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Original Article

A very brief self-report scale for measuring insomnia severity using two items from the Insomnia Severity Index - development and validation in a clinical population

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ABSTRACT

Objective: To develop a very brief scale with selected items from the Insomnia Severity Index (ISI), and to investigate the psychometric properties of the proposed scale in a psychiatric sample.
Methods: Patient data from seven Cognitive Behavioral Therapy (CBT) for insomnia trials and from regular care were used in psychometric analyses (N = 280-15 653). The samples included patients screening (N = 6936) or receiving treatment (N = 1725) for insomnia and other psychiatric conditions. Six criteria relating to component structure, sensitivity to change and clinical representativeness were used to select items. Psychometric analyses for the proposed very brief scale were performed.
Results: One item representing satisfaction/dissatisfaction with current sleep pattern and one item representing interferences with daily functioning, were selected to create the 2-item ISI version. Correlations with the full scale were high at screening, pre and post, and for change (0.82-0.94). Categorical omega was $\omega_C = 0.86$. With a cut-off of 6 points, the scale could detect Insomnia Disorder with a sensitivity of 84% and a specificity of 76%, which was close to the full ISI showing 86% and 80% respectively.
Conclusions: The systematic psychometric evaluation based on a large sample from different contexts makes the proposed 2-item ISI version (ISI-2) a strong candidate for a very brief scale measuring insomnia, both for detecting cases and for measuring change during CBT with an overall high discriminative validity. ISI-2 is especially useful in clinical settings or population studies where there is a need to measure more than one condition at a time without overburdening patients.
Clinical trials: Trials used in this analysis: ClinicalTrials.gov identifier: NCT01105052 (https://www.clinicaltrials.gov/ct2/show/NCT01105052) (sample b), ClinicalTrials.gov identifier: NCT01256099 (https://clinicaltrials.gov/ct2/show/NCT01256099) (sample c and d), German clinical trial (DRKS), registration ID: DRKS00008745 (https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00008745) (sample e), ClinicalTrials.gov identifier: NCT01663844 (https://clinicaltrials.gov/ct2/show/NCT01663844) (sample f and g), ClinicalTrials.gov Identifier: NCT02743338 (https://clinicaltrials.gov/ct2/show/NCT02743338) (sample h).
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1. Introduction

The point prevalence of insomnia disorder is 10–22% in the general population [1], and comorbidity with anxiety and affective disorders is high [2]. Having effective ways of detecting and

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monitoring disorder severity to detect treatment effects is essential to improve care for patients in clinical settings.

Several measures of insomnia have been developed, such as the Athens Insomnia Scale (AIS) [3], The Bergen Insomnia Scale (BIS) [4], the Sleep Condition Indicator (SCI) [5], Basic Scale on Insomnia complaints and Quality of Sleep (BaSIQS) [6], and the Insomnia Severity Index (ISI) [7]. These scales all have adequate psychometric properties, are reliable and valid. Of these scales, the AIS and the ISI have both been shown to be sensitive to change [8]. With over 3000 citations, the ISI is the most commonly used measure in insomnia research, and is seen as an essential measure for global sleep and insomnia symptoms [9].

The above measures are all relatively brief with only 6–8 items, and capture important aspects of insomnia. However, six to eight items can still be demanding for patients to fill out, for example when given within a battery of questionnaires screening for a range of conditions or symptoms, or when given repeatedly (eg, weekly) during treatment to monitor symptom change. In addition, most measures of insomnia symptoms have focused on detecting insomnia in different samples, and from a psychometric perspective, a goal has often been to compose measures with high internal consistency. However, a possible overlap between measures of insomnia and measures of other conditions have seldom been thoroughly examined, and thus the specificity when it comes to discriminating towards other conditions and measuring insomnia specific symptom change is unknown. This is especially problematic in psychiatric settings, where patients often suffer from comorbid conditions. Having patients fill out several scales where many items either overlap between scales or are very similar and correlated to other items in the same scale would produce a high, and in many cases unnecessary, burden on patients, especially if administered weekly. Very brief measures are thus called for, especially when more than one symptom area is to be screened for or monitored over time.

Very brief scales of two to three items have been developed for other disorders such as depression, generalized anxiety and social anxiety [10–12]. Recently, our research group has proposed a two-item version of the Panic Disorder Severity Scale (PDSS) [13] using a set of pre-defined criteria including good component structure and sensitivity to change [14].

Regarding insomnia, a previous three-item insomnia scale, is the Minimal Insomnia Symptom Scale (MISS) [15]. Evidence was provided for the utility of MISS in epidemiological settings. MISS also showed promise as a convenient very brief screening measure of insomnia in health care settings, but has, to the best of our knowledge, not been tested for sensitivity to symptom change. The two-item version of the Sleep Condition Indicator (SCI) [5] has been tested as a screening instrument in a primary care setting, with good sensitivity and specificity compared to the full scale, but has not been tested in relation to a clinical diagnosis of insomnia disorder. We have not found studies testing the SCI for sensitivity to change, ie as a treatment outcome measure. Another example of a short form scale is the 5 item version of the Athens Insomnia Scale, (AIS-5) [3]. The AIS-5 represents only the night-time aspects of insomnia and is therefore not an alternative to a scale aiming at also measuring daytime consequences of insomnia.

Morin and colleagues [16] have analyzed individual ISI items using item response theory (IRT) analyses, to examine response patterns and receiver-operating characteristics (ROC) in a community sample and for assessing treatment response in a clinical sample. The study found adequate discriminatory capacity for 5 (staying asleep, satisfaction, interference, noticeable, distressed) of the 7 items in the full ISI. One conclusion by the authors of this study was that the development of new instruments with two or three main items is warranted, eg for case findings in large epidemiological studies. Consequently, a three item version of ISI has recently been proposed, but the empirical data in this study was very restricted consisting of a small group of 86 war veterans with posttraumatic stress disorder [17]. Furthermore, the study did not assess sensitivity to change in the proposed brief ISI. Another recent study also proposed a three item version of ISI [18]. This study was much larger (N = 3444) but consisted solely of screening data administered to older adults.

From a theoretical and clinical perspective, insomnia can be seen as consisting of two components - nighttime problems and daytime problems. Component analysis on some of the insomnia scales, such as the AIS-8, have found these two components [19]. A very brief scale should ideally contain items that represent both components.

1.1. Aims of the study

We aim to develop a very brief self-report version of the Insomnia Severity Index (ISI), suitable both as a screener and as an outcome measure that can be used repeatedly during treatment, by selecting items from the full scale according to six comprehensive and previously used criteria [14]. The scale should reflect core aspects of insomnia (for example nighttime and daytime problems respectively), be able to specifically detect insomnia also in a population with several comorbid conditions (ie showing discriminative validity), be reliable, and be sensitive to change during treatment. We also aim to test the psychometric properties of the proposed brief scale.

2. Methods

2.1. Participants

The current study uses patient reported screening, diagnostic, and outcome data from eight original sources (a-h) and one merged data source including the other sources plus screening and diagnostic data from the Stockholm Internet Psychiatry Clinic. These samples were selected for pragmatic reasons, since all participants had been assessed and received treatment at the Internet Psychiatry Clinic where the researchers reside, and since they reflected different populations in terms of what conditions they primarily had sought care for and if they received treatment within a clinical trial or regular care.

(a) Patients in routine care at the Internet Psychiatry Clinic within the Stockholm county public health care, Sweden (effectiveness studies for subsamples of this sample have been published) [20–22]. The sample, all diagnosed with the condition they were treated for, consists of patients included in therapist-guided Internet-delivered Cognitive Behavioral Therapy (ICBT) for insomnia (ICBT-i) (n = 442), panic disorder (n = 1810), major depressive disorder (n = 3168), social anxiety disorder (n = 1852) and health anxiety (n = 276) between October 2007 and November 2019 (N = 7552).
(b) Participants diagnosed with insomnia from a study by Jernelöv and colleagues [23] (N = 133), where the authors compared three groups receiving insomnia treatment: bibliotherapy with telephone support (n = 44), bibliotherapy without telephone support (n = 45) and a waitlist control group that got delayed bibliotherapy without support (n = 44).
(c) Participants diagnosed with insomnia from a study by Kaldo and colleagues [24] (N = 148), where ICBT-i (n = 73) was compared with an active internet based control condition (n = 75).

(d) Participants from a study by Blom and colleagues [25] (N = 43), where ICBT-i (n = 22) was compared to ICBT for depression (n = 21) for patients diagnosed with both insomnia and depression.
(e) Participants diagnosed with various mental health disorders from a study by Hallgren and colleagues [26] receiving tailored cognitive behavioural therapy in the randomised controlled trial REGASSA (N = 317).
(f) Participants diagnosed with insomnia from a study by Forsell & Jernelöv and colleagues [27] where ICBT-i was delivered with or without individualized additional support (N = 251).
(g) Participants diagnosed with insomnia and depression from a study by Blom and colleagues (not yet published) (N = 156), comparing combined ICBT for insomnia and depression (n = 78) to ICBT for depression with a placebo intervention for insomnia (n = 78).
(h) Participants diagnosed with insomnia from a study by Jernelöv, Rosén and colleagues (not yet published) receiving ICBT in a randomized controlled trial comparing two forms of ICBT for insomnia (N = 241).
(i) A merged sample with screening data and for some patients, diagnostic data from all sources a-h above, plus available data from people who after screening or assessment were not included for treatment, from both the regular Internet Psychiatry Clinic and all the above studies (N = 15 653). Thus, this sample also includes 6812 participants who were screened, and in some cases diagnostically assessed, in the studies or at the Internet Psychiatry Clinic.

2.2. Ethical approvals

All samples were from studies approved by the Regional Ethics Review Board in Stockholm, with registration numbers: (a) 2011/2091-31/3, (b) 2008/23-31/4, (c) and (d) 2009/1810-31/3, (e) 2010/1779-31/4, (f) and (g) 2012/934-31/4, (h) 2016/44-31/4.

2.3. Measures

2.3.1. Diagnostic assessment

The procedures for diagnosing insomnia were slightly different in the different samples, but all diagnosing was based on the DSM-5 criteria [28] (samples a, f, g and h) or the diagnostic research criteria [29] (samples b,c,d and e), which are in essence similar to those in DSM-5. For samples a, f and g, the diagnosis was based on face to face interviews by physicians, for the other samples diagnosing was done in a structured telephone interview by licensed psychologists or psychology master students in their final year, under supervision by a licensed psychologist. Note, that for sample a), a thorough diagnostic assessment for insomnia has been done primarily for patients who sought and received insomnia treatment with CBT-i. Patients in the other treatments (depression, panic disorder and social anxiety disorder) have only been assessed for insomnia since 2017 when the insomnia treatment was introduced, and in some of these cases a comorbid insomnia diagnosis has probably not have recorded since it was not a target for treatment.

2.3.2. ISI

The Insomnia Severity Index (ISI) is a seven item scale measuring insomnia symptoms with scores ranging between 0 and 28 points. The scale has previously been shown reliable and sensitive to change [7,16]. All samples included the ISI as a screening and/or outcome measurement.

2.3.3. MADRS-S

The Montgomery-Åsberg Depression Rating Scale-Self assessment (MADRS-S) is a self-rated version of a clinical rated depression scale designed to be sensitive to change [30]. The MADRS-S can be used online without affecting the psychometric properties in a clinically meaningful way [31]. MADRS-S was included as a screening measurement in all samples, and as an outcome measure in samples a, d, e, f and g.

2.3.4. PDSS-SR

The PDSS [13] was developed for the assessment of panic disorder severity, it has subsequently sensitivity to change when used as a self-report measure (PDSS-SR) [32]. PDSS-SR was included as a screening measurement in samples a and e, and as an outcome measure in sample e.

2.3.5. LSAS-SR

The Liebowitz Social Anxiety Scale (LSAS) [33] is a clinician-administered social anxiety rating scale. The LSAS assesses the degree of anxiety or avoidance in a number of typical social and performance situations. The self-report version of LSAS (LSAS-SR) shows good psychometric properties and it compares well to the clinical-administered version [34,35]. LSAS-SR was included as a screening measurement in samples a and e, and as an outcome measure in sample e.

2.3.6. SHAI

The Short Health Anxiety Index (SHAI) [36] measures symptoms of health anxiety and hypochondriasis with 14 items scored on a scale ranging from 0 to 3 points. SHAI was included as a screening and outcome measure in a subsample (n = 269) of sample a.

2.3.7. SLEEP-50

The SLEEP-50 questionnaire (SLEEP-50) [37] is a self-administered questionnaire investigating sleep complaints. The questionnaire consists of 50 questions scored on a 4-point scale (1–4 p). The scale has the following sub-scales: Sleep Apnea, Insomnia, Narcolepsy, Restless Legs/PLMD, Circadian Rhythm Sleep Disorder, Sleepwalking, Nightmares, Factors Influencing Sleep, and the Impact of Sleep Complaints on Daily Functioning. SLEEP-50 was used as a screening measure in samples f, g and h.

2.3.8. GAD-7

The Generalized Anxiety Disorder - 7 item (GAD-7) [38] measures worry and anxiety with 7 items scored 0–3 points. GAD-7 was included as a screening measure in a subsample (n = 269) of sample a, as well as in sample h.

2.3.9. PSWQ

The Penn State Worry Questionnaire (PSWQ) [39,40] measures worry with 16 items scored 1–5 points. PSWQ was used as an outcome measure in sample e.

2.3.10. PSS-10

The Perceived Stress Scale –10 items (PSS-10) [41] measures perceived stress in daily life with 10 items scored 0–4 points. PSS-10 was used as an outcome measure in samples b, c, d and e.

2.4. Choice of items for the very brief version of ISI

The goal was to shorten the questionnaire as much as possible while retaining its previously demonstrated psychometric properties. With that goal in mind, we used the following six criteria, which were previously used in the analysis of the PDSS-SR [14], for item selection. Since the scale is an already well-established

instrument to measure the construct in question, face validity is expected to be high among all items and hence it is not evaluated until the fifth step in the selection process.

2.4.1. Relevant component structure

The items should present high component loadings to one or more relevant constructs in the original scale, and if component loadings show that two or more important subscales exist in the original scale, the items should load to different subscales to cover the full clinical spectrum.

2.4.2. Discriminative validity toward other constructs

The items should not be heavily associated to other related phenomena, as that might be indicative of a more generally salient item (eg, psychological distress or low mood) rather than being a uniquely specific item for the target construct (ie, insomnia in this case).

2.4.3. Correlation with diagnosis

The items should correlate strongly with the occurrence of the relevant diagnosis (ie, insomnia) as detected by a thorough clinical assessment (or other Gold Standard indicator of disease).

2.4.4. Sensitivity to change

Pre-to post-treatment change score for an item should be large compared to other items, and should correlate strongly with other gold-standard clinical markers of change.

2.4.5. Clinical representativeness (face validity)

The items must be as specifically worded towards key phenomena within the disorder and as weakly related to other forms of psychological distress as possible. The items must capture as full a picture as possible of the entire disorder.

2.4.6. Correlation of very brief scale with total scale

The proposed very brief scale should correlate strongly with the full scale compared to other possible very brief scales according to earlier criteria (ie if several items perform similarly well according to criteria I–V, this last criterion can be used as a tie-breaking test, but does not replace the item per item-analyses). The correlations between the total scale candidates for very brief scales should be done with raw scores, and change scores, to retain sensitivity to change.

Table 1 gives an overview of which samples were used in the dataset of the respective analyses in the steps described above, including an overview of the different samples used for criterion II which had to be performed in six different samples ($II^{a\text{-}f}$). The items of the ISI were subjected to tests covering all of the criteria I-VI until a final very brief measure had been decided. That scale was then subjected to psychometric testing in the following way.

2.5. Psychometric testing of the proposed very brief version

2.5.1. Reliability

Categorical omega (ω_C) was used as a measure of reliability [42], to avoid the many deficiencies of using Cronbach alpha [43]: alpha has been shown to rely on statistical assumptions that are nearly never met, which cause the measure to be overinflated, and often the point estimate does not reflect the variability in the estimation of the parameter. In comparison, the omega makes fewer assumptions of the data, and attenuates the problems with inflation. In addition, bootstrapping and generating confidence intervals improves the interpretation of the estimation. While the ω_C is interpreted in the same way as alpha, it has been shown to be much less biased [44,45]. The omega was bias-corrected bootstrapped (n = 18 000) for confidence intervals to reflect the nature of our sample and data [46].

2.5.2. Receiver operator characteristics curve-analysis

The proposed very brief scale was tested against the gold standard psychiatric assessment of insomnia diagnosis carried out at intake for those individuals who had been assessed for insomnia. A ROC-analysis was used, and then Area under the curve (AUC) as well as sensitivity and specificity were calculated for different cut-off values of the short scale.

2.5.3. Sensitivity analysis: correlation with insomnia versus other sleep disorders

As a sensitivity analysis, the proposed very brief scale was correlated against insomnia and other sleep disorders represented by the SLEEP-50-subscales to explore the insomnia specificity of the proposed scale.

Table 1
Description of the samples used in the analyses.

Analysis	Samples used	Dataset size
I Relevant component structure	All samples (i)	N = 15 653
II Discriminative validity toward other constructs		
II^a: ISI vs MADRS-S, LSAS-SR, PDSS-SR	II^a (samples e, i)	II^a N = 12 877
II^b: ISI vs SHAI	II^b (subsample from a)	II^b N = 269
II^c ISI vs PSS-10	II^c (samples b, e)	II^c N = 438
II^d ISI vs PSWQ	II^d (sample e)	II^d N = 280
II^e ISI vs GAD-7	II^e (subsample from a, h)	II^e N = 810
II^f ISI vs SLEEP-50 subscales	II^f (samples f, g, h)	II^f N = 1281
III Correlation with diagnosis	(subsample from a)	N = 2234
IV Sensitivity to change	(subsample from a, b, c, d, f, g, h)	N = 826
V Clinical representativeness (face validity)	–	–
VI Correlation of very brief scale with total scale	All samples (i)	N = 15 653

ISI, Insomnia Severity Index; MADRS-S, Montgomery-Åsberg Depression Rating Scale - Self Rated; LSAS-SR, The Liebowitz Social Anxiety Scale - Self Rated; PDSS-SR, Panic Disorder Severity Scale-Self Rated; SHAI, Short Health Anxiety Index; PSS-10, Perceived Stress Scale-10 items; PSWQ, Penn State Worry Questionnaire; GAD-7, Generalized Anxiety Disorder Scale; SLEEP-50, SLEEP-50 questionnaire (a questionnaire screening for multiple sleep disorders). Samples: a (routine internet psychiatry), b (insomnia treatment with or without telephone support), c (full insomnia treatment vs active control), d (insomnia treatment vs depression treatment), e (individually tailored treatment including insomnia component), f (insomnia treatment with adaptive additional support), g (treatment for insomnia and depression vs depression treatment with insomnia placebo component), h (comparing 2 active insomnia protocols), and i (full sample including a-h plus ISI screening data also for other disorders than insomnia).

2.6. Statistical analyses

Principal component analysis (PCA) with Varimax rotation was used for all exploratory component analyses. Since our aims was to reduce the ISI, a set of observed variables, and not reassess the latent factors measured by the ISI, PCA was chosen over factor analysis. PCA seeks to find the optimal representation of the observed variables (All items in the scale) rather than focus on providing loadings for latent factors. Varimax rotation was chosen because it allows us to look specifically for opposing components rather than closely similar ones, and PCA does generally assume orthogonal components [47]. All component loadings below 0.20 are suppressed in tables. Pearson's r was used for all correlations. All statistical tests were two-sided and the alpha-level for statistical significance was set to 0.01. The categorical omega reliability analysis was conducted in R [48] using the MBESS package [49]. All other analyses were performed with either R or IBM SPSS version 25.

3. Results

3.1. Patient characteristics

Characteristics of the patients in the samples can be found in Table 2. In the full sample, 65.7% were women, mean age at screening was 36.5 years and mean insomnia severity measured with the ISI was 13.7. Insomnia was the main/primary diagnosis in 16% (n = 2503) of cases: all participants in the insomnia studies (b, c, d, f, g) had an insomnia diagnosis while sample (a), (e) and (i) also included participants with other primary conditions. Sex differences in individual ISI-items at screening are presented in Supplement B, Table S1. Women scored consistently higher at all ISI items compared to men.

3.2. Choice of items for the very brief version of ISI

This section presents the results of the criteria-related analysis of data performed in order to decide which items we want to propose for the very brief version of ISI.

3.2.1. Relevant component structure - component analysis with ISI items only

Kaiser-Meyer-Olkin Measure of Sampling Adequacy, which was above 0.70 for all performed Principal component analyses (PCA), and Bartlett's Test of Sphericity ($p < 0.001$) both indicated that the sample was suitable for component analysis at all timepoints. Measures of Sampling Adequacy values were all above 0.70 at all timepoints for all items, indicating that no single item was unsuitable for component analysis.

Table 3 summarizes the component loadings for each item to the supposed single underlying construct at each time point. PCA of the ISI at screening generated a single component with an eigenvalue above 1 (4.39) explaining 62.7% of the total variance in ISI. At pretreatment, PCA generated two components with eigenvalue above 1 (3.09 &1.34) explaining 44.09% and 19.17% of the variance in ISI respectively. The second component consisted of 1b and 1c and 1a loaded weakly in both of the components, indicating that 1a could be rather independent from 1b and 1c rather than them being purely additive. In Table 3, only the first and strongest component is presented for comparison purposes towards the other two time points. At post-treatment, the PCA generated 1 component with an eigenvalue above 1 (4.43) explaining 63.31% of the variance in ISI.

Across all time points, items 2, 3 and 5 had the strongest loadings to the single component and items 1a, 1b and 1c the weakest loadings.

3.2.2. Discriminative validity toward other constructs – component analysis including ISI and other scales

In analysis II[a], including all items from the ISI, PDSS-SR, MADRS-S and LSAS-SR at Screening (n = 12 597) initially generated 14 components with an eigenvalue above 1 where all ISI items formed a single component together with the sleep item of MADRS-S (item 3). The scree plot indicated a four-component solution, and the same component with all ISI items and MADRS-S sleep item was found here (factor loadings for the 4-component solution are presented in Supplement B, Table S2).

In analysis II[b], including items from the ISI and SHAI from individuals in sample a (n = 269) generated 3 components with an eigenvalue above 1, also supported by the scree plot. All ISI items formed a single component, but item 1c showed some minor component loadings with the components otherwise including SHAI items (factor loadings for the 3-component solution are presented in Supplement B, Table S3). A component solution with only two components showed clearly that ISI constituted its own component.

In analysis II[c], including items from the ISI and PSS-10 from individuals in sample b and e (n = 438) generated 3 components according to both the eigenvalue and scree plot criteria. All ISI items formed a single component while PSS was split in two (factor

Table 2
Characteristics of the different samples used in the analyses.

Data source (sample)	a	b	c	d	e	f	g	h	i (total sample)
Age m (sd)	35.44 (11.78)	46.68 (14.95)	46.89 (14.75)	47.16 (12.28)	43.67 (12.34)	46.13 (13.73)	43.05 (12.75)	42.97 (13.50)	36.49 (12.72)
	n = 7514	n = 472	n = 589	n = 43	n = 280	n = 290	n = 155	n = 509	n = 15 621
Sex = Female (%)	4700 (62.5%)	378 (80.1%)	417 (70.9%)	23 (53.5%)	204 (72.6%)	205 (70.7%)	95 (61.3%)	370 (72.3%)	10 275 (65.7%)
	n = 7524	n = 472	n = 588	n = 43	n = 281	n = 290	n = 155	n = 512	n = 15 640
ISI SCREEN m (sd)	11.75 (6.48)	18.53 (4.21)	19.51 (4.37)	21.30 (3.44)	–	19.77 (3.87)	19.94 (3.92)	19.64 (3.88)	13.70 (6.84)
	n = 6844	n = 469	n = 589	n = 43		n = 290	n = 154	n = 512	n = 15 653
ISI PRE m (sd)	18.35 (3.99)	17.10 (3.86)	16.58 (3.80)	19.28 (4.08)	13.72 (6.29)	17.49 (4.26)	18.55 (3.85)	16.93 (4.25)	17.03 (4.77)
	n = 432	n = 159	n = 156	n = 43	n = 280	n = 285	n = 150	n = 219	n = 1725
ISI POST m (sd)	8.44 (5.88)	11.30 (5.49)	10.18 (4.99)	14.98 (6.99)	9.33 (6.50)	9.25 (5.07)	13.23 (5.30)	–	8.82 (5.93)
	n = 4021	n = 128	n = 130	n = 41	n = 210	n = 264	n = 129		n = 4924

CI, 95% Confidence interval; ISI, Insomnia Severity Index; PDSS-SR, Panic Disorder Severity Scale-Self Rated; MADRS-S, Montgomery-Åsberg Depression Rating Scale - Self Rated; LSAS-SR, The Liebowitz Social Anxiety Scale - Self Rated. Samples: a (routine internet psychiatry, regardless of primary diagnosis), b (insomnia treatment with or without telephone support), c (full insomnia treatment vs active control), d (insomnia treatment vs depression treatment), e (individually tailored treatment including insomnia component), f (insomnia treatment with adaptive additional support), g (treatment for insomnia and depression vs depression treatment with insomnia placebo component), h (comparing 2 active insomnia protocols), and i (full sample including a-h plus ISI screening data from all routine internet psychiatry patients regardless of primary diagnosis, also for patients not receiving treatment later).

Table 3
Mean and standard deviation for each ISI item and item component loadings with a single component at three different time points.

	SCREEN *N = 15 653*		PRE *N = 1725*		POST *N = 4924*	
	m (sd)	Load	m (sd)	Load	m (sd)	Load
Item 1a - Difficulty falling asleep	1.78 (1.31)	0.667	2.04 (1.25)	0.382	1.07 (1.05)	0.669
Item 1b - Difficulty staying asleep	1.85 (1.30)	0.734	2.41 (1.20)	0.595	1.24 (1.07)	0.730
Item 1c - Problems waking up too early	1.53 (1.32)	0.648	2.04 (1.28)	0.557	1.03 (1.05)	0.675
Item 2 - Satisfied/dissatisfied with current sleep pattern	2.76 (1.05)	0.865	3.28 (0.79)	0.760	2.02 (1.08)	0.865
Item 3 - Interferences with daily functioning	2.23 (1.21)	0.881	2.62 (0.92)	,777	1.42 (1.11)	0.886
Item 4 - Noticeable impact of quality of life (to others)	1.61 (1.22)	0.808	1.87 (1.02)	0.665	0.93 (1.02)	0.819
Item 5 - Distressed about current sleep problems	1.94 (1.32)	0.902	2.78 (0.99)	0.808	1.11 (1.11)	0.889

ISI, Insomnia Severity Index; m, mean; sd, standard deviation; N, sample size; SCREEN, data collected at screening; PRE, data collected at treatment start; POST, data collected posttreatment.

loadings for the 3-component solution are presented in Supplement B, Table S4).

In analysis II[d], including items from the ISI and PSWQ from individuals in sample e (n = 280) generated 4 components with an eigenvalue above 1. All ISI items formed a single component. The same was found when a three-component solution was tested, as indicated by the scree plot (factor loadings for the 3-component solution are presented in Supplement B, Table S5).

In analysis II[e], items from the ISI and GAD-7 from individuals in sample a and h (n = 810) generated 3 components with an eigenvalue above 1. All ISI items formed a single component. This was confirmed in a two-component solution indicated by the scree plot (factor loadings for the 2-component solution are presented in Supplement B, Table S6). Item 7 in GAD-7, (Feeling afraid as if something awful might happen), double loaded with −0.31 in the ISI component, but all ISI items were still kept together.

In analysis II[f], including items from the ISI and SLEEP-50 from individuals in sample f, g and h (n = 1281) generated 4 components with an eigenvalue above 1, also partly supported by the scree plot, showed a more complex pattern then previous component analyses. ISI items 2, 3 4 and 5 formed a component together with subscales representing daytime symptoms in SLEEP-50. Items 1b and 1c formed a component together with the insomnia items in SLEEP-50, and 1a formed a component together with items from SLEEP-50 representing circadian disturbances and other components influencing sleep (component loadings for the 4-component solution are presented in Supplement B, Table S7). When forced into a two-component solution, all ISI items except 1a formed one component, 1a instead joined the SLEEP-50 insomnia scale.

In all these analyses, the pattern from step I was generally repeated, where items 2, 3 and 5 had the strongest component loadings in the ISI component. Item 1b and 1c tended to stick together and 1a was in some cases related more to other sleep constructs.

3.2.3. Correlation with diagnosis

These analyses were based on patients in sample (a) after the diagnostic assessment was broadened to include insomnia in 2017. After screening, these patients went through a diagnostic assessment for insomnia and other psychiatric conditions regardless of which condition they primarily might have sought care for. All items correlated significantly with insomnia diagnosis ($p < 0.001$) at screening (n = 2234). Correlations ranged from $r = .428$ to 0.661. Items 2,3 and 5 had the strongest correlations with diagnosis. Correlations are presented in Table 4.

3.2.4. Sensitivity to change

Items 2, 3 and 5 had the largest mean change scores and effect sizes (Hedges *g*) pre to post treatment for those treated for insomnia (n = 826). Mean change scores and pre to post treatment effect sizes for each item is presented in Table 4.

3.2.5. Clinical representativeness (face validity)

No single item in the ISI (full scale with exact wording, translated from Swedish to English, of items is found in Supplement A) was considered to have a face validity low enough to be removed from consideration in constructing the very brief scale. Item 1a, 1b and 1c concern different forms of insomnia problems, and none of them can be considered a comprehensive criterion for insomnia on its own, since you can have significant problems in one but not the others. Item 2 and 5 are similar in that they focus on evaluating your current insomnia problems, although item 5 has the element of worry/distress instead of satisfaction/dissatisfaction. This could make the item behave more similarly to other scales measuring worry or anxiousness. Item 3 and 4 are similar in that they are more concerned with the impact on quality of life and daytime functioning, although the focus of item 4 on how noticeable this impact of insomnia is to others makes the item stand out as different to all other items because of the possibility of large insomnia problems that are only noticed by the sufferer.

3.3. From items to possible very brief scale candidates

From criteria I to IV we conclude that items 2 (Satisfied/dissatisfied with current sleep pattern), 3 (Interferences with daily functioning) and 5 (Distressed about current sleep problems) were the strongest candidate items for a very brief scale due to their component loadings, correlation with diagnosis and sensitivity to change. From criteria V we cannot conclude that any of the items 2, 3 and 5 would be bad choices for a candidate very brief scale, although there is a possibility that items 2 and 5 are too similar to one another, which would possibly lower the face validity of a very brief scale with just these two items. Since we wanted to reduce the scale as much as possible we then tested all three possible two-item combinations against each other in terms of correlation with the total scale. We also compared them against item 5 alone since this item had the highest component loadings, correlation with diagnosis and was the item most sensitive to change.

3.3.1. Correlation of very brief scale with total scale

The correlations between the means of the three possible two-item scale candidates using items 2, 3 and 5 were compared to the mean of the full scales at screening, pre- and post-treatment as well as with change scores pre-to post-treatment in order to act as a tiebreaker. All two-item combinations performed very similarly with high correlations with the full scale in all analyses, and markedly higher correlations than the one-item candidate we used for comparison. The correlations of the items within the two-item

Table 4
Correlations with ISI item scores, or change scores, and clinical assessments as well as average change scores and effect sizes. All correlations are significant at the 0.01 level (2-tailed).

	ISI item at SCREEN correlated with Insomnia disorder diagnosis	Mean Change PRE-POST (sd)	Effect size PRE-POST, Hedge's *g* (CI)
N	2234	826	826
Item 1a - Difficulty falling asleep	0.496	1.06 (1.09)	0.95 (0.87–1.03)
Item 1b - Difficulty staying asleep	0.495	1.15 (1.16)	1.05 (0.96–1.14)
Item 1c - Problems waking up too early	0.454	0.87 (1.15)	0.74 (0.66–0.81)
Item 2 - Satisfied/dissatisfied with current sleep pattern	0.582	1.33 (1.12)	1.53 (1.40–1.66)
Item 3 - Interferences with daily functioning	0.521	1.24 (1.05)	1.32 (1.21–1.42)
Item 4 - Noticeable impact of quality of life (to others)	0.428	0.87 (1.04)	0.91 (0.83–1.00)
Item 5 - Distressed about current sleep problems	0.661	1.54 (1.11)	1.62 (1.49–1.74)

ISI, Insomnia Severity Index; SCREEN, data collected at screening; PRE, data collected at treatment start; POST, data collected posttreatment. CI, 95% Confidence interval.

subscales themselves showed that items 2 and 3 were more distinctly different from each other than the other possible combinations. These results are presented in Table 5.

3.4. Final decision on items to include in the very brief scale

Considering criteria I-VI we propose that item 2 (Satisfied/dissatisfied with current sleep pattern) and 3 (Interferences with daily functioning) of ISI would constitute good candidates for a very brief insomnia scale (ISI-2).

3.5. Psychometric testing of the chosen very brief version

3.5.1. Reliability

The reliability of the proposed 2-item scale (item 2 and 3) was $\omega_C = 0.861$ (95% CI: 0.855,0.866), while the reliability of the full scale ISI was $\omega_C = 0.940$ (95% CI: 0.936,0.943). The underlying assumption of using a reliability measure is that all items load on the same component [46], thus caution is required when interpreting this reliability, since the two items in the brief scale are deliberately different.

3.5.2. Receiver operator characteristics curve-analysis

The ROC-analysis comparing the score of the proposed 2-item version of ISI (items 2 and 3) with whether or not the psychiatric assessment at intake resulted in a diagnosis of insomnia (n = 2234; diagnosis, n = 917; no diagnosis, n = 1317) produced an area under the curve (AUC) of 0.857 (95% CI: 0.842, 0.872) and a cutoff of 6 or more points produced a sensitivity of 0.839 and a specificity of 0.758.

The performance of the proposed 2-item scale was good and close to the ROC-analysis of the full-scale version of ISI, which produced an AUC of 0.892 (95% CI: 0.878, 0.905) and an optimal cutoff of 16 or more points produced a sensitivity of 0.860 and a specificity of 0.797.

In the sensitivity analysis correlating the proposed scale to different sleep disorders (Table 6) the correlation between ISI-2 and the insomnia sub-scale in SLEEP-50 was, as indicated by the non-overlapping correlations, significantly higher than correlations with other sleep disorders as measured with SLEEP-50.

4. Discussion

We aimed to develop and test a very brief diagnosis-specific scale for measuring sleep difficulties and to use as a screener for insomnia diagnosis by selecting items from the ISI according to six specified criteria. We propose a two-item version of the ISI (ISI-2) using items 2 (Satisfied/dissatisfied with current sleep pattern) and 3 (Interferences with daily functioning) of the Swedish version of ISI (See Supplement A). The proposed scale reflects some core aspects of Insomnia Disorder, has a high enough discriminative validity toward a range of non-sleep related psychiatric symptoms and can also discriminate towards other sleep disorders, is well able to detect Insomnia Disorder in a psychiatric, comorbid, population when compared to the full scale, and is also reliable and sensitive to change during CBT.

We chose these items because of how they relate to the six specified criteria used. The two selected items did not necessarily perform the highest on each individual sub-test, but they were deemed most suitable in the overall evaluation, after all criteria had been tested. Performance on the six criteria were as follows: The items had high loadings to the underlying component at screening, pre- and post-treatment (I). The items did not cross load with other underlying components: social phobia, depression, panic disorder, health anxiety and other sleep disorders (II). The items correlated relatively strongly with diagnosis at intake (III). The items demonstrated a relatively high sensitivity to change during CBT (IV). The items were worded in such a way that they encompassed both nighttime and daytime problems, constituting good face-validity (V). Out of the three most promising possible two-item subscales, the one with the selected items (2 and 3) had similarly high correlations with the full scale compared to the other candidates. Additionally, it had the lowest inter-scale correlation,

Table 5
Sum of 2-item scale candidates correlated with the total sum of ISI and the inter-subscale correlation of the items in a subscale, plus the 1-item scale candidate. All correlations are significant at the 0.01 level (2-tailed).

Proposed scale, 2-item combo or 1-item alone	SCREEN n = 15 650	PRE n = 1724	POST n = 4923	Change pre-post n = 1226	Inter-scale correlation
Item 2 - Satisfied/dissatisfied with current sleep pattern Item 3 - Interferences with daily functioning	0.92	0.82	0.94	0.88	0.73
Item 2 - Satisfied/dissatisfied with current sleep pattern Item 5 - Distressed about current sleep problems	0.92	0.81	0.94	0.90	0.79
Item 3 - Interferences with daily functioning Item 5 - Distressed about current sleep problems	0.93	0.83	0.94	0.89	0.78
Item 5 alone - Distressed about current sleep problems	0.89	0.74	0.88	0.83	N/A

ISI, Insomnia Severity Index; SCREEN, data collected at screening; PRE, data collected at treatment start; POST, data collected posttreatment.

Table 6
Correlations at the screening time point of the proposed very brief version of ISI with different sleep disorders represented by the relevant SLEEP 50-subscales, including 95% confidence intervals, n = 1281.

SLEEP 50-subscale	Insomnia r [95% CI]	Sleep apnea r [95% CI]	Narcolepsy r [95% CI]	Restless legs r [95% CI]	Circadian rhythm r [95% CI]	Sleepwalk r [95% CI]	Nightmares r [95% CI]
Proposed very brief ISI: Item 2 - Satisfied/dissatisfied with current sleep pattern Item 3 - Interferences with daily functioning	0.38** [0.33, 0.43]	0.17** [0.12, 0.22]	0.12** [0.07, 0.18]	0.13** [0.07, 0.18]	0.09** [0.03, 0.14]	0.09** [0.04, 0.15]	0.05 [-0.01, 0.12]

ISI, Insomnia Severity Index; SLEEP-50, SLEEP-50 questionnaire (a questionnaire screening for multiple sleep disorders); * indicates $p < 0.05$. ** indicates $p < 0.01$.

indicating that it captured the broadest clinical picture of the three candidates (VI).

The proposed very brief scale performed well when screening for a diagnosis of Insomnia Disorder compared with ROC-analysis to the full scale, matching the full scale closely when using a cut-off of 6 points or more on the 2-item scale. When considering the reliability analysis, the omega was lower for the very brief scale, but still within the acceptable range. The somewhat lower omega may be an effect of the items in the very brief scale being deliberately different from each other and the reliability analysis assumes a single component. The same pattern was seen in the lower correlation between items 2 and 3 compared to other combinations (as seen in criteria VI). It is reasonable that if only two items are included, they should relate strongly to their respective underlying construct, but the level of similarity between the items should not be too high.

Overall, the component analyses involving items from other measures showed a very clear discriminative validity of all items in the ISI, including the two chosen ones. The exception was with other sleep disorders as measured with the SLEEP-50. Some minor overlap was seen in the component analysis combining items from these two scales. Still, the proposed 2-item scale was clearly and significantly more correlated with the SLEEP-50 insomnia sub-scale than with its other sub-scales, indicating it being an insomnia-specific measure. However, the ability of both the original ISI and our proposed very brief version in discriminating between insomnia and other sleep disorders needs to be further tested in samples where more stringent criteria for other sleep disorders are utilized and where those disorders are more common. Before then, none of these scales should be used to rule out the presence of other sleep disorders. Additionally, the wordings of the two proposed items are similar to the two domains in the PROMIS Sleep Disturbance and Sleep-Related Impairments scales, which were developed to measure sleep disturbance and impairment in general, but may be useful to grade insomnia severity in particular [50].

4.1. Comparison with other very brief insomnia questionnaires

Other short-version measures for similar purposes as the new proposed 2-item version of the ISI is intended for, are the MISS [15] and SCI-02 [5]. The development of these measures differs from the current study, for instance, the MISS was developed “from scratch” and there is no long version of that scale. The items of MISS show corrected item-total correlations of 0.54–0.57, with a total Cronbach's alpha of 0.73, and AUC for the MISS was 0.92 with an optimal cut-off score of ≥6 to detect cases of insomnia. This is slightly higher than the 0.86 we found for the very brief ISI, but in the validation of the MISS as a screener, target diagnosis was set completely on the basis of a self-rated questionnaire, which is likely to increase the association with other self-ratings on insomnia compared to the procedures used in the current study, which were based both on self-ratings and decisions by a clinician. The SCI-02 on the other hand is developed from the full, eight item SCI, using stepwise linear regression to find the subset of items that would explain the greatest proportion of variance. The standardized β coefficients for the items in SCI-02 were 0.491 and 0.515 respectively, and the SCI-02 correlated strongly with the full scale (r = 0.904) [5]. In another study of the SCI-02, the authors found a cut-off of ≤2 for the SCI-02 predicting those identified with probable insomnia according to the full SCI, with a specificity of 81% and sensitivity of 80% [51]. This is in line with the screening capacity we found, but again, since the 2-item ISI was tested against a more independent assessment of diagnosis utilizing structured interviews, rather than just the result of screening with the full ISI, it can be argued that we performed a more conservative test with less risk of being overfitted. Also, the sensitivity of SCI-02 to symptom change is unknown. Reliability of these two scales, and indeed most studies of the reliability of psychological symptom scales, have been presented with Cronbach's alpha, which is not the optimal analysis for this type of data [43] and cannot be directly compared to the categorical omega used in this study. The two studies on war veterans and older adults proposing a 3-item version of ISI [17,18] both concluded that the most suitable three items were sleep satisfaction, distress, and interference; the same three items as were the three main candidates in the current analysis (Items 2, 3 and 5 in the version of ISI used in this study). We have shown, however, that a 2-item version of ISI, with just items on sleep satisfaction and daytime interference, has adequate properties and better represents the two-component structure of insomnia. An interesting future direction of research would be to analyze ISI items with Item Response Theory to investigate how well both the original and very brief version of ISI measures insomnia symptoms at different levels of severity.

4.2. Strengths and limitations

A major strength of this study is the large sample size used in the primary component analyses, and the fact that it includes samples from multiple trials as well as regular care. Additional strengths are the use of patients with a clinical insomnia diagnosis, the use of multiple assessment points before and after evidence-based ICBT-i, and the use of a predefined and structured procedure for item selection.

A possible limitation with the proposed very brief version of ISI is that it leaves the items representing the core symptoms 1a-c out. Core symptoms of insomnia are problems falling asleep, maintaining sleep and waking up too early. Because these symptoms do not have to be present at the same time in one patient, none of them could be included in the very brief scale proposed here on its own. A very brief scale without these items should therefore mention the three core symptoms and state clearly that the questions refer to these symptoms. Although the two chosen items

constitute a very good proxy measure for Insomnia severity and can be used to screen for diagnosis, it is of limited clinical value if the goal is to get a broader clinical picture of a patient's Insomnia symptoms. We also believe it could be useful to develop a new version of a brief scale, where items 1a-c were collapsed into one item. This was, however, not within the scope of the current study. Additionally, the two proposed items are sensitive to change during CBT. It is possible that other candidate items would be more sensitive to other treatment options such as hypnotics, but this needs to be examined in future studies.

One limitation of this study was that the clinicians engaged in the diagnostic procedure were not blind to the participants self-rated ISI-scores. This can affect the reliability of the conclusions relating to criteria III on the correlations between items and diagnosis.

Another limitation was that the diagnosing of Insomnia Disorder was entered into the procedure of the routine care at the Internet Psychiatry Clinic in October 2017. After this period, patients in all treatments should have gotten a diagnostic assessment of insomnia, which would be entered as data for this dataset. Out of the 1469 patients receiving treatment for panic disorder, major depression, social anxiety disorder or health anxiety after October 2017, only 105 (7%) had a second diagnosis of insomnia registered. This low number may indicate that when a participant has self-referred primarily for another condition than insomnia, comorbid insomnia was not properly assessed or registered. This may have affected the above analysis of correlation between ISI-items and diagnosis. The fact that this correlation also was based on data from participants in insomnia trials where the diagnostic procedures were more rigorous constitutes some remedy to this limitation. Also, the purpose was to compare how strongly each item related to the insomnia diagnosis, to inform item selection for the very brief scale, and this limitation is mainly related to the task of defining an optimal screening cut-off. Hence, the proposed cut-off of 6 or more points to indicate an insomnia diagnosis should be further evaluated.

5. Conclusions

The very brief insomnia scale proposed in this study enables researchers and clinicians to measure insomnia symptoms in a valid and reliable way without burdening the respondents with a long questionnaire. This is especially useful when screening for a number of disorders or monitoring several disorder-specific symptoms at once, for instance in transdiagnostic or individually tailored treatments. The very brief scale does not eliminate the need for a thorough assessment of psychiatric conditions and other sleep disorders than insomnia, and the use of the full scale is still warranted at assessments where it is important to get a broader clinical picture.

Statement of significance

There is a need to screen for insomnia in population studies and within health care, and to monitor symptoms in patients receiving treatment. Very brief measures, with only a few items, aim to accomplish valid and reliable screening and monitoring of symptoms without burdening the respondents with long questionnaires. Insomnia Severity Index (ISI) is a widely used insomnia scale. This construction of a very brief version of the ISI utilizes six comprehensive criteria for item selection used in a previous study, aiming to create a very brief disorder-specific scale. The resulting 2-item scale is also proposed to be used to keep track of disorder-specific symptoms in comorbid samples such as those participating in transdiagnostic and individually tailored psychological treatments.

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Conflict of interest

None.

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: https://doi.org/10.1016/j.sleep.2021.03.003.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sleep.2021.03.003.

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