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

Colin A. Espie, PhD<sup>1,3</sup>, Simon D. Kyle, PhD<sup>2</sup>, Peter Hames, MA Oxon<sup>3</sup>, Maria Gardani, PhD<sup>4</sup>, Leanne Fleming, PhD<sup>4</sup>, John Cape, PhD<sup>5</sup>

<sup>1</sup> Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, UK  
*Colin A. Espie, Professor*

<sup>2</sup> School of Psychological Sciences, University of Manchester, UK  
*Simon D. Kyle, Lecturer*

<sup>3</sup> Sleepio Limited, London, UK  
*Peter Hames, co-founder*

<sup>4</sup> Institute of Health & Wellbeing, University of Glasgow, UK  
*Maria Gardani, Research Fellow, Leanne Fleming, Research Fellow*

<sup>5</sup> Camden & Islington NHS Trust, London, UK  
*John Cape, Professor & Head of Psychological Therapies*

Corresponding Author:

Colin A. Espie, Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU, UK.

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 ( $\alpha \geq 0.86$ ), and 92% sensitivity (SCI score  $\leq 4.6$ ) / 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,<sup>1</sup> it is seldom adequately assessed and treatment is often poor.<sup>2,3</sup> This perhaps reflects the perspective that insomnia is usually a symptom,<sup>4</sup> coupled with minimal medical education on sleep and its disorders.<sup>5</sup> 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.<sup>6</sup> 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*".<sup>7</sup> Moreover, insomnia is not necessarily transient or benign. Once established, insomnia is remarkably persistent,<sup>8,9</sup> and constitutes a risk factor for the development of physical and mental health problems, notably depression,<sup>10-12</sup> as well as adverse effects upon quality of life.<sup>13</sup> Third, insomnia is treatable. There is a substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),<sup>14,15</sup> although the latter are very seldom available.<sup>3,16</sup>

Insomnia is ubiquitous<sup>17</sup> 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<sup>18</sup> for depression,<sup>19</sup> anxiety<sup>20</sup> and alcohol problems.<sup>21</sup> Two potential scales are the Pittsburgh Sleep Quality Index (PSQI)<sup>22</sup> and the Insomnia Severity Index (ISI).<sup>23</sup> 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<sup>24</sup> and recommended quantitative parameters for sleep disturbance.<sup>25</sup> In keeping with DSM-5, the SCI also evaluates associated

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

### 20 **Sample characteristics**

21 Data are reported from five validation studies (total n=30,941; 71% Female) in which  
22 SCI items were administered. The Great British Sleep Survey (GBSS) was an open  
23 access, web-based survey completed by adults (18+yr.) with a UK postcode yielding  
24 data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between  
25 February 2010 and August 2011.<sup>27</sup> The GBSS+ was a revision of the GBSS,  
26 extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017;  
27 68% Female; 42.3yr (16.5)). The TV sample was obtained in response to a network  
28 programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice  
29 (n=6,876; 76% F, 36.4yr (13.3)). Glasgow Science Centre data (n=256; 56% Female,  
30 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the  
31 relationship between salivary alpha-amylase, sleep pressure and diurnal  
32 preference.<sup>28</sup> Finally, an RCT sample comprised 164 participants (72% F, 48.9yr  
33 (13.7)) recruited in February 2011 into a placebo-controlled evaluation of CBT for  
34 insomnia.<sup>29</sup>  
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51 Across our combined largest samples (GBSS, GBSS+, TV), women were  
52 slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs;  $t(27638) = 7.94, p < .0001$ ]  
53 and the great majority was in average or better physical health (86%) and mental  
54 health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very  
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3 poor']. Around 57% screened positive for possible DSM-5 Insomnia Disorder.<sup>27</sup>  
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5 These are not prevalence data as we did not adopt a formal population sampling  
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7 approach. Nevertheless, the inevitable bias of these open access surveys towards  
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9 those with sleep concerns does permit us a) to profile many respondents, against  
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11 criteria;<sup>27</sup> b) to conduct powerful analyses of the properties of the SCI; and c) to make  
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13 comparisons with sizeable cohorts of good sleepers. Respondents who made some  
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15 use of prescription sleeping pills (9.1%) were 7 years older than those who did not  
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17 [46.2 (15.1) vs 39.1 (15.1)yr,  $t(20813) = 19.6$ ,  $p < .0001$ ]. A higher proportion took  
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19 over-the-counter sleep aids (OTCs; 18.1%), and more than one-third of those taking  
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21 sleeping pills also used OTCs.  
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## 25 **Design and Measurement**

26  
27 This is a psychometric scale development study. Standard approaches to the  
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29 appraisal of validity, reliability and sensitivity were applied, making appropriate  
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31 selection amongst the available datasets. These methods and datasets will be  
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33 introduced in an integrated way in subsequent sections, so that the research process  
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35 can be more clearly expressed and understood.  
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## 39 **RESULTS**

### 40 **Development of the Sleep Condition Indicator (SCI)**

#### 41 *Content Validity*

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43 An 8-item scale was developed (see Appendix) based strictly upon DSM-5  
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45 recommendations.<sup>6,7</sup> The SCI comprised 2 quantitative items on sleep continuity  
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47 [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on sleep  
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49 satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two  
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51 quantitative items on severity [item 3: nights per week; item 8: duration of problem],  
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53 and two qualitative items on attributed daytime consequences of poor sleep [item 5:  
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3 effects on mood, energy, or relationships (personal functioning); item 6: effects on  
4 concentration, productivity, or ability to stay awake (daytime performance)].  
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9 Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall asleep)  
10 served as responses for sleep continuity items 1 and 2.<sup>7,24,25</sup> Items 5 and 6 on  
11 daytime effects were derived by Principal Components Analysis (PCA; Varimax  
12 rotation) of six individual proposed DSM-5 impact areas, using combined datasets  
13 (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-  
14 Olkin (KMO=0.874) and Bartlett ( $p<.0001$ ) statistics. Iteration converged after 3  
15 rotations. A two component model explained 75.8% of variance. Component 1  
16 (Eigenvalue=3.83; 63.8% of variance) comprised 'mood' (loading = .812) 'energy'  
17 (.651) and 'relationships' (.859), and was subsequently named 'personal functioning'.  
18 Component 2 (Eigenvalue=0.72; 12.0% of variance) comprised 'concentration'  
19 (.719), 'get through work' (.724), and 'stay awake' (.875) may be regarded as  
20 'daytime performance'. PCA offered a relatively pure solution, although 'energy' also  
21 loaded significantly on component 2 (.519).  
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38 We then investigated the inter-relationships of our 8 SCI items. PCA with Varimax  
39 Rotation (KMO=0.888; Bartlett,  $p<.0001$ ) yielded a two component solution (66.4%  
40 explained variance). Component 1 (Eigenvalue=4.256, 53.2% variance), named  
41 'sleep pattern' comprised items 1, 2, 3, 4 and 8 with factor loading ranging from 0.453  
42 to 0.776. Component 2 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact'  
43 comprised item 5 (factor loading 0.886), and item 6 (0.911). Consistent with clinical  
44 presentation, concerns about sleep (item 7) loaded significantly, and similarly, on  
45 both 'sleep pattern' (0.616) and 'sleep-related impact' components (0.576).  
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### *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<sup>30</sup> was modest, and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale<sup>31</sup>: 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  $SCI \leq 15$  (on the 0-32 scaled version) and  $SCI \leq 4.6$  (on the 0–10 scaled version) correctly identified 92% of people scoring positive for minimal DSM-5 ID criteria (sensitivity),<sup>27</sup> whereas  $SCI > 16$  and  $SCI > 4.6$ , respectively, correctly identified 87% of individuals who did not meet criteria.

### *Internal consistency*

Cronbach's  $\alpha$  for the GBSS sample was strong at 0.857 (range of  $\alpha$ -if-item-deleted 0.822-0.860). Replication of these internal consistency data was obtained from the GBSS+ sample ( $\alpha=0.865$ ). 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.<sup>29</sup> 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).<sup>32</sup> 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  $\beta = .515$ ) and item 8 '... troubled you in general' ( $\beta = .491$ ) 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,  $SCI-02 \leq 3$  (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.<sup>33</sup> It is a common subjective complaint, difficult to evaluate, and with no clear pathway for its management.<sup>3,16,17</sup> Despite the majority being unsure whether or not to mention it to their doctor,<sup>34</sup> twelve million prescriptions are written annually in the UK,<sup>35</sup> to doubtful benefit.<sup>36-38</sup> 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,<sup>39</sup> there is mounting evidence that poor sleep often becomes persistent,<sup>8,9</sup> and that persistent insomnia is detrimental to health and wellbeing.<sup>10-13</sup>

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

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3 (EMA; premature awakening with inability to return to sleep) – a symptom which has  
4 recently been incorporated into DSM-5 criteria. However, to our knowledge,  
5 quantitative values for EMA are yet to be defined. To some extent, SCI item 2 on  
6 wakefulness during the night may capture this complaint, but we recommend that the  
7 clinician follows-up a 'positive' answer to locate the nature and temporal position of  
8 wakefulness during the sleep period.  
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### 15 16 17 **Contributorship Statement**

18 All authors engaged in the following study tasks:

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20  
21 1) substantial contributions to conception and design, acquisition of data, or analysis  
22 and interpretation of data;  
23  
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25 2) drafting the article or revising it critically for important intellectual content; and  
26  
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28 3) final approval of the version to be published.  
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### 31 **Competing Interests**

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

Item	Score				
	4	3	2	1	0
<b>Thinking about a typical night in the last month ...</b>					
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 awakenings 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
<b>Thinking about the past month, to what extent has poor sleep ...</b>					
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
<b>Finally ...</b>					
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:

- Add the item scores to obtain the SCI total (minimum 0, maximum 32)
- A higher score means better sleep
- Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
- 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



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

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

Colin A. Espie, PhD<sup>1,3</sup>, Simon D. Kyle, PhD<sup>2</sup>, Peter Hames, MA Oxon<sup>3</sup>, Maria Gardani, PhD<sup>4</sup>, Leanne Fleming, PhD<sup>4</sup>, John Cape, PhD<sup>5</sup>

<sup>1</sup> Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, UK  
*Colin A. Espie, Professor*

<sup>2</sup> School of Psychological Sciences, University of Manchester, UK  
*Simon D. Kyle, Lecturer*

<sup>3</sup> Sleepio Limited, London, UK  
*Peter Hames, co-founder*

<sup>4</sup> Institute of Health & Wellbeing, University of Glasgow, UK  
*Maria Gardani, Research Fellow, Leanne Fleming, Research Fellow*

<sup>5</sup> Camden & Islington NHS Trust, London, UK  
*John Cape, Professor & Head of Psychological Therapies*

Corresponding Author:

Colin A. Espie, Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU, UK.

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, 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 ( $\alpha \geq 0.86$ ) 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,<sup>1</sup> it is seldom adequately assessed and treatment services are often poor.<sup>2,3</sup> This perhaps reflects the perspective that insomnia is usually a symptom,<sup>4</sup> coupled with minimal medical education on sleep and its disorders.<sup>5</sup> 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),<sup>6</sup> and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.<sup>7,8</sup> 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*".<sup>9</sup> Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,<sup>10,11</sup> constituting a risk factor for the development of physical and mental health problems, notably depression,<sup>12-14</sup> as well as adverse effects upon quality of life.<sup>15</sup> Chronic insomnia is also associated with high societal cost,<sup>16</sup> and is, for example, a robust predictor of work disability.<sup>17</sup> Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),<sup>18,19</sup> although the latter are very seldom available.<sup>3,20</sup>

Insomnia is ubiquitous<sup>21</sup> 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,<sup>22</sup> for example, for depression,<sup>23</sup> anxiety<sup>24</sup> and alcohol problems.<sup>25</sup> In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)<sup>26</sup> and the Insomnia Severity Index (ISI).<sup>27</sup> The PSQI is 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.

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

### 34 **Sample characteristics**

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36 Data are reported from five validation studies (total n=30,941; 71% Female) in which  
37 SCI items were administered. The Great British Sleep Survey (GBSS) was an open  
38 access, web-based survey completed by adults (18+yr.) with a UK postcode yielding  
39 data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between  
40 February 2010 and August 2011.<sup>27</sup> The GBSS+ was a revision of the GBSS,  
41 extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017;  
42 68% Female; 42.3yr (16.5)). The TV sample was obtained in response to a network  
43 programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice  
44 (n=6,876; 76% F, 36.4yr (13.3)). Glasgow Science Centre data (n=256; 56% Female,  
45 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the  
46 relationship between salivary alpha-amylase, sleep pressure and diurnal  
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3 preference.<sup>28</sup> Finally, an RCT sample comprised 164 participants (72% F, 48.9yr  
4 (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.<sup>29</sup> Ethical  
5 agreement concerning the latter two studies are provided in the source manuscripts.  
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7 For the open access web surveys participation was covered by the site terms.  
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11 Across our combined largest samples (GBSS, GBSS+, TV), women were  
12 slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs;  $t(27638) = 7.94, p < .0001$ ]  
13 and the great majority was in average or better physical health (86%) and mental  
14 health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very  
15 poor']. Around 57% screened positive for possible Insomnia Disorder.<sup>31</sup> These are  
16 not prevalence data as we did not adopt a formal population sampling approach.  
17 Nevertheless, the inevitable bias of these open access surveys towards those with  
18 sleep concerns does permit us a) to profile many respondents, against criteria; b) to  
19 conduct powerful analyses of the properties of the SCI; and c) to make comparisons  
20 with sizeable cohorts of good sleepers. Respondents who made some use of  
21 prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2  
22 (15.1) vs 39.1 (15.1)yr,  $t(20813) = 19.6, p < .0001$ ] and had a substantially poorer SCI  
23 score [8.56 (4.93) vs 15.6 (7.80),  $t(20813) = 38.8, p < .0001$ ]. Of the total sample,  
24 18.1% took over-the-counter sleep aids (OTCs), and more than one-third of those  
25 taking sleeping pills also used OTCs.  
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#### 44 **Design and Measurement**

45 This is a psychometric scale development study. Standard approaches to the  
46 appraisal of validity, reliability and sensitivity were applied, making appropriate  
47 selection amongst the available datasets. These methods and datasets will be  
48 introduced in an integrated way in subsequent sections, so that the research process  
49 can be more clearly expressed and understood.  
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## 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).<sup>7,8</sup> 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.<sup>8,28,29</sup> 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  $\geq 10\%$ ) explained 75.8% of total variance, with item loadings  $\geq .60$ . 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).

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

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

45 Data from the Science Centre sample demonstrated that the SCI correlates inversely  
46 with the PSQI ( $r = -.734$ ) and the ISI ( $r = -.793$ ), suggesting measurement properties  
47 consistent with these related measures. There was also a small but significant  
48 association of sleep condition with self-rated physical health ( $r = .222$ ), and an  
49 association also with mental health ( $r = .335$ ). Using more specific measures, in the  
50 Science Centre sample, correlation of the SCI with symptoms of depression ( $r = -.426$ )  
51 and anxiety ( $r = -.400$ ) on the Hospital Anxiety and Depression Scale<sup>34</sup> was modest,  
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3 and greater than we observed in our RCT sample [on the Depression Anxiety Stress  
4 Scale<sup>35</sup>: depression ( $r=-.267$ ), anxiety ( $r=-.236$ ) and stress ( $r=-.263$ )].  
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9 We have not at this stage tested the discriminant validity of the SCI against clinical  
10 diagnosis of insomnia disorder. As a first step, however, using our Science Centre  
11 sample, we were able to compare the discriminant ability of SCI score  $\leq 16$ , reflecting  
12 minimum criteria for putative Insomnia Disorder (see appendix), with published ISI  
13 cut-off scores. We first categorized our sample according to ISI ranges (ISI score=0-  
14 14, reflecting “absence of insomnia” or “sub-threshold insomnia” [n=228] versus  
15 “moderate or severe insomnia” ISI score=15-28, n=27)<sup>36</sup> and conducted an  
16 independent *t*-test on SCI total score. Mean SCI values for the probable insomnia  
17 disorder category were 10.7 (SD=5.3) versus 22.9 (SD=6.2) for no insomnia disorder  
18 ( $t=9.86$ ,  $p<.0001$ ). Applying SCI cut-off  $\leq 16$ , 89% of the sample were correctly  
19 identified as having probable insomnia disorder (ISI scores of  $\geq 15$ ), while SCI score  
20 of  $>16$  correctly identified 82% of those with no insomnia disorder. These findings  
21 therefore suggest good discriminant validity for the SCI and help to confirm that a  
22 score of  $\leq 16$  on the SCI seems reasonable to detect possible insomnia disorder.  
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#### 40 *Internal consistency*

41 Cronbach's  $\alpha$  for the GBSS sample was strong at 0.857 (range of  *$\alpha$ -if-item-deleted*  
42 0.822-0.860). Replication of these internal consistency data was obtained from the  
43 GBSS+ sample ( $\alpha=0.865$ ). Mean corrected item-total correlation was moderate  
44 ( $r=0.620$ ) indicating substantial unique variance per item (shared variance = 38%).  
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#### 51 *Sensitivity to change*

52 We have previously reported that the SCI is sensitive as a measure of treatment  
53 outcome.<sup>33</sup>  
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### 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).<sup>37</sup> 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  $\beta = .515$ ) and item 8 ‘... troubled you in general’ ( $\beta = .491$ ) 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

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

## 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

Item	Score				
	4	3	2	1	0
<b>Thinking about a typical night in the last month ...</b>					
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 awakenings 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
<b>Thinking about the past month, to what extent has poor sleep ...</b>					
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
<b>Finally ...</b>					
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:

- Add the item scores to obtain the SCI total (minimum 0, maximum 32)
- A higher score means better sleep
- Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
- 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](http://www.sleepio.com/clinic)

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

Colin A. Espie, PhD<sup>1,3</sup>, Simon D. Kyle, PhD<sup>2</sup>, Peter Hames, MA Oxon<sup>3</sup>, Maria Gardani, PhD<sup>4</sup>, Leanne Fleming, PhD<sup>4</sup>, John Cape, PhD<sup>5</sup>

<sup>1</sup> Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, UK  
*Colin A. Espie, Professor*

<sup>2</sup> School of Psychological Sciences, University of Manchester, UK  
*Simon D. Kyle, Lecturer*

<sup>3</sup> Sleepio Limited, London, UK  
*Peter Hames, co-founder*

<sup>4</sup> Institute of Health & Wellbeing, University of Glasgow, UK  
*Maria Gardani, Research Fellow, Leanne Fleming, Research Fellow*

<sup>5</sup> Camden & Islington NHS Trust, London, UK  
*John Cape, Professor & Head of Psychological Therapies*

Corresponding Author:

Colin A. Espie, Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU, UK.

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 ( $\alpha \geq 0.86$ ) and showed convergent validity with the Pittsburgh Sleep Quality Index and Insomnia Severity Index. ~~and 92% sensitivity (SCI score  $\leq 4.6$ ) / 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 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.
- 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,<sup>1</sup> it is seldom adequately assessed and **treatment services** are often poor.<sup>2,3</sup> This perhaps reflects the perspective that insomnia is usually a symptom,<sup>4</sup> coupled with minimal medical education on sleep and its disorders.<sup>5</sup> 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),<sup>6</sup> and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.<sup>7,8</sup> 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*".<sup>9</sup> Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,<sup>10,11</sup> constituting a risk factor for the development of physical and mental health problems, notably depression,<sup>12-14</sup> as well as adverse effects upon quality of life.<sup>15</sup> **Chronic insomnia is also associated with high societal cost,<sup>16</sup> and is, for example, a robust predictor of work disability.<sup>17</sup>** Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),<sup>18,19</sup> although the latter are very seldom available.<sup>3,20</sup>

Insomnia is ubiquitous<sup>21</sup> 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,<sup>22</sup> for example, for depression,<sup>23</sup> anxiety<sup>24</sup> and alcohol problems.<sup>25</sup> In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)<sup>26</sup> and the Insomnia Severity Index (ISI).<sup>27</sup> 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.



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

### 36 Sample characteristics

37 Data are reported from five validation studies (total n=30,941; 71% Female) in which  
38 SCI items were administered. The Great British Sleep Survey (GBSS) was an open  
39 access, web-based survey completed by adults (18+yr.) with a UK postcode yielding  
40 data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between  
41 February 2010 and August 2011.<sup>27</sup> The GBSS+ was a revision of the GBSS,  
42 extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017;  
43 68% Female; 42.3yr (16.5)]. The TV sample was obtained in response to a network  
44 programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice  
45 (n=6,876; 76% F, 36.4yr (13.3)]. Glasgow Science Centre data (n=256; 56% Female,  
46 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the  
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6 relationship between salivary alpha-amylase, sleep pressure and diurnal  
7 preference.<sup>28</sup> Finally, an RCT sample comprised 164 participants (72% F, 48.9yr  
8 (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.<sup>29</sup> Ethical  
9 agreement concerning the latter two studies are provided in the source manuscripts.  
10 For the open access web surveys participation was covered by the site terms.  
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15 Across our combined largest samples (GBSS, GBSS+, TV), women were  
16 slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs;  $t(27638) = 7.94, p < .0001$ ]  
17 and the great majority was in average or better physical health (86%) and mental  
18 health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very  
19 poor']. Around 57% screened positive for possible Insomnia Disorder.<sup>31</sup> These are  
20 not prevalence data as we did not adopt a formal population sampling approach.  
21 Nevertheless, the inevitable bias of these open access surveys towards those with  
22 sleep concerns does permit us a) to profile many respondents, against criteria; b) to  
23 conduct powerful analyses of the properties of the SCI; and c) to make comparisons  
24 with sizeable cohorts of good sleepers. Respondents who made some use of  
25 prescription sleeping pills (9.1%) were 7 years older than those who did not [46.2  
26 (15.1) vs 39.1 (15.1)yr,  $t(20813) = 19.6, p < .0001$ ] and had a substantially poorer SCI  
27 score [8.56\_(4.93) vs 15.6 (7.80),  $t(20813) = 38.8, p < .0001$ ]. Of the total sample,  
28 18.1% took over-the-counter sleep aids (OTCs), and more than one-third of those  
29 taking sleeping pills also used OTCs.  
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#### 44 **Design and Measurement**

45 This is a psychometric scale development study. Standard approaches to the  
46 appraisal of validity, reliability and sensitivity were applied, making appropriate  
47 selection amongst the available datasets. These methods and datasets will be  
48 introduced in an integrated way in subsequent sections, so that the research process  
49 can be more clearly expressed and understood.  
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## 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).<sup>7,8</sup> 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.<sup>8,28,29</sup> 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  $\geq 10\%$ ) explained 75.8% of total variance, with item loadings  $\geq .60$ . 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).

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6 We then investigated the inter-relationships of our 8 SCI items using the  
7 same methodology, but applying this time a minimum item loading of 0.40, to permit  
8 incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett,  
9  $p < .0001$ ) yielded a two component solution (66.4% explained variance). Component  
10 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2,  
11 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2  
12 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor  
13 loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns  
14 about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616)  
15 and 'sleep-related impact' components (0.576).  
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#### 24 25 26 *Response format*

27 Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range,  
28 reflecting threshold criteria for Insomnia Disorder (shaded area: see Appendix). The  
29 clinician can then see at a glance the profile of possible concerns. Possible total  
30 score ranges from 0–32, with higher values indicative of better sleep. However,  
31 scores can be readily transformed into a more intuitive 0-10 SCI range, either by  
32 dividing the total by 3.2, or by using an online version with automated scoring, which  
33 is available free of charge ([www.sleepio.com/clinic/](http://www.sleepio.com/clinic/)).  
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#### 42 43 *Concurrent Validity and association with related domains*

44 Data from the Science Centre sample demonstrated that the SCI correlates inversely  
45 with the PSQI ( $r = -.734$ ) and the ISI ( $r = -.793$ ), suggesting measurement properties  
46 consistent with these related measures. There was also a small but significant  
47 association of sleep condition with self-rated physical health ( $r = .222$ ), and an  
48 association also with mental health ( $r = .335$ ). Using more specific measures, in the  
49 Science Centre sample, correlation of the SCI with symptoms of depression ( $r = -.426$ )  
50 and anxiety ( $r = -.400$ ) on the Hospital Anxiety and Depression Scale<sup>34</sup> was modest,  
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and greater than we observed in our RCT sample [on the Depression Anxiety Stress Scale<sup>35</sup>: 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  $SCI \leq 15$  (on the 0-32 scaled version) and  $SCI \leq 4.6$  (on the 0-10 scaled version) correctly identified 92% of people scoring positive against the DSM-5 draft criteria (sensitivity),<sup>34</sup> whereas  $SCI > 16$  and  $SCI > 4.6$ , respectively, correctly identified 87% of individuals who would appear not to meet these criteria.~~ Using our Science Centre sample, we were able to compare the discriminant ability of SCI score  $\leq 16$ , 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)]<sup>36</sup> 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  $\leq 16$ , 89% of the sample were correctly identified as having probable insomnia disorder (ISI scores of  $\geq 15$ ), 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  $\leq 16$  on the SCI seems reasonable to detect possible insomnia disorder.

#### *Internal consistency*

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

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6 GBSS+ sample ( $\alpha=0.865$ ). Mean corrected item-total correlation was moderate  
7 ( $r=0.620$ ) indicating substantial unique variance per item (shared variance = 38%).  
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### 10 11 *Sensitivity to change*

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13 We have previously reported that the SCI is sensitive as a measure of treatment  
14 outcome.<sup>33</sup>  
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### 17 18 **Short-form version of the SCI**

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20 Although the SCI is brief, in clinical practice ultra short-form scales is often helpful  
21 (e.g. GAD-2).<sup>37</sup> Accordingly, we conducted a linear regression analysis to determine  
22 which subset of items (independent variables) explained the greatest proportion of  
23 variance in the dependent variable, SCI total score. A two-item (SCI-02), comprising  
24 item 3 '...how many nights' (standardized  $\beta = .515$ ) and item 8 '... troubled you in  
25 general' ( $\beta = .491$ ) together predicted 82% of variance (Adjusted  $R^2 = .820$ ) in the full  
26 scale SCI [ $R^2$  change =  $.672 + .148$ ;  $F(2,27637) = 62770$ ,  $p < .0001$ ]. As a check on  
27 the independence of residuals we computed the Durbin-Watson statistic, which was  
28 found to be 1.80, suggesting no serial correlation. The SCI-02 also correlated  
29 strongly with the SCI score total ( $r = .904$ ).  
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38 ~~Applying ROC analyses, SCI-02  $\leq 3$  (on the 0-8 scaled version) correctly identified~~  
39 ~~87% of people scoring positive for ID (sensitivity), whereas SCI-02  $> 3$  correctly~~  
40 ~~identified 91% of individuals who did not meet draft DSM-5 criteria.~~  
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### 46 47 **DISCUSSION**

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49 ~~Neither patients nor physicians quite know what to do about insomnia.<sup>38</sup> It is a~~  
50 ~~common subjective complaint, difficult to evaluate, and with no clear pathway for its~~  
51 ~~management.<sup>3,16,17</sup> Despite the majority being unsure whether or not to mention it to~~  
52 ~~their doctor,<sup>39</sup> twelve million prescriptions are written annually in the UK,<sup>40</sup> to doubtful~~  
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benefit.<sup>41-43</sup> ~~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,<sup>44</sup> there is mounting evidence that poor sleep often becomes persistent,<sup>40,41</sup> and that persistent insomnia is detrimental to health and wellbeing.<sup>42-45</sup>~~

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, focuses upon 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  $\leq 16$ ), s~~ Studies of predictive validity with reference to independent clinical evaluation of Insomnia Disorder ~~are essential-necessary before firm conclusions can be made~~ would be welcome. Furthermore, Finally, it should be noted that the SCI does not contain

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

Item	Score				
	4	3	2	1	0
<b>Thinking about a typical night in the last month ...</b>					
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 awakenings 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
<b>Thinking about the past month, to what extent has poor sleep ...</b>					
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
<b>Finally ...</b>					
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:

- Add the item scores to obtain the SCI total (minimum 0, maximum 32)
- A higher score means better sleep
- Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
- 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](http://www.sleepio.com/clinic)



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

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

Colin A. Espie, PhD<sup>1,3</sup>, Simon D. Kyle, PhD<sup>2</sup>, Peter Hames, MA Oxon<sup>3</sup>, Maria  
Gardani, PhD<sup>4</sup>, Leanne Fleming, PhD<sup>4</sup>, John Cape, PhD<sup>5</sup>

<sup>1</sup> Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience  
Institute, University of Oxford, UK  
*Colin A. Espie, Professor*

<sup>2</sup> School of Psychological Sciences, University of Manchester, UK  
*Simon D. Kyle, Lecturer*

<sup>3</sup> Sleepio Limited, London, UK  
*Peter Hames, co-founder*

<sup>4</sup> Institute of Health & Wellbeing, University of Glasgow, UK  
*Maria Gardani, Research Fellow, Leanne Fleming, Research Fellow*

<sup>5</sup> Camden & Islington NHS Trust, London, UK  
*John Cape, Professor & Head of Psychological Therapies*

Corresponding Author:

Colin A. Espie, Nuffield Department of Clinical Neurosciences/ Sleep & Circadian  
Neuroscience Institute, University of Oxford, Level 6, West Wing, John Radcliffe  
Hospital, Oxford, OX3 9DU, UK.

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 ( $\alpha \geq 0.86$ ) 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,<sup>1</sup> it is seldom adequately assessed and treatment services are often poor.<sup>2,3</sup> This perhaps reflects the perspective that insomnia is usually a symptom,<sup>4</sup> coupled with minimal medical education on sleep and its disorders.<sup>5</sup> 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),<sup>6</sup> and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.<sup>7,8</sup> 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*".<sup>9</sup> Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,<sup>10,11</sup> constituting a risk factor for the development of physical and mental health problems, notably depression,<sup>12-14</sup> as well as adverse effects upon quality of life.<sup>15</sup> Chronic insomnia is also associated with high societal cost,<sup>16</sup> and is, for example, a robust predictor of work disability.<sup>17</sup> Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),<sup>18,19</sup> although the latter are very seldom available.<sup>3,20</sup>

Insomnia is ubiquitous<sup>21</sup> 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,<sup>22</sup> for example, for depression,<sup>23</sup> anxiety<sup>24</sup> and alcohol problems.<sup>25</sup> In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)<sup>26</sup> and the Insomnia Severity Index (ISI).<sup>27</sup> The PSQI is 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.

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

### 34 **Sample characteristics**

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36 Data are reported from five validation studies (total n=30,941; 71% Female) in which  
37 SCI items were administered. The Great British Sleep Survey (GBSS) was an open  
38 access, web-based survey completed by adults (18+yr.) with a UK postcode yielding  
39 data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between  
40 February 2010 and August 2011.<sup>31</sup> The GBSS+ was a revision of the GBSS,  
41 extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017;  
42 68% Female; 42.3yr (16.5)). The TV sample was obtained in response to a network  
43 programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice  
44 (n=6,876; 76% F, 36.4yr (13.3)). Glasgow Science Centre data (n=256; 56% Female,  
45 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the  
46 relationship between salivary alpha-amylase, sleep pressure and diurnal  
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3 preference.<sup>32</sup> Finally, an RCT sample comprised 164 participants (72% F, 48.9yr  
4 (13.7)] recruited into a placebo-controlled evaluation of CBT for insomnia.<sup>33</sup> Ethical  
5 agreement concerning the latter two studies are provided in the source manuscripts.  
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7 For the open access web surveys participation was covered by the site terms.  
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11 Across our combined largest samples (GBSS, GBSS+, TV), women were  
12 slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs;  $t(27638) = 7.94, p < .0001$ ]  
13 and the great majority was in average or better physical health (86%) and mental  
14 health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very  
15 poor']. Respondents who made some use of prescription sleeping pills (9.1%) were 7  
16 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr,  $t(20813) = 19.6,$   
17  $p < .0001$ ] and had a substantially poorer SCI score [8.56 (4.93) vs 15.6 (7.80),  
18  $t(20813) = 38.8, p < .0001$ ]. Of the total sample, 18.1% took over-the-counter sleep  
19 aids (OTCs), and more than one-third of those taking sleeping pills also used OTCs.  
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### 31 **Design and Measurement**

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

### 49 **Development of the Sleep Condition Indicator (SCI)**

#### 50 *Content Validity*

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52 An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft  
53 criteria that were available at the time (in 2010).<sup>7,8</sup> At that stage, a consultation  
54 process was underway and draft information was posted on the APA website.  
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3 Consequently, the SCI items generated comprised 2 quantitative items on sleep  
4 continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on  
5 sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two  
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7 quantitative items on severity [item 3: nights per week; item 8: duration of problem],  
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9 and two qualitative items on attributed daytime consequences of poor sleep [item 5:  
10 effects on mood, energy, or relationships (personal functioning); item 6: effects on  
11 concentration, productivity, or ability to stay awake (daytime performance)].  
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17 Validated quantitative criteria for sleep disruption (e.g. 31-45 minutes to fall  
18 asleep) served as responses for sleep continuity items 1 and 2.<sup>8,28,29</sup> Items 5 and 6  
19 on daytime effects were derived by Principal Components Analysis (PCA; Varimax  
20 rotation) of six individual proposed DSM-5 impact areas, using combined datasets  
21 (GBSS, GBSS+, TV, RCT: valid n= 29,650). PCA yielded satisfactory Kaiser-Meyer-  
22 Olkin (KMO=0.874) and Bartlett ( $p<.0001$ ) statistics. Iteration converged after 3  
23 rotations. A two component model (derived from inspection of the scree plot and a  
24 criterion for associated variance  $\geq 10\%$ ) explained 75.8% of total variance, with item  
25 loadings  $\geq .60$ . Component 1 (Eigenvalue=3.83; 63.8% of variance) comprised  
26 'mood' (loading = .812) 'energy' (.651) and 'relationships' (.859), and was  
27 subsequently named 'personal functioning'. Component 2 (Eigenvalue=0.72; 12.0%  
28 of variance) comprised 'concentration' (.719), 'get through work' (.724), and 'stay  
29 awake' (.875) may be regarded as 'daytime performance'. PCA offered a relatively  
30 pure solution, although 'energy' also loaded significantly on component 2 (.519).  
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46 We then investigated the inter-relationships of our 8 SCI items using the  
47 same methodology, but applying this time a minimum item loading of 0.40, to permit  
48 incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett,  
49  $p<.0001$ ) yielded a two component solution (66.4% explained variance). Component  
50 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2,  
51 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2  
52 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor  
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3 loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns  
4 about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616)  
5 and 'sleep-related impact' components (0.576).  
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### 10 *Response format*

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

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31 Data from the Science Centre sample demonstrated that the SCI correlates inversely  
32 with the PSQI ( $r=-.734$ ) and the ISI ( $r=-.793$ ), suggesting measurement properties  
33 consistent with these related measures. There was also a small but significant  
34 association of sleep condition with self-rated physical health ( $r =.222$ ), and an  
35 association also with mental health ( $r=.335$ ). Using more specific measures, in the  
36 Science Centre sample, correlation of the SCI with symptoms of depression ( $r=-.426$ )  
37 and anxiety ( $r=-.400$ ) on the Hospital Anxiety and Depression Scale<sup>34</sup> was modest,  
38 and greater than we observed in our RCT sample [on the Depression Anxiety Stress  
39 Scale<sup>35</sup>: depression ( $r=-.267$ ), anxiety ( $r=-.236$ ) and stress ( $r=-.263$ )].  
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52 We have not at this stage tested the discriminant validity of the SCI against clinical  
53 diagnosis of insomnia disorder. As a first step, however, using our Science Centre  
54 sample, we tested the concurrent validity of SCI cut-offs (score  $\leq 16$ ), reflecting  
55 minimum criteria for putative Insomnia Disorder (see appendix), against published  
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3 validated ISI cut-off scores. We first categorized our sample according to ISI ranges  
4 (ISI score=0-14, reflecting “no insomnia disorder” [n=228] versus “probable insomnia  
5 disorder” ISI score=15-28, n=27]) and conducted an independent *t*-test on SCI total  
6 score. Mean SCI values for the “probable insomnia disorder” category were 10.7  
7 (SD=5.3) versus 22.9 (SD=6.2) for “no insomnia disorder” ( $t=9.86$ ,  $p<.0001$ ).  
8 Applying SCI cut-off  $\leq 16$ , 89% of the sample were correctly identified as having  
9 “probable insomnia disorder” (ISI scores of  $\geq 15$ ), while SCI score of  $>16$  correctly  
10 identified 82% of those with “no insomnia disorder”. These findings provide further  
11 evidence of concurrent validity for the SCI and help to confirm that a score of  $\leq 16$  on  
12 the SCI seems reasonable to detect possible insomnia disorder.  
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#### 24 25 *Internal consistency*

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27 Cronbach's  $\alpha$  for the GBSS sample was strong at 0.857 (range of  $\alpha$ -if-item-deleted  
28 0.822-0.860). Replication of these internal consistency data was obtained from the  
29 GBSS+ sample ( $\alpha=0.865$ ). Mean corrected item-total correlation was moderate  
30 ( $r=0.620$ ) indicating substantial unique variance per item (shared variance = 38%).  
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#### 38 *Sensitivity to change*

39 We have previously reported that the SCI is sensitive as a measure of treatment  
40 outcome.<sup>33</sup>  
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#### 46 **Short-form version of the SCI**

47 Although the SCI is brief, in clinical practice ultra short-form scales is often helpful  
48 (e.g. GAD-2).<sup>36</sup> Accordingly, we conducted a stepwise linear regression analysis to  
49 determine which subset of items (independent variables) explained the greatest  
50 proportion of variance in the dependent variable, SCI total score. A two-item (SCI-  
51 02), comprising item 3 ‘...how many nights’ (standardized  $\beta = .515$ ) and item 7 ‘...  
52 troubled you in general’ ( $\beta = .491$ ) together predicted 82% of variance (Adjusted  $R^2 =$   
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3 .820) in the full scale SCI [ $R^2$  change = .672 + .148;  $F(2,27637) = 62770$ ,  $p < .0001$ ].  
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5 As a check on the independence of residuals we computed the Durbin-Watson  
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7 statistic, which was found to be 1.80, suggesting no serial correlation. The SCI-02  
8  
9 also correlated strongly with the SCI score total ( $r = .904$ ).  
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## 11 12 13 14 15 **DISCUSSION**

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17 Pre-requisite to improved insomnia care is the availability and regular use of  
18  
19 reliable and valid insomnia assessment. Only then can a clinical problem be  
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21 recognised as distinct from normal variation, and a persistent problem be  
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23 differentiated from a transient one. We have reported here the development and  
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25 preliminary validation of the SCI; a DSM-5 compliant, brief screening measure that  
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27 may be fit for such purposes. Results indicate that the SCI is internally consistent,  
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29 sensitive to change, and correlates strongly with established screening instruments,  
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31 known to be sensitive to clinical insomnia (PSQI and ISI). Principal components  
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33 analysis revealed a 2-component solution (66% of the variance), reflecting the  
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35 underlying complaint of insomnia; that is, concerns about sleep pattern and concerns  
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37 about the impact of poor sleep, both of which need to be addressed in clinical  
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39 practice. The derived 2-item short-form version, focusing on the severity of the  
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41 presenting complaint coupled with frequency of the sleep problem, correlated  
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43 strongly with total SCI score and we would suggest that these might be the lead  
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45 questions for a clinician to use in the context of their consulting room practice.  
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49 Of course, further work is required, particularly real world studies of how the  
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51 SCI might be used in population screening and in the evaluation of outcome following  
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53 an episode of care. While comparisons with ISI cut-offs provide evidence of  
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55 concurrent validity and indicate that SCI score  $\leq 16$  may help detect probable  
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57 insomnia disorder, studies of predictive validity with reference to independent clinical  
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3 evaluation of Insomnia Disorder (the gold standard), are essential before firm  
4 conclusions can be made.  
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7 It should be noted that over half of respondents to our online surveys,  
8 screened positive for possible Insomnia Disorder. These, of course, are not  
9 prevalence data as we did not adopt a formal population sampling approach.  
10 Nevertheless, the inevitable bias of these open access surveys towards those with  
11 sleep concerns does permit us a) to profile many respondents, against criteria; b) to  
12 conduct powerful analyses of the properties of the SCI; and c) to make comparisons  
13 with sizeable cohorts of good sleepers. Importantly, for our Science Centre sample,  
14 approximately 10% scored in the probable insomnia disorder range (ISI score  $\geq 15$ ),  
15 consistent with prevalence data,<sup>2</sup> providing further support for our ISI-SCI concurrent  
16 validity analysis.  
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27 Furthermore, a limitation of the SCI is that it does not contain specific  
28 questions relating to early morning awakenings (EMA; premature awakening with  
29 inability to return to sleep) – a symptom which has recently been incorporated into  
30 DSM-5 criteria. While established insomnia questionnaires, including the ISI<sup>27</sup> and  
31 Athens Insomnia Scale<sup>37</sup> probe perceived severity of EMA, quantitative values for  
32 EMA, to our knowledge, are yet to be defined. To some extent, SCI item 2 on  
33 wakefulness during the night may capture this complaint, but we recommend that the  
34 clinician follows-up a 'positive' answer to locate the nature and temporal position of  
35 wakefulness during the sleep period. Moreover, other core DSM-5 criteria do not  
36 feature as SCI items (e.g. the sleep difficulty occurs despite adequate opportunity for  
37 sleep; the insomnia is not better explained by and does not occur exclusively during  
38 the course of another sleep-wake disorder; and the insomnia is not attributable to the  
39 physiological effects of a substance). However, these items are not easy to probe  
40 unambiguously with a self-completed psychometric instrument and would require  
41 careful scrutiny by a treating clinician. It is, of course, possible that sleep disorders  
42 other than insomnia (e.g. circadian rhythm sleep disorders, sleep-breathing  
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3 disorders) may also lead to low scores on the SCI. Thus the SCI should be viewed as  
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5 an insomnia screening tool, consistent with features of DSM-5, but requiring careful  
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7 follow-up in clinical practice to fully define the nature of sleep disturbance.  
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For peer review only

**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

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Insomnia Disorder

Colin A. Espie, PhD<sup>1,3</sup>, Simon D. Kyle, PhD<sup>2</sup>, Peter Hames, MA Oxon<sup>3</sup>, Maria Gardani, PhD<sup>4</sup>, Leanne Fleming, PhD<sup>4</sup>, John Cape, PhD<sup>5</sup>

<sup>1</sup> Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, UK  
*Colin A. Espie, Professor*

<sup>2</sup> School of Psychological Sciences, University of Manchester, UK  
*Simon D. Kyle, Lecturer*

<sup>3</sup> Sleepio Limited, London, UK  
*Peter Hames, co-founder*

<sup>4</sup> Institute of Health & Wellbeing, University of Glasgow, UK  
*Maria Gardani, Research Fellow, Leanne Fleming, Research Fellow*

<sup>5</sup> Camden & Islington NHS Trust, London, UK  
*John Cape, Professor & Head of Psychological Therapies*

Corresponding Author:

Colin A. Espie, Nuffield Department of Clinical Neurosciences/ Sleep & Circadian Neuroscience Institute, University of Oxford, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU, UK.

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,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 ( $\alpha \geq 0.86$ ) 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.

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### **STRENGTHS AND LIMITATIONS**

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- 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,<sup>1</sup> it is seldom adequately assessed and treatment services are often poor.<sup>2,3</sup> This perhaps reflects the perspective that insomnia is usually a symptom,<sup>4</sup> coupled with minimal medical education on sleep and its disorders.<sup>5</sup> 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),<sup>6</sup> and recently the DSM-5 Workgroup recognised that the previous dichotomy of primary versus secondary insomnia is not evidence-based.<sup>7,8</sup> 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*".<sup>9</sup> Second, insomnia is not necessarily transient or benign. Once established, it is remarkably persistent,<sup>10,11</sup> constituting a risk factor for the development of physical and mental health problems, notably depression,<sup>12-14</sup> as well as adverse effects upon quality of life.<sup>15</sup> Chronic insomnia is also associated with high societal cost,<sup>16</sup> and is, for example, a robust predictor of work disability.<sup>17</sup> Third, insomnia is treatable. There is a very substantial level 1 evidence-base, evaluating pharmacological and cognitive-behavioural therapies (CBT),<sup>18,19</sup> although the latter are very seldom available.<sup>3,20</sup>

Insomnia is ubiquitous<sup>21</sup> 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,<sup>22</sup> for example, for depression,<sup>23</sup> anxiety<sup>24</sup> and alcohol problems.<sup>25</sup> In the insomnia field, two scales in particular are widely used: the Pittsburgh Sleep Quality Index (PSQI)<sup>26</sup> and the Insomnia Severity Index (ISI).<sup>27</sup> 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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6 psychometrically, and is more specific and based on DSM-IV criteria for insomnia. It  
7 is used in the main to select people for clinical trials and as an outcome measure.  
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10 In this paper, we present a further measure (the Sleep Condition Indicator:  
11 SCI) that may have some useful features. The SCI is informed by the development  
12 phase for DSM-5 insomnia disorder,<sup>7,8</sup> coupled with published research diagnostic  
13 criteria<sup>28</sup> and recommended quantitative parameters for sleep disturbance.<sup>29</sup> In  
14 keeping with DSM-5, the SCI also evaluates associated daytime factors, which are  
15 important drivers of clinical complaint<sup>21</sup> and should be incorporated in insomnia  
16 measurement.<sup>15,30</sup> In terms of utility, the SCI is brief but versatile. It yields a)  
17 a dimensional perspective on sleep quality: on an intuitive, global scale where higher  
18 scores represent better sleep; b) a visual profile of night-time and daytime symptoms  
19 that the clinician can use in consultations; and c) indicative cut-off points for clinically-  
20 significant Insomnia. This paper summarises the development and evaluation of the  
21 SCI across several studies, and in doing so addresses two major questions. First,  
22 does the SCI have adequate psychometric properties?; and second, is it possible to  
23 derive an even briefer, short-form, SCI that has similar psychometric characteristics?  
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## 37 **METHODS**

### 38 **Sample characteristics**

39 Data are reported from five validation studies (total n=30,941; 71% Female) in which  
40 SCI items were administered. The Great British Sleep Survey (GBSS) was an open  
41 access, web-based survey completed by adults (18+yr.) with a UK postcode yielding  
42 data on 12,628 participants [72% Female; mean age = 38.7yr (SD = 14.5)] between  
43 February 2010 and August 2011.<sup>31</sup> The GBSS+ was a revision of the GBSS,  
44 extended to any valid zip code worldwide, from May 2011 to March 2012 (n=11,017;  
45 68% Female; 42.3yr (16.5)). The TV sample was obtained in response to a network  
46 programme (The Food Hospital, Channel 4) on the sleep benefits of tart cherry juice  
47 (n=6,876; 76% F, 36.4yr (13.3)). Glasgow Science Centre data (n=256; 56% Female,  
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6 40.3yr (14.9)) were collected in 2009-2010 during a study which assessed the  
7 relationship between salivary alpha-amylase, sleep pressure and diurnal  
8 preference.<sup>2832</sup> Finally, an RCT sample comprised 164 participants (72% F, 48.9yr  
9 (13.7)) recruited into a placebo-controlled evaluation of CBT for insomnia.<sup>3329</sup> Ethical  
10 agreement concerning the latter two studies are provided in the source manuscripts.  
11 For the open access web surveys participation was covered by the site terms.  
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17 Across our combined largest samples (GBSS, GBSS+, TV), women were  
18 slightly younger than men [38.5 (14.9) vs 40.1 (14.7) yrs;  $t(27638) = 7.94$ ,  $p < .0001$ ]  
19 and the great majority was in average or better physical health (86%) and mental  
20 health (82%) [5-point scale: 0 'very good', 1 'good', 2 'average', 3 'poor', 4 'very  
21 poor']. Respondents who made some use of prescription sleeping pills (9.1%) were 7  
22 years older than those who did not [46.2 (15.1) vs 39.1 (15.1)yr,  $t(20813) = 19.6$ ,  
23  $p < .0001$ ] and had a substantially poorer SCI score [8.56 (4.93) vs 15.6 (7.80),  
24  $t(20813) = 38.8$ ,  $p < .0001$ ]. Of the total sample, 18.1% took over-the-counter sleep  
25 aids (OTCs), and more than one-third of those taking sleeping pills also used OTCs.  
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### 35 Design and Measurement

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

### 50 Development of the Sleep Condition Indicator (SCI)

#### 51 Content Validity

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6 An 8-item scale was developed (see Appendix) based upon DSM-5 workgroup draft  
7 criteria that were available at the time (in 2010).<sup>7,8</sup> At that stage, a consultation  
8 process was underway and draft information was posted on the APA website.  
9  
10 Consequently, the SCI items generated comprised 2 quantitative items on sleep  
11 continuity [item 1: getting to sleep; item 2: remaining asleep], two qualitative items on  
12 sleep satisfaction/dissatisfaction [item 4: sleep quality; item 7: troubled or not], two  
13 quantitative items on severity [item 3: nights per week; item 8: duration of problem],  
14 and two qualitative items on attributed daytime consequences of poor sleep [item 5:  
15 effects on mood, energy, or relationships (personal functioning); item 6: effects on  
16 concentration, productivity, or ability to stay awake (daytime performance)].

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

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49 We then investigated the inter-relationships of our 8 SCI items using the  
50 same methodology, but applying this time a minimum item loading of 0.40, to permit  
51 incorporation of all eight items. PCA with Varimax Rotation (KMO=0.888; Bartlett,  
52  $p<.0001$ ) yielded a two component solution (66.4% explained variance). Component  
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6 1 (Eigenvalue=4.256, 53.2% variance), named 'sleep pattern' comprised items 1, 2,  
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8 3, 4 and 8 with factor loading ranging from 0.453 to 0.776. Component 2  
9  
10 (Eigenvalue=1.06, 13.2% variance), 'sleep-related impact' comprised item 5 (factor  
11  
12 loading 0.886), and item 6 (0.911). Consistent with clinical presentation, concerns  
13  
14 about sleep (item 7) loaded significantly, and similarly, on both 'sleep pattern' (0.616)  
15  
16 and 'sleep-related impact' components (0.576).

### 17 18 19 *Response format*

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21 Each item was scored on a 5-point scale (0 - 4), with lower scores, in the 0 – 2 range,  
22  
23 reflecting putative threshold criteria for Insomnia Disorder (shaded area: see  
24  
25 Appendix). The clinician can then see at a glance the profile of possible concerns.  
26  
27 Possible total score ranges from 0–32, with higher values indicative of better sleep.  
28  
29 However, scores can be readily transformed into a more intuitive 0-10 SCI range,  
30  
31 either by dividing the total by 3.2, or by using an online version with automated  
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33 scoring, which is available free of charge ([www.sleepio.com/clinic/](http://www.sleepio.com/clinic/)).

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### 34 35 36 *Concurrent Validity and association with related domains*

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38 Data from the Science Centre sample demonstrated that the SCI correlates inversely  
39  
40 with the PSQI ( $r=-.734$ ) and the ISI ( $r=-.793$ ), suggesting measurement properties  
41  
42 consistent with these related measures. There was also a small but significant  
43  
44 association of sleep condition with self-rated physical health ( $r=.222$ ), and an  
45  
46 association also with mental health ( $r=.335$ ). Using more specific measures, in the  
47  
48 Science Centre sample, correlation of the SCI with symptoms of depression ( $r=-.426$ )  
49  
50 and anxiety ( $r=-.400$ ) on the Hospital Anxiety and Depression Scale<sup>34</sup> was modest,  
51  
52 and greater than we observed in our RCT sample [on the Depression Anxiety Stress  
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54 Scale<sup>35</sup>: depression ( $r=-.267$ ), anxiety ( $r=-.236$ ) and stress ( $r=-.263$ )].



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6 We have not at this stage tested the discriminant validity of the SCI against clinical  
7 diagnosis of insomnia disorder. As a first step, however, using our Science Centre  
8 sample, we tested the concurrent validity of SCI cut-offs, ~~were able to compare the~~  
9 ~~discriminant ability of SCI (score  $\leq 16$ ),~~ reflecting minimum criteria for putative  
10 ~~Insomnia Disorder (see appendix), against~~ published validated ISI cut-off scores.  
11 We first categorized our sample according to ISI ranges (ISI score=0-14, reflecting  
12 ~~“no insomnia disorder” “absence of insomnia” or “sub-threshold insomnia”~~ [n=228]  
13 versus ~~“probable insomnia disorder” “moderate or severe insomnia”~~ ISI score=15-28,  
14 n=27]<sup>36</sup> and conducted an independent *t*-test on SCI total score. Mean SCI values  
15 for the ~~“probable insomnia disorder”~~ category were 10.7 (SD=5.3) versus 22.9  
16 (SD=6.2) for ~~“no insomnia disorder”~~ ( $t=9.86, p<.0001$ ). Applying SCI cut-off  $\leq 16$ , 89%  
17 of the sample were correctly identified as having ~~“probable insomnia disorder”~~ (ISI  
18 scores of  $\geq 15$ ), while SCI score of  $>16$  correctly identified 82% of those with ~~“no~~  
19 ~~insomnia disorder”~~. These findings provide further evidence of concurrent  
20 ~~validity~~ therefore suggest good discriminant validity for the SCI and help to confirm  
21 that a score of  $\leq 16$  on the SCI seems reasonable to detect possible insomnia  
22 disorder.  
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#### 37 38 *Internal consistency*

39 Cronbach's  $\alpha$  for the GBSS sample was strong at 0.857 (range of  *$\alpha$ -if-item-deleted*  
40 0.822-0.860). Replication of these internal consistency data was obtained from the  
41 GBSS+ sample ( $\alpha=0.865$ ). Mean corrected item-total correlation was moderate  
42 ( $r=0.620$ ) indicating substantial unique variance per item (shared variance = 38%).  
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#### 49 *Sensitivity to change*

50 We have previously reported that the SCI is sensitive as a measure of treatment  
51 outcome.<sup>33</sup>  
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### 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).<sup>376</sup> 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  $\beta = .515$ ) and item **78** '...troubled you in general' ( $\beta = .491$ ) 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 ( $r = .904$ ).

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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 that suggest good discriminant ability of the SCI score  $\leq 16$  may help to detect probable insomnia disorder, ~~(score  $\leq 16$ )~~, 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.<sup>3</sup> 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  $\geq 15$ ), consistent with prevalence data (Morin reference),<sup>2</sup> providing further support for our ISI-SCI concurrent validity analysis comparing the ISI and SCI in this sample.

Furthermore, ~~a limitation of it 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<sup>27</sup> and Athens Insomnia Scale<sup>37</sup> 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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6 5 criteria do not feature as SCI items (e.g. the sleep difficulty occurs despite  
7 adequate opportunity for sleep; the insomnia is not better explained by and does not  
8 occur exclusively during the course of another sleep-wake disorder; and the insomnia  
9 is not attributable to the physiological effects of a substance). However, these items  
10 are not easy to probe unambiguously with a self-completed psychometric instrument  
11 and would require careful scrutiny by a treating clinician. It is, of course, possible that  
12 sleep disorders other than insomnia (e.g. circadian rhythm sleep disorders, sleep-  
13 breathing disorders) may also lead to low scores on the SCI. -Thus, the SCI should  
14 be viewed as an insomnia screening tool, consistent with features of DSM-5, but  
15 requiring careful follow-up in clinical practice to fully define the nature of sleep  
16 disturbance.  
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## Appendix: The Sleep Condition Indicator

Item	Score				
	4	3	2	1	0
<b>Thinking about a typical night in the last month ...</b>					
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 awakenings 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
<b>Thinking about the past month, to what extent has poor sleep ...</b>					
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
<b>Finally ...</b>					
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:

- Add the item scores to obtain the SCI total (minimum 0, maximum 32)
- A higher score means better sleep
- Scores can be converted to 0 – 10 format (minimum 0, maximum 10) by dividing total by 3.2
- 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](http://www.sleepio.com/clinic)

## Appendix: The Sleep Condition Indicator

Item	Score				
	4	3	2	1	0
<b>Thinking about a typical night in the last month ...</b>					
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 awakenings 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
<b>Thinking about the past month, to what extent has poor sleep ...</b>					
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
<b>Finally ...</b>					
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:

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

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