCI is brief, in clinical practice ultra short-form scales is often helpful (e.g. GAD-2).[37] Accordingly, we conducted a linear regression analysis to determine which subset of items (independent variables) explained the greatest proportion of variance in the dependent variable, SCI total score. A two-item (SCI-02), comprising item 3 '…how many nights' (standardized ß = .515) and item 8 '… troubled you in general' (ß = .491) together predicted 82% of variance (Adjusted R^2 = .820) in the full scale SCI [R^2 change = .672 + .148; F(2,27637) = 62770, p < .0001]. As a check on the independence of residuals we computed the Durbin-Watson statistic, which was found to be 1.80, suggesting no serial correlation. The SCI-02 also correlated strongly with the SCI score total (r = .904).

DISCUSSION

Pre-requisite to improved insomnia care is the availability and regular use of reliable and valid insomnia assessment. Only then can a clinical problem be recognised as distinct from normal variation, and a persistent problem be differentiated from a transient one. We have reported here the development and preliminary validation of the SCI; a DSM-5 compliant, brief screening measure that may be fit for such purposes. Results indicate that the SCI is internally consistent, sensitive to change, and correlates strongly with established screening instruments, known to be sensitive to clinical insomnia (PSQI and ISI). Principal components analysis revealed a 2-component solution (66% of the variance), reflecting the underlying complaint of insomnia; that is, concerns about sleep pattern and concerns about the impact of poor sleep, both of which need to be addressed in clinical practice. The derived 2-item short-form version, focusing on the severity of the presenting complaint coupled with frequency of the sleep problem, correlated

strongly with total SCI score and we would suggest that these might be the lead questions for a clinician to use in the context of their consulting room practice.

Of course, further work is required, particularly real world studies of how the SCI might be used in population screening and in the evaluation of outcome following an episode of care. While comparisons with ISI cut-offs suggest good discriminant ability of the SCI to detect probable insomnia disorder (score ≤16), studies of predictive validity with reference to independent clinical evaluation of Insomnia Disorder are essential before firm conclusions can be made. Furthermore, it should be noted that the SCI does not contain specific questions relating to early morning awakenings (EMA; premature awakening with inability to return to sleep) – a symptom which has recently been incorporated into DSM-5 criteria. While established insomnia questionnaires, including the ISI[27] and Athens Insomnia Scale[37] probe perceived severity of EMA,, quantitative values for EMA, to our knowledge, are yet to be defined. To some extent, SCI item 2 on wakefulness during the night may capture this complaint, but we recommend that the clinician follows-up a 'positive' answer to locate the nature and temporal position of wakefulness during the sleep period. Moreover, other core DSM-5 criteria do not feature as SCI items (e.g. the sleep difficulty occurs despite adequate opportunity for sleep; the insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder; and the insomnia is not attributable to the physiological effects of a substance). However, these items are not easy to probe unambiguously with a self-completed psychometric instrument and would require careful scrutiny by a treating clinician. Thus, the SCI should be viewed as a screening tool, consistent with features of DSM-5, but requiring careful follow-up in clinical practice.

CONTRIBUTORSHIP STATEMENT

All authors engaged in the following study tasks: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be publishe

DATA SHARING STATEMENT

N/A

COMPETING INTERESTS

All authors have completed the ICMJE uniform disclosure form and declare: CE is Clinical and Scientific Director of Sleepio Ltd. and PH is co-founder, shareholder and board member of Sleepio Ltd. SK has acted as a consultant for Sleepio Ltd.

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Appendix: The Sleep Condition Indicator

	Score				
Item	4	3	2	1	0
Thinking about a typical night in the last month … 1. … how long does it take you to fall asleep?	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
2. … if you then wake up during the night … how long are you awake for in total? (add all the wakenings up)	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
3. … how many nights a week do you have a problem with your sleep?	0 - 1	2	3	4	5 - 7
4. … how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month, to what extent has poor sleep … 5. … affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6. … affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
7. … troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally … 8. … how long have you had a problem with your sleep?	I don't have a problem / < 1 mo	1 – 2 mo	3 – 6 mo	7 – 12 mo	> 1 yr

Scoring instructions:

a. Add the item scores to obtain the SCI total (minimum 0, maximum 32)
b. A higher score means better sleep
c. Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
d. Item scores in grey area represent threshold criteria for Insomnia Disorder

A free online version, with built-in score convertor can be found at www.sleepio.com/clinic

The Sleep Condition Indicator: a clinical screening tool to evaluate Insomnia Disorder

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Key words: insomnia, assessment, patient outcomes, DSM-5, psychometric, scale

ABSTRACT

Objective: Describe the development and psychometric validation of a brief scale [The Sleep Condition Indicator (SCI)] to evaluate Insomnia Disorder in everyday clinical practice.

Design: The SCI was evaluated across five studies, including large scale surveys and a placebo-controlled trial of Cognitive Behavioural Therapy (CBT) for insomnia. Content validity, internal consistency, ~~sensitivity and specificity,~~ concurrent validity, and responsiveness to change were investigated.

Participants: 30,941 individuals (71% female) completed the SCI along with other descriptive demographic and clinical information.

Setting: Data acquired on dedicated web-sites.

Results: The 8-item SCI (concerns about getting to sleep, remaining asleep, sleep quality, daytime personal functioning, daytime performance, duration of sleep problem, nights per week having a sleep problem, and extent troubled by poor sleep) had robust internal consistency (α ≥0.86) and showed convergent validity with the Pittsburgh Sleep Quality Index and Insomnia Severity Index.~~, and 92% sensitivity (SCI score ≤ 4.6) / 87% specificity (SCI score >15) for Insomnia Disorder~~. Sensitivity to treatment outcome using CBT (relative) to placebo was demonstrated in a randomised trial (*d*=0.95). A 2-item short-form (SCI-02: nights per week having a sleep problem, extent troubled by poor sleep), derived using linear~~egistic~~ regression modelling, correlated strongly with the SCI total score (*r*=.90).

Conclusions: The SCI has potential as a clinical screening tool for appraising insomnia complaints against DSM-5 criteria.

STRENGTHS AND LIMITATIONS

- Existing instruments used to evaluate insomnia lack specificity or do not permit assessment against the latest diagnostic criteria. This study describes the development and validation of a new instrument (the sleep condition indicator) for use in everyday clinical practice. The SCI is valid, reliable and sensitive to change in insomnia severity. Its brevity and appealing visual format permit rapid assessment and interpretation of poor sleep, against contemporary clinical diagnostic criteria.
- While we have used large surveys and treatment evaluation to assess SCI properties, more work is required to assess predictive validity with reference to independent clinical evaluation of Insomnia Disorder.

INTRODUCTION

Although insomnia is the most common of all mental health complaints,[1] it is seldom adequately assessed and treatment services are often poor.[2,3] This perhaps reflects the perspective that insomnia is usually a symptom,[4] coupled with minimal medical education on sleep and its disorders.[5] However, there are three reasons why this perspective must now change. First, insomnia is not merely a symptom. It has for some time been proposed as a genuine diagnosis (see Harvey review),[6] and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.[7,8] Accordingly, DSM-5 now recommends that 'Insomnia Disorder' should be coded "*whenever diagnostic criteria are met whether or not there is a co-existing physical, mental or sleep disorder*".[9] Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,[10,11] constituting a risk factor for the development of physical and mental health problems, notably depression,[12-14] as well as adverse effects upon quality of life.[15] Chronic insomnia is also associated with high societal cost,[16] and is, for example, a robust predictor of work disability.[17] Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),[18,19] although the latter are very seldom available.[3,20]

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This is a psychometric scale development study. Standard approaches to the appraisal of validity, reliability and sensitivity were applied, making appropriate selection amongst the available datasets. These methods and datasets will be introduced in an integrated way in subsequent sections, so that the research process can be more clearly expressed and understood.

RESULTS

Development of the Sleep Condition Indicator (SCI)

Content Validity

An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft criteria that were available at the time (in 2010).[7,8] At that stage, a consultation process was underway and draft information was posted on the APA website. Consequently, the SCI items generated comprised 2 quantitative items on sleep continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two quantitative items on severity [item 3: nights per week; item 8: duration of problem], and two qualitative items on attributed daytime consequences of poor sleep [item 5: effects on mood, energy, or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)].

Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall asleep) served as responses for sleep continuity items 1 and 2.[8,28,29] Items 5 and 6 on daytime effects were derived by Principal Components Analysis (PCA; Varimax rotation) of six individual proposed DSM-5 impact areas, using combined datasets (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-Olkin (KMO=0.874) and Bartlett ($p<.0001$) statistics. Iteration converged after 3 rotations. A two component model (derived from inspection of the scree plot and a criterion for associated variance ≥ 10%) explained 75.8% of total variance, with item loadings ≥ .60. Component 1 (Eigenvalue=3.83; 63.8% of variance) comprised 'mood' (loading = .812) 'energy' (.651) and 'relationships' (.859), and was subsequently named 'personal functioning'. Component 2 (Eigenvalue=0.72; 12.0% of variance) comprised 'concentration' (.719), 'get through work' (.724), and 'stay awake' (.875) may be regarded as 'daytime performance'. PCA offered a relatively pure solution, although 'energy' also loaded significantly on component 2 (.519).

We then investigated the inter-relationships of our 8 SCI items using the same methodology, but applying this time a minimum item loading of 0.40, to permit incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett, p<.0001) yielded a two component solution (66.4% explained variance). Component 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2, 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616) and 'sleep-related impact' components (0.576).

Response format

Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range, reflecting threshold criteria for Insomnia Disorder (shaded area: see Appendix). The clinician can then see at a glance the profile of possible concerns. Possible total score ranges from 0–32, with higher values indicative of better sleep. However, scores can be readily transformed into a more intuitive 0-10 SCI range, either by dividing the total by 3.2, or by using an online version with automated scoring, which is available free of charge (www.sleepio.com/clinic/).

Concurrent Validity and association with related domains

Data from the Science Centre sample demonstrated that the SCI correlates inversely with the PSQI (r=-.734) and the ISI (r=-.793), suggesting measurement properties consistent with these related measures. There was also a small but significant association of sleep condition with self-rated physical health (r =.222), and an association also with mental health (r=.335). Using more specific measures, in the Science Centre sample, correlation of the SCI with symptoms of depression (r=-.426) and anxiety (r=-.400) on the Hospital Anxiety and Depression Scale[34] was modest,

and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale[35]: depression (*r*=-.267), anxiety (*r*=-.236) and stress (*r*=-.263)].

~~*Sensitivity/ Specificity of SCI*~~

We have not at this stage tested the discriminant validity of the SCI against clinical diagnosis of insomnia disorder. As a first step, however, ~~we have used our GBSS dataset to propose possible thresholds for insomnia. Applying cut offs of SCI ≤ 15 (on the 0-32 scaled version) and SCI ≤ 4.6 (on the 0-10 scaled version) correctly identified 92% of people scoring positive against the DSM-5 draft criteria (sensitivity),[31] whereas SCI > 16 and SCI > 4.6, respectively, correctly identified 87% of individuals who would appear not to meet these criteria.~~ and sUusing our Science Centre sample, we were ~~also~~ able to compare the discriminant ability of SCI score ≤16, reflecting minimum criteria for putative Insomnia Disorder (see appendix), ~~these cut offs~~ with published ISI cut-off scores. We first categorized our sample according to ISI ranges (ISI score=0-14, reflecting "absence of insomnia" or "sub-threshold insomnia" [n=228] versus "moderate or severe insomnia" ISI score=15-28, n=27])[36] and conducted an independent *t*-test on SCI total score. Mean SCI values for the probable insomnia disorder category were 10.7 (SD=5.3) versus 22.9 (SD=6.2) for no insomnia disorder (*t*=9.86, *p*<.0001). Applying SCI cut-off ≤16, 89% of the sample were correctly identified as having probable insomnia disorder (ISI scores of ≥15), while SCI score of >16 correctly identified 82% of those with no insomnia disorder. These findings therefore suggest good discriminant validity for the SCI and help to confirm that a score of ≤16 on the SCI seems reasonable to detect possible insomnia disorder.

Internal consistency

Cronbach's *α* for the GBSS sample was strong at 0.857 (range of *α-if-item-deleted* 0.822-0.860). Replication of these internal consistency data was obtained from the

GBSS+ sample (α=0.865). Mean corrected item-total correlation was moderate (r=0.620) indicating substantial unique variance per item (shared variance = 38%).

Sensitivity to change

We have previously reported that the SCI is sensitive as a measure of treatment outcome.[33]

Short-form version of the SCI

Although the SCI is brief, in clinical practice ultra short-form scales is often helpful (e.g. GAD-2).[37] Accordingly, we conducted a linear regression analysis to determine which subset of items (independent variables) explained the greatest proportion of variance in the dependent variable, SCI total score. A two-item (SCI-02), comprising item 3 '…how many nights' (standardized ß = .515) and item 8 '… troubled you in general' (ß = .491) together predicted 82% of variance (Adjusted R^2 = .820) in the full scale SCI [R^2 change = .672 + .148; F(2,27637) = 62770, p < .0001]. As a check on the independence of residuals we computed the Durbin-Watson statistic, which was found to be 1.80, suggesting no serial correlation. The SCI-02 also correlated strongly with the SCI score total (r = .904).

~~Applying ROC analyses, SCI-02 ≤ 3 (on the 0-8 scaled version) correctly identified 87% of people scoring positive for ID (sensitivity), whereas SCI-02 > 3 correctly identified 91% of individuals who did not meet draft DSM-5 criteria.~~

DISCUSSION

~~Neither patients nor physicians quite know what to do about insomnia.[38] It is a common subjective complaint, difficult to evaluate, and with no clear pathway for its management.[3,16,17] Despite the majority being unsure whether or not to mention it to their doctor,[39] twelve million prescriptions are written annually in the UK,[40] to doubtful~~

benefit.[41-43] If insomnia were simply a transient blemish then all this might not matter. However, consistent with the fact that sleep, like oxygen, water and food, is crucial to effective functioning,[44] there is mounting evidence that poor sleep often becomes persistent,[10,11] and that persistent insomnia is detrimental to health and wellbeing.[12-15]

Pre-requisite to improved insomnia care is the availability and regular use of reliable and valid insomnia assessment. Only then can a clinical problem be recognised as distinct from normal variation, and a persistent problem be differentiated from a transient one. We have reported here the development and preliminary validation of the SCI; a DSM-5 compliant, brief screening measure that may be fit for such purposes. Results indicate that the SCI is internally consistent, sensitive to change, and correlates strongly with established screening instruments, known to be sensitive to clinical insomnia (PSQI and ISI). Principal components analysis revealed a 2-component solution (66% of the variance),Importantly, the SCI items reflecting the underlying complaint of insomnia; that is, concerns about sleep pattern and concerns about the impact of poor sleep, both of which need to be addressed in clinical practice. The SCI, at 8 items, is simple and quick to complete and, based on several sizable studies, it has very promising psychometric characteristics. The derived 2-item short-form version, focusinges upon the severity of the presenting complaint coupled with frequency of the sleep problem, correlated strongly with total SCI score andso we would suggest that these might be the lead questions for a clinician to use in the context of their consulting room practice.

Of course, further work is required, particularly real world studies of how the SCI might be used in population screening and in the evaluation of outcome following an episode of care. While comparisons with ISI cut-offs suggest good discriminant ability of the SCI to detect probable insomnia disorder (score ≤16), sStudies of predictive validity with reference to independent clinical evaluation of Insomnia Disorder are essential necessary before firm conclusions can be madewould be welcome. Furthermore, Finally, iIt should be noted that the SCI does not contain

specific questions relating to early morning awakenings (EMA; premature awakening with inability to return to sleep) – a symptom which has recently been incorporated into DSM-5 criteria. While established insomnia questionnaires, including the ISI[27] and Athens Insomnia Scale[37] probe perceived severity of EMA, ~~However, to our knowledge~~, quantitative values for EMA, to our knowledge, are yet to be defined. To some extent, SCI item 2 on wakefulness during the night may capture this complaint, but we recommend that the clinician follows-up a 'positive' answer to locate the nature and temporal position of wakefulness during the sleep period. Moreover, other core DSM-5 criteria do not feature as SCI items (e.g. the sleep difficulty occurs despite adequate opportunity for sleep; the insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder; and the insomnia is not attributable to the physiological effects of a substance). However, these items are not easy to probe unambiguously with a self-completed psychometric instrument~~tool~~ and would require careful scrutiny by a treating clinician. Thus, the SCI should be viewed as a screening tool, consistent with features of DSM-5, but requiring careful follow-up in clinical practice.

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Appendix: The Sleep Condition Indicator

	Score				
Item	4	3	2	1	0
Thinking about a typical night in the last month … 1. … how long does it take you to fall asleep?	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
2. … if you then wake up during the night … how long are you awake for in total? (add all the wakenings up)	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
3. … how many nights a week do you have a problem with your sleep?	0 - 1	2	3	4	5 - 7
4. … how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month, to what extent has poor sleep … 5. … affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6. … affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
7. … troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally … 8. … how long have you had a problem with your sleep?	I don't have a problem / < 1 mo	1 – 2 mo	3 – 6 mo	7 – 12 mo	> 1 yr

Scoring instructions:

a. Add the item scores to obtain the SCI total (minimum 0, maximum 32)
b. A higher score means better sleep
c. Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
d. Item scores in grey area represent threshold criteria for Insomnia Disorder

A free online version, with built-in score convertor can be found at www.sleepio.com/clinic

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The Sleep Condition Indicator: a clinical screening tool to evaluate Insomnia Disorder

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Key words: insomnia, assessment, patient outcomes, DSM-5, psychometric, scale

ABSTRACT

Objective: Describe the development and psychometric validation of a brief scale [The Sleep Condition Indicator (SCI)] to evaluate Insomnia Disorder in everyday clinical practice.

Design: The SCI was evaluated across five study samples..Content validity, internal consistency and concurrent validity were investigated.

Participants: 30,941 individuals (71% female) completed the SCI along with other descriptive demographic and clinical information.

Setting: Data acquired on dedicated web-sites.

Results: The 8-item SCI (concerns about getting to sleep, remaining asleep, sleep quality, daytime personal functioning, daytime performance, duration of sleep problem, nights per week having a sleep problem, and extent troubled by poor sleep) had robust internal consistency (α ≥0.86) and showed convergent validity with the Pittsburgh Sleep Quality Index and Insomnia Severity Index.. A 2-item short-form (SCI-02: nights per week having a sleep problem, extent troubled by poor sleep), derived using linear regression modelling, correlated strongly with the SCI total score (r=.90).

Conclusions: The SCI has potential as a clinical screening tool for appraising insomnia complaints against DSM-5 criteria.

STRENGTHS AND LIMITATIONS

- Existing instruments used to evaluate insomnia lack specificity or do not permit assessment against the latest diagnostic criteria. This study describes the development and validation of a new instrument (the sleep condition indicator) for use in everyday clinical practice. The SCI is valid, reliable and sensitive to change in insomnia severity. Its brevity and appealing visual format permit rapid assessment and interpretation of poor sleep, against contemporary clinical diagnostic criteria.
- While we have used large surveys and treatment evaluation to assess SCI properties, more work is required to assess predictive validity with reference to independent clinical evaluation of Insomnia Disorder.

INTRODUCTION

Although insomnia is the most common of all mental health complaints,[1] it is seldom adequately assessed and treatment services are often poor.[2,3] This perhaps reflects the perspective that insomnia is usually a symptom,[4] coupled with minimal medical education on sleep and its disorders.[5] However, there are three reasons why this perspective must now change. First, insomnia is not merely a symptom. It has for some time been proposed as a genuine diagnosis (see Harvey review),[6] and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.[7,8] Accordingly, DSM-5 now recommends that 'Insomnia Disorder' should be coded "*whenever diagnostic criteria are met whether or not there is a co-existing physical, mental or sleep disorder*".[9] Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,[10,11] constituting a risk factor for the development of physical and mental health problems, notably depression,[12-14] as well as adverse effects upon quality of life.[15] Chronic insomnia is also associated with high societal cost,[16] and is, for example, a robust predictor of work disability.[17] Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),[18,19] although the latter are very seldom available.[3,20]

Insomnia is ubiquitous[21] so it is important that clinicians, GPs in particular, have a reliable, valid, and brief, screening tool. A wide range of such instruments is a standard part of patient-centred care,[22] for example, for depression,[23] anxiety[24] and alcohol problems.[25] In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)[26] and the Insomnia Severity Index (ISI).[27] The PSQI is a an established research tool, which has a cut-off score indicative of sleep disturbance. However, it lacks specificity for insomnia. The ISI is very sound psychometrically, and is more specific and based on DSM-IV criteria for insomnia. It is used in the main to select people for clinical trials and as an outcome measure.

In this paper, we present a further measure (the Sleep Condition Indicator: SCI) that may have some useful features. The SCI is informed by the development phase for DSM-5 insomnia disorder,[7,8] coupled with published research diagnostic criteria[28] and recommended quantitative parameters for sleep disturbance.[29] In keeping with DSM-5, the SCI also evaluates associated daytime factors, which are important drivers of clinical complaint[21] and should be incorporated in insomnia measurement.[15,30] In terms of utility, the SCI is brief but versatile. It yields a) a dimensional perspective on sleep quality: on an intuitive, global scale where higher scores represent better sleep; b) a visual profile of night-time and daytime symptoms that the clinician can use in consultations; and c) indicative cut-off points for clinically-significant Insomnia. This paper summarises the development and evaluation of the SCI across several studies, and in doing so addresses two major questions. First, does the SCI have adequate psychometric properties?; and second, is it possible to derive an even briefer, short-form, SCI that has similar psychometric characteristics?

METHODS

Sample characteristics

Data are reported from five validation studies (total n=30,941; 71% Female) in which SCI items were administered. The Great British Sleep Survey (GBSS) was an open access, web-based survey completed by adults (18+yr.) with a UK postcode yielding data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between February 2010 and August 2011.[31] The GBSS+ was a revision of the GBSS, extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017; 68% Female; 42.3yr (16.5)]. The TV sample was obtained in response to a network programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice (n=6,876; 76% F, 36.4yr (13.3)]. Glasgow Science Centre data (n=256; 56% Female, 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the relationship between salivary alpha-amylase, sleep pressure and diurnal

preference.[32] Finally, an RCT sample comprised 164 participants (72% F, 48.9yr (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.[33] Ethical agreement concerning the latter two studies are provided in the source manuscripts. For the open access web surveys participation was covered by the site terms.

Across our combined largest samples (GBSS, GBSS+, TV), women were slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs; t(27638) = 7.94, p<.0001] and the great majority was in average or better physical health (86%) and mental health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very poor']. Respondents who made some use of prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr, t(20813) = 19.6, p<.0001] and had a substantially poorer SCI score [8.56 (4.93) vs 15.6 (7.80), t(20813) = 38.8, p<.0001]. Of the total sample, 18.1% took over-the-counter sleep aids (OTCs), and more than one-third of those taking sleeping pills also used OTCs.

Design and Measurement

This is a psychometric scale development study. Standard approaches to the appraisal of validity, reliability and sensitivity were applied, making appropriate selection amongst the available datasets. These methods and datasets will be introduced in an integrated way in subsequent sections, so that the research process can be more clearly expressed and understood.

RESULTS

Development of the Sleep Condition Indicator (SCI)

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An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft criteria that were available at the time (in 2010).[7,8] At that stage, a consultation process was underway and draft information was posted on the APA website.

Consequently, the SCI items generated comprised 2 quantitative items on sleep continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two quantitative items on severity [item 3: nights per week; item 8: duration of problem], and two qualitative items on attributed daytime consequences of poor sleep [item 5: effects on mood, energy, or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)].

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Data from the Science Centre sample demonstrated that the SCI correlates inversely with the PSQI (r=-.734) and the ISI (r=-.793), suggesting measurement properties consistent with these related measures. There was also a small but significant association of sleep condition with self-rated physical health (r =.222), and an association also with mental health (r=.335). Using more specific measures, in the Science Centre sample, correlation of the SCI with symptoms of depression (r=-.426) and anxiety (r=-.400) on the Hospital Anxiety and Depression Scale[34] was modest, and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale[35]: depression (r=-.267), anxiety (r=-.236) and stress (r=-.263)].

We have not at this stage tested the discriminant validity of the SCI against clinical diagnosis of insomnia disorder. As a first step, however, using our Science Centre sample, we tested the concurrent validity of SCI cut-offs (score ≤16), reflecting minimum criteria for putative Insomnia Disorder (see appendix), against published

validated ISI cut-off scores. We first categorized our sample according to ISI ranges (ISI score=0-14, reflecting "no insomnia disorder"" [n=228] versus "probable insomnia disorder"" ISI score=15-28, n=27]) and conducted an independent *t*-test on SCI total score. Mean SCI values for the "probable insomnia disorder" category were 10.7 (SD=5.3) versus 22.9 (SD=6.2) for "no insomnia disorder" (*t*=9.86, *p*<.0001). Applying SCI cut-off ≤16, 89% of the sample were correctly identified as having "probable insomnia disorder" (ISI scores of ≥15), while SCI score of >16 correctly identified 82% of those with "no insomnia disorder". These findings provide further evidence of concurrent validity for the SCI and help to confirm that a score of ≤16 on the SCI seems reasonable to detect possible insomnia disorder.

Internal consistency

Cronbach's *α* for the GBSS sample was strong at 0.857 (range of *α-if-item-deleted* 0.822-0.860). Replication of these internal consistency data was obtained from the GBSS+ sample (*α*=0.865). Mean corrected item-total correlation was moderate (*r*=0.620) indicating substantial unique variance per item (shared variance = 38%).

Sensitivity to change

We have previously reported that the SCI is sensitive as a measure of treatment outcome.[33]

Short-form version of the SCI

Although the SCI is brief, in clinical practice ultra short-form scales is often helpful (e.g. GAD-2).[36] Accordingly, we conducted a stepwise linear regression analysis to determine which subset of items (independent variables) explained the greatest proportion of variance in the dependent variable, SCI total score. A two-item (SCI-02), comprising item 3 '…how many nights' (standardized ß = .515) and item 7 '… troubled you in general' (ß = .491) together predicted 82% of variance (Adjusted R^2 =

.820) in the full scale SCI [R^2 change = .672 + .148; F(2,27637) = 62770, p < .0001]. As a check on the independence of residuals we computed the Durbin-Watson statistic, which was found to be 1.80, suggesting no serial correlation. The SCI-02 also correlated strongly with the SCI score total (r = .904).

DISCUSSION

Pre-requisite to improved insomnia care is the availability and regular use of reliable and valid insomnia assessment. Only then can a clinical problem be recognised as distinct from normal variation, and a persistent problem be differentiated from a transient one. We have reported here the development and preliminary validation of the SCI; a DSM-5 compliant, brief screening measure that may be fit for such purposes. Results indicate that the SCI is internally consistent, sensitive to change, and correlates strongly with established screening instruments, known to be sensitive to clinical insomnia (PSQI and ISI). Principal components analysis revealed a 2-component solution (66% of the variance), reflecting the underlying complaint of insomnia; that is, concerns about sleep pattern and concerns about the impact of poor sleep, both of which need to be addressed in clinical practice. The derived 2-item short-form version, focusing on the severity of the presenting complaint coupled with frequency of the sleep problem, correlated strongly with total SCI score and we would suggest that these might be the lead questions for a clinician to use in the context of their consulting room practice.

Of course, further work is required, particularly real world studies of how the SCI might be used in population screening and in the evaluation of outcome following an episode of care. While comparisons with ISI cut-offs provide evidence of concurrent validity and indicate that SCI score ≤16 may help detect probable insomnia disorder, studies of predictive validity with reference to independent clinical

evaluation of Insomnia Disorder (the gold standard), are essential before firm conclusions can be made.

It should be noted that over half of respondents to our online surveys, screened positive for possible Insomnia Disorder. These, of course, are not prevalence data as we did not adopt a formal population sampling approach. Nevertheless, the inevitable bias of these open access surveys towards those with sleep concerns does permit us a) to profile many respondents, against criteria; b) to conduct powerful analyses of the properties of the SCI; and c) to make comparisons with sizeable cohorts of good sleepers. Importantly, for our Science Centre sample, approximately 10% scored in the probable insomnia disorder range (ISI score ≥15), consistent with prevalence data,[2] providing further support for our ISI-SCI concurrent validity analysis.

Furthermore, a limitation of the SCI is that it does not contain specific questions relating to early morning awakenings (EMA; premature awakening with inability to return to sleep) – a symptom which has recently been incorporated into DSM-5 criteria. While established insomnia questionnaires, including the ISI[27] and Athens Insomnia Scale[37] probe perceived severity of EMA, quantitative values for EMA, to our knowledge, are yet to be defined. To some extent, SCI item 2 on wakefulness during the night may capture this complaint, but we recommend that the clinician follows-up a 'positive' answer to locate the nature and temporal position of wakefulness during the sleep period. Moreover, other core DSM-5 criteria do not feature as SCI items (e.g. the sleep difficulty occurs despite adequate opportunity for sleep; the insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder; and the insomnia is not attributable to the physiological effects of a substance). However, these items are not easy to probe unambiguously with a self-completed psychometric instrument and would require careful scrutiny by a treating clinician. It is, of course, possible that sleep disorders other than insomnia (e.g. circadian rhythm sleep disorders, sleep-breathing

disorders) may also lead to low scores on the SCI. Thus the SCI should be viewed as an insomnia screening tool, consistent with features of DSM-5, but requiring careful follow-up in clinical practice to fully define the nature of sleep disturbance.

Contributorship Statement

All authors have completed the ICMJE uniform disclosure form and declare: CE is Clinical and Scientific Director of Sleepio Ltd. and PH is co-founder, shareholder and board member of Sleepio Ltd. SK has acted as a consultant for Sleepio Ltd.

Competing Interests

All authors engaged in the following study tasks: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published.

Data Sharing Statement

N/A

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The Sleep Condition Indicator: a clinical screening tool to evaluate Insomnia Disorder

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Key words: insomnia, assessment, patient outcomes, DSM-5, psychometric, scale

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ABSTRACT

Objective: Describe the development and psychometric validation of a brief scale [The Sleep Condition Indicator (SCI)] to evaluate Insomnia Disorder in everyday clinical practice.

Design: The SCI was evaluated across five study samples.~~ies, including large-scale surveys, and a placebo-controlled trial of Cognitive-Behavioural Therapy (CBT) for insomnia~~.~~—~~Content validity, internal consistency and~~,~~ concurrent validity~~ , ~~, and responsiveness to change~~ were investigated.

Participants: 30,941 individuals (71% female) completed the SCI along with other descriptive demographic and clinical information.

Setting: Data acquired on dedicated web-sites.

Results: The 8-item SCI (concerns about getting to sleep, remaining asleep, sleep quality, daytime personal functioning, daytime performance, duration of sleep problem, nights per week having a sleep problem, and extent troubled by poor sleep) had robust internal consistency (α ≥0.86) and showed convergent validity with the Pittsburgh Sleep Quality Index and Insomnia Severity Index.~~. Sensitivity to treatment outcome using CBT (relative) to placebo was demonstrated in a randomised trial (*d*=0.95)~~. A 2-item short-form (SCI-02: nights per week having a sleep problem, extent troubled by poor sleep), derived using linear regression modelling, correlated strongly with the SCI total score (*r*=.90).

Conclusions: The SCI has potential as a clinical screening tool for appraising insomnia complaints against DSM-5 criteria.

STRENGTHS AND LIMITATIONS

- Existing instruments used to evaluate insomnia lack specificity or do not permit assessment against the latest diagnostic criteria. This study describes the development and validation of a new instrument (the sleep condition indicator) for use in everyday clinical practice. The SCI is valid, reliable and sensitive to change in insomnia severity. Its brevity and appealing visual format permit rapid assessment and interpretation of poor sleep, against contemporary clinical diagnostic criteria.
- While we have used large surveys and treatment evaluation to assess SCI properties, more work is required to assess predictive validity with reference to independent clinical evaluation of Insomnia Disorder.

INTRODUCTION

Although insomnia is the most common of all mental health complaints,[1] it is seldom adequately assessed and treatment services are often poor.[2,3] This perhaps reflects the perspective that insomnia is usually a symptom,[4] coupled with minimal medical education on sleep and its disorders.[5] However, there are three reasons why this perspective must now change. First, insomnia is not merely a symptom. It has for some time been proposed as a genuine diagnosis (see Harvey review),[6] and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.[7,8] Accordingly, DSM-5 now recommends that 'Insomnia Disorder' should be coded "*whenever diagnostic criteria are met whether or not there is a co-existing physical, mental or sleep disorder*".[9] Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,[10,11] constituting a risk factor for the development of physical and mental health problems, notably depression,[12-14] as well as adverse effects upon quality of life.[15] Chronic insomnia is also associated with high societal cost,[16] and is, for example, a robust predictor of work disability.[17] Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),[18,19] although the latter are very seldom available.[3,20]

Insomnia is ubiquitous[21] so it is important that clinicians, GPs in particular, have a reliable, valid, and brief, screening tool. A wide range of such instruments is a standard part of patient-centred care,[22] for example, for depression,[23] anxiety[24] and alcohol problems.[25] In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)[26] and the Insomnia Severity Index (ISI).[27] The PSQI is a an established research tool, which has a cut-off score indicative of sleep disturbance. However, it lacks specificity for insomnia. The ISI is very sound

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psychometrically, and is more specific and based on DSM-IV criteria for insomnia. It is used in the main to select people for clinical trials and as an outcome measure.

In this paper, we present a further measure (the Sleep Condition Indicator: SCI) that may have some useful features. The SCI is informed by the development phase for DSM-5 insomnia disorder,[7,8] coupled with published research diagnostic criteria[28] and recommended quantitative parameters for sleep disturbance.[29] In keeping with DSM-5, the SCI also evaluates associated daytime factors, which are important drivers of clinical complaint[21] and should be incorporated in insomnia measurement.[15,30] In terms of utility, the SCI is brief but versatile. It yields a) a dimensional perspective on sleep quality: on an intuitive, global scale where higher scores represent better sleep; b) a visual profile of night-time and daytime symptoms that the clinician can use in consultations; and c) indicative cut-off points for clinically-significant Insomnia. This paper summarises the development and evaluation of the SCI across several studies, and in doing so addresses two major questions. First, does the SCI have adequate psychometric properties?; and second, is it possible to derive an even briefer, short-form, SCI that has similar psychometric characteristics?

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METHODS

Sample characteristics

Data are reported from five validation studies (total n=30,941; 71% Female) in which SCI items were administered. The Great British Sleep Survey (GBSS) was an open access, web-based survey completed by adults (18+yr.) with a UK postcode yielding data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between February 2010 and August 2011.[31] The GBSS+ was a revision of the GBSS, extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017; 68% Female; 42.3yr (16.5)]. The TV sample was obtained in response to a network programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice (n=6,876; 76% F, 36.4yr (13.3)]. Glasgow Science Centre data (n=256; 56% Female,

40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the relationship between salivary alpha-amylase, sleep pressure and diurnal preference.[28,32] Finally, an RCT sample comprised 164 participants (72% F, 48.9yr (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.[33,29] Ethical agreement concerning the latter two studies are provided in the source manuscripts. For the open access web surveys participation was covered by the site terms.

Across our combined largest samples (GBSS, GBSS+, TV), women were slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs; t(27638) = 7.94, p<.0001] and the great majority was in average or better physical health (86%) and mental health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very poor']. Respondents who made some use of prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr, t(20813) = 19.6, p<.0001] and had a substantially poorer SCI score [8.56 (4.93) vs 15.6 (7.80), t(20813) = 38.8, p<.0001]. Of the total sample, 18.1% took over-the-counter sleep aids (OTCs), and more than one-third of those taking sleeping pills also used OTCs.

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Design and Measurement

This is a psychometric scale development study. Standard approaches to the appraisal of validity, reliability and sensitivity were applied, making appropriate selection amongst the available datasets. These methods and datasets will be introduced in an integrated way in subsequent sections, so that the research process can be more clearly expressed and understood.

RESULTS

Development of the Sleep Condition Indicator (SCI)

Content Validity

An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft criteria that were available at the time (in 2010).[7,8] At that stage, a consultation process was underway and draft information was posted on the APA website. Consequently, the SCI items generated comprised 2 quantitative items on sleep continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two quantitative items on severity [item 3: nights per week; item 8: duration of problem], and two qualitative items on attributed daytime consequences of poor sleep [item 5: effects on mood, energy, or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)].

Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall asleep) served as responses for sleep continuity items 1 and 2.[8,28,29] Items 5 and 6 on daytime effects were derived by Principal Components Analysis (PCA; Varimax rotation) of six individual proposed DSM-5 impact areas, using combined datasets (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-Olkin (KMO=0.874) and Bartlett (p<.0001) statistics. Iteration converged after 3 rotations. A two component model (derived from inspection of the scree plot and a criterion for associated variance ≥ 10%) explained 75.8% of total variance, with item loadings ≥ .60. Component 1 (Eigenvalue=3.83; 63.8% of variance) comprised 'mood' (loading = .812) 'energy' (.651) and 'relationships' (.859), and was subsequently named 'personal functioning'. Component 2 (Eigenvalue=0.72; 12.0% of variance) comprised 'concentration' (.719), 'get through work' (.724), and 'stay awake' (.875) may be regarded as 'daytime performance'. PCA offered a relatively pure solution, although 'energy' also loaded significantly on component 2 (.519).

We then investigated the inter-relationships of our 8 SCI items using the same methodology, but applying this time a minimum item loading of 0.40, to permit incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett, p<.0001) yielded a two component solution (66.4% explained variance). Component

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1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2, 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616) and 'sleep-related impact' components (0.576).

Response format

Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range, reflecting putative threshold criteria for Insomnia Disorder (shaded area: see Appendix). The clinician can then see at a glance the profile of possible concerns. Possible total score ranges from 0–32, with higher values indicative of better sleep. However, scores can be readily transformed into a more intuitive 0-10 SCI range, either by dividing the total by 3.2, or by using an online version with automated scoring, which is available free of charge (www.sleepio.com/clinic/).

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Short-form version of the SCI

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DISCUSSION

Pre-requisite to improved insomnia care is the availability and regular use of reliable and valid insomnia assessment. Only then can a clinical problem be recognised as distinct from normal variation, and a persistent problem be differentiated from a transient one. We have reported here the development and preliminary validation of the SCI; a DSM-5 compliant, brief screening measure that may be fit for such purposes. Results indicate that the SCI is internally consistent, sensitive to change, and correlates strongly with established screening instruments, known to be sensitive to clinical insomnia (PSQI and ISI). Principal components analysis revealed a 2-component solution (66% of the variance), reflecting the underlying complaint of insomnia; that is, concerns about sleep pattern and concerns about the impact of poor sleep, both of which need to be addressed in clinical practice. The derived 2-item short-form version, focusing on the severity of the presenting complaint coupled with frequency of the sleep problem, correlated

strongly with total SCI score and we would suggest that these might be the lead questions for a clinician to use in the context of their consulting room practice.

Of course, further work is required, particularly real world studies of how the SCI might be used in population screening and in the evaluation of outcome following an episode of care. While comparisons with ISI cut-offs provide evidence of concurrent validity and indicate thatsuggest good discriminant ability of the SCI score ≤16 may help to detect probable insomnia disorder, (score ≤16), studies of predictive validity with reference to independent clinical evaluation of Insomnia Disorder (, as the gold standard), are essential before firm conclusions can be made.

It should be noted that over half of respondents to our online surveys, screened positive for possible Insomnia Disorder (cf.). These, of course, are not prevalence data as we did not adopt a formal population sampling approach. Nevertheless, the inevitable bias of these open access surveys towards those with sleep concerns does permit us a) to profile many respondents, against criteria; b) to conduct powerful analyses of the properties of the SCI; and c) to make comparisons with sizeable cohorts of good sleepers. Importantly, for our Science Centre sample, approximately 10% scored in the probable insomnia disorder range (ISI score ≥15), consistent with prevalence data (Morin reference),[2] providing further support for our ISI-SCI concurrent validity analysis comparing the ISI and SCI in this sample.

Furthermore, a limitation ofit should be noted that the SCI is that it does not contain specific questions relating to early morning awakenings (EMA; premature awakening with inability to return to sleep) – a symptom which has recently been incorporated into DSM-5 criteria. While established insomnia questionnaires, including the ISI[27] and Athens Insomnia Scale[37] probe perceived severity of EMA, quantitative values for EMA, to our knowledge, are yet to be defined. To some extent, SCI item 2 on wakefulness during the night may capture this complaint, but we recommend that the clinician follows-up a 'positive' answer to locate the nature and temporal position of wakefulness during the sleep period. Moreover, other core DSM-

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5 criteria do not feature as SCI items (e.g. the sleep difficulty occurs despite adequate opportunity for sleep; the insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder; and the insomnia is not attributable to the physiological effects of a substance). However, these items are not easy to probe unambiguously with a self-completed psychometric instrument and would require careful scrutiny by a treating clinician. It is, of course, possible that sleep disorders other than insomnia (e.g. circadian rhythm sleep disorders, sleep-breathing disorders) may also lead to low scores on the SCI. Thus, the SCI should be viewed as an insomnia screening tool, consistent with features of DSM-5, but requiring careful follow-up in clinical practice to fully define the nature of sleep disturbance.

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Appendix: The Sleep Condition Indicator

	Score				
Item	4	3	2	1	0
Thinking about a typical night in the last month … 1. … how long does it take you to fall asleep?	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
2. … if you then wake up during the night … how long are you awake for in total? (add all the wakenings up)	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
3. … how many nights a week do you have a problem with your sleep?	0 - 1	2	3	4	5 - 7
4. … how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month, to what extent has poor sleep … 5. … affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6. … affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
7. … troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally … 8. … how long have you had a problem with your sleep?	I don't have a problem / < 1 mo	1 – 2 mo	3 – 6 mo	7 – 12 mo	> 1 yr

Scoring instructions:

a. Add the item scores to obtain the SCI total (minimum 0, maximum 32)
b. A higher score means better sleep
c. Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
d. Item scores in grey area represent threshold criteria for Insomnia Disorder

A free online version, with built-in score convertor can be found at www.sleepio.com/clinic

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