The Development of Sleep Condition Indicator (SCI) Thai Version to Diagnose and Follow Up Thai Patients with Insomnia

Abstract

Background: Insomnia disorder is a common condition that is often unrecognized. Therefore, a simple battery, especially for local language, is required.

Methods: The Sleep Condition Indicator (SCI) was translated from the original English into Thai by two bilinguists (English/Thai). Patients in out-patient clinic of Phramongkutklao hospital both clinically insomnia (base on DSM-V) and no insomnia were self-rated by SCI. Receiver operating characteristic (ROC) and area under the ROC curve (AuROC) calculations were analyzed for cut-off points. The reliable change index (RCI) was further assessed among 4-week post-treatment patients.

Results: A total of 179 adults, 92 had insomnia disorder (study group) and 87 had no insomnia (control group). Sleep condition indicator (SCI)-Thai had an AuROC value of 0.984 (95%CI: 0.965-1.000). When considering the cut-off point from Youden's index, it was found that an SCI score of less than or equal to 26 was the most accurate in diagnosing insomnia. The sensitivity was 94.6% (95% CI: 87.8-98.2), and the specificity was 100% (95% CI: 95.8-100). Fifty-two of 92 patients with significant clinical improvement after 4 weeks of treatment had a reliable change index (RCI) mean of 3.81 (95% CI: 3.32-4.30; p-value< 0.001). The group with medicine treatment had a 1.53-point difference in the pre-and post-treatment SCI scores more than the non-medicine treatment group (95%CI:0.34-2.73).

Conclusion: The SCI Thai version is an efficiency tool for diagnosing insomnia (a cut-off of 26) and following up for post-treatment improvement (a RCI of 4), and all medicine-treated participants had improved clinical symptoms.

Keywords: Insomnia disorder, Sleep condition indicator (SCI), Increase Reliable change index (RCI)

Atichok Pitakkittiporn,
Pasiri Sithinamsuwan

Atichok Pitakkittiporn, Pasiri Sithinamsuwan
Department of Internal Medicine, Phramongkutklao Hospital

Corresponding author:
Pasiri Sithinamsuwan
Department of Internal Medicine, Phramongkutklao Hospital
E-mail : Joepcm35@gmail.com

Introduction

1. Background and signification of the research problem

Insomnia is one of the most common mental health problems worldwide especially among those with age older than 60 years old[1] or those with neurological condition especially neurodegenerative disorders. It affects quality of life as individuals often develop clinically hypersomnolence affecting both physical and mental healths.[2] The standard diagnosis of insomnia is based on diagnostic criteria of insomnia disorder from the Fifth Edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-V)[3] that the general practice may not recognize. Therefore, there are various insomnia batteries developed for using in insomnia field i.e., the Pittsburgh sleep quality index (PSQI), Insomnia severity index (ISI) and the sleep condition indicator (SCI).[4]

The sleep condition indicator (SCI) was recently developed.[4] It composes of eight items (Table 1.), comprising two 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). The SCI was validated quantitative criteria indicative of insomnia disorder (e.g., 31-45 minutes to fall asleep) serve as responses for sleep continuity items 1 and 2. Items 5 and 6 on daytime effects were derived by principal components analysis, as described in the initial validation report.

Table 1 Sleep condition indicator (SCI)

Thinking about a typical night in the last month:

Item		Score				
		4	3	2	1	0
1	How long does is 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 up all the wakening)	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
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 finally:	Not at all	A little	Somewhat	Much	Very much
8	How long have you had a problem with your sleep?	I don't have a problem /<1month	1-2 months	3-6 months	7-12 months	>1 year

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 to facilitate interpretation; Item scores in grey area represent thereshold criteria for DSM-5 insomnia disorder.

The SCI was translated into many languages including Italian[5], Romanian[6], Chinese[7] and French[8] and has been validated with the Fifth Edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-V) criteria. The cut-off of 16 for possible insomnia disorder and the increase Reliable change index (RCI) of 7 point or greater is the most parsimonious value for using in clinical and research practices that represent clinical improvement in insomnia disorder. However, there is no Thai version of SCI available. We therefore aimed to develop and validate the SCI-Thai version as an insomnia questionnaire.

2. Research Objective

2.1 Primary Objectives

2.1.1 To develop a Thai version of SCI

2.1.2 To find a cut-off value from the SCI Thai version for diagnosing insomnia.

2.2 Secondary Objectives

2.2.1 To determine the change of RCI that indicates a clinical response.

2.2.2 To compare the efficacy between pharmacological and non-pharmacological treatments, using our SCI-Thai version.

3. Research Hypothesis

Based on our SCI-Thai version of the insomnia questionnaire, a cut-off less than or equal to 16 can be employed to diagnose insomnia

4. Expected Benefit

To develop a Thai version as a questionnaire to diagnose and follow up patients with insomnia efficiently.

Methodology

1. Research Model

A cross-sectional study

2. Population Characteristics

2.1 Target Population

Volunteers who attended out-patient clinics at Phramongkutklao Hospital

2.2 Sampling

Consecutive patients were invited and read the information sheet. Individuals who accepted to participate in the study signed a consent form.

2.3 Sample Size

The target population included a group of patients with insomnia which could not be estimated. Therefore, to calculate the sample size, it was necessary to calculate the acceptable error level.

It was estimated that for the samples in this study as acceptable error, (e) was estimated to be less than 10%. A population of at least 100 volunteers therefore was required.

2.4 Inclusion Criteria

- Volunteers aged 20-75 years old who visited to Phramongkutklao Hospital

- Volunteers who voluntarily participated in the study signed their written consent

2.5 Exclusion Criteria

- Volunteers with previously diagnosed with one or more sleep disorders, such as breathing-related sleep disorder, narcolepsy, circadian rhythm sleep-wake disorder, and parasomnia

- Body mass index (BMI) > 35 kg/m²

- Volunteers with significant psychiatric disorder

- Volunteers with metabolic equivalent (MET) score < 4

- Volunteers with any other severe diseases and inability to control disease as follows:

- Cardiovascular diseases, such as decompensated heart failure, uncontrolled arrhythmia, severe valvular heart disease, etc.

- Uncontrolled respiratory diseases such as Asthma, COPD, pulmonary fibrosis, etc.

- Chronic infectious diseases, such as AIDs, active tuberculosis disease, etc.

- Severe anemia

- Advanced cirrhosis

- Advanced cancer

- Volunteers withsubstance abuse or currently having neuropsychiatric symptoms from prescription drugs

- Volunteers with significant visual problems

- Pregnancy and lactation

- Currently taking sleeping pills regularly

- shift worker

3. Methods

3.1 **To develop the SCI-Thai** The original sleep condition indicator (SCI) was translated from English into Thai language by two bi- linguists (Thai-English) who had different backgrounds, one was medical personal, and the other was non-medical (Table 2).

Table 2 Thai Version of the Insomnia Questionnaire

แบบสอบถามประเมินโรคนอนไม่หลับ

โดยให้ผู้กรอกแบบสอบถามกากบาทลงในช่องประเมินระดับคะแนนโรคนอนไม่หลับในแต่ละหัวข้อ และรวมผลคะแนนจากการทดสอบ

หัวข้อ	ระดับคะแนน				
	4	3	2	1	0
1. ท่านใช้เวลานานเพียงใดขณะที่เริ่มเข้านอนจนหลับ	0-15 นาที	16-30 นาที	31-45 นาที	46-60 นาที	มากกว่า 60 นาที
2. ถ้าท่านตื่นหลังจากเข้านอนไปแล้ว เวลาที่ท่านตื่นคิดเป็นเวลาประมาณเท่าไร (นับรวมเวลาทุกครั้งที่ตื่นระหว่างคืน)	0-15 นาที	16-30 นาที	31-45 นาที	46-60 นาที	มากกว่า 60 นาที
3. ท่านมีปัญหาเกี่ยวกับการนอนจำนวนกี่ครั้งต่อสัปดาห์	0-1 วันต่อสัปดาห์	2 วันต่อสัปดาห์	3 วันต่อสัปดาห์	4 วันต่อสัปดาห์	5-7 วันต่อสัปดาห์
4. ท่านประเมินคุณภาพการนอนว่าดีเพียงใด	ดีเยี่ยม	ดี	ปานกลาง	แย่	แย่มาก
5. อาการนอนไม่หลับส่งผลกระทบต่ออารมณ์ พลังงาน และความสัมพันธ์ต่อบุคคลรอบข้างของท่านเพียงใด	ไม่ส่งผล	ส่งผลเล็กน้อย	ส่งผลปานกลาง	ส่งผลมาก	ส่งผลมากที่สุด
6. อาการนอนไม่หลับส่งผลต่อสมาธิ ประสิทธิภาพการทำงาน และความตื่นตัวของท่านเพียงใด	ไม่ส่งผล	ส่งผลเล็กน้อย	ส่งผลปานกลาง	ส่งผลมาก	ส่งผลมากที่สุด
7. อาการนอนไม่หลับของท่านส่งผลต่อชีวิตโดยรวมของท่านมากน้อยเพียงใด	ไม่ส่งผล	ส่งผลเล็กน้อย	ส่งผลปานกลาง	ส่งผลมาก	ส่งผลมากที่สุด
8. ท่านประสบปัญหาเกี่ยวกับอาการนอนไม่หลับมานานเพียงใด	น้อยกว่า 1 เดือน	1-2 เดือน	3-6 เดือน	7-12 เดือน	มากกว่า 1 ปี

ผลคะแนนรวมเท่ากับ_____/32

คะแนนรวมทั้งหมดจากแบบประเมินต่ำที่สุดเท่ากับ 0 คะแนน และสูงที่สุดเท่ากับ 32 คะแนน กรณีที่ได้คะแนนสูงบ่งบอกถึงการมีสุขภาวะการนอนที่ดี

คะแนนตั้งแต่ 0-2 คะแนนในแต่ละหัวข้อ บ่งบอกถึงค่าเกณฑ์การวินิจฉัยโรคนอนไม่หลับตาม DSM-5

3.2 Procedures

Individuals were evaluated at out-patient clinic of Phramongkutklao Hospital and classified clinically into insomnia (experiment) groups and non-insomnia groups using DSM-V diagnostic criteria. Demographic data were collected. Both groups were asked to complete a general information questionnaire and the Thai version of the Sleep Condition Indicator (SCI). Treatments for insomnia were initiated. There were 1) pharmacological treatment group and 2) non-pharmacological group. After that, theose individuals with clinical diagnosis as insomnia, were followed up and re-evaluated for another SCI-Thai at 4 weeks.

4. Data Collection

The demographic data and the result of the study were kept and confidential. Only the researcher could access them.

5. Data Analysis Using Statistical Packages

The data were classified as two groups. The qualitative data reported as number and percent; the quantitative data reported as mean and standard deviation or the median and quartile range as appropriate for the information. The results of Receiver operating characteristic (ROC) and Area under the ROC curve (AuROC) calculations, considering the selection of cut-off points from Youden's index, were reported with sensitivity, specificity, accuracy, positive predictive value (PPV), negative predictive value (NPV) and the reliable change index (RCI) that represent of clinical improvement.

The reliable change index (RCI) was assessed by the change of the Thai version of the SCI between pre and 4-week post treatments. To determine the RCI, paired t-test was used and the medical treatment group and non-medical treatment group were compared. A Propensity Score Analysis was used if the pharmacological treatment and non-pharmacological treatment groups resulted in common different characteristics of the samples. Analysis was performed using SPSS Statistics package version 22.

Result

1. Population General Data

From November 2021 to April 2022, 179 participants were enlisted, divided into 2 groups: the experimental group (n=92) and the control group (n=87), Table 3. There were some parameters that were statistically significant difference between group, i.e. body mass index (23.88±3.95 vs 21.34±3.64; $p<0.001$), marital status (68.5% vs 49.4%; $p<0.001$), and underlying disease (69.6% vs 31% ; p. <0.001) while other characteristics of both groups were not different.
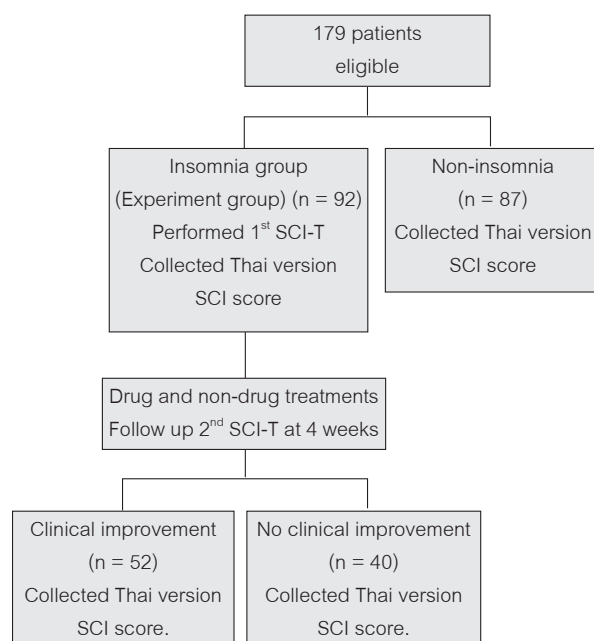

Figure 1 Screening, grouping and follow-up

Table 3 Demographic characteristics

Characteristics	Insomnia (n = 92) N (%)		Non-insomnia (n = 87) N (%)		p-value
Gender					
Male	55	(59.8)	42	(48.3)	0.123
Female	37	(40.2)	45	(51.7)	
Age (years), Mean±SD	59.91±17.00		52.55±15.64		0.003
Weight (kg), Mean±SD	64.23±14.55		58.38±11.04		0.003
BMI (kg/m2), Mean±SD	23.88±3.95		21.34±3.64		<0.001
Normal (18.5-22.9 kg/m^2)	38	(41.3)	64	(73.6)	<0.001
Overweight (23-24.9 kg/m^2)	21	(22.8)	11	(12.6)	
Obesity (over 25 kg/m^2)	33	(35.9)	12	(13.8)	
Marital status					
Married	63	(68.5)	43	(49.4)	<0.001
Not married	23	(25.0)	44	(50.6)	
Divorced	6	(6.5)	0	(0.0)	
Education					
Not education	1	(1.1)	0	(0.0)	<0.001
Primary school	29	(31.5)	24	(27.6)	
High school	41	(44.6)	17	(19.5)	
Bachelor's degree	17	(18.5)	46	(52.9)	
Master's degree or higher	4	(4.3)	0	(0.0)	
Income					
<10,000 baht per month	22	(23.9)	18	(20.7)	0.013
10,001-20,000 baht per month	17	(18.5)	19	(21.8)	
20,001-30,000 baht per month	38	(41.3)	46	(52.9)	
30,001-50,000 baht per month	5	(5.4)	4	(4.6)	
50,001-100,000 baht per month	10	(10.9)	0	(0.0)	
Underlying disease	64	(69.6)	27	(31.0)	<0.001
Dyslipidemia	48	(52.2)	16	(18.4)	<0.001
Hypertension	40	(43.5)	15	(17.2)	<0.001
Diabetes	13	(14.1)	4	(4.6)	0.030
Old cerebrovascular disease	7	(7.6)	0	(0.0)	0.014
Chronic kidney disease	2	(2.2)	0	(0.0)	0.498
Tea drinking	12	(13)	12	(13.8)	0.883
Coffee drinking	36	(39.1)	37	(42.5)	0.644
Smoking	15	(16.3)	20	(23.0)	0.260
Alcohol drinking	21	(22.8)	28	(32.2)	0.160

BMI: body mass index

3.2 Findings

Primary finding: The Thai version of the questionnaire to diagnose and follow-up

The insomnia questionnaire tool in Thai version to diagnose insomnia patients was validated by receiver operating characteristic (ROC) and area under the ROC curve (AuROC). It was found that the AuROC value was 0.984 (95%CI: 0.965-1.000). (Figure 2. and Table 4.)
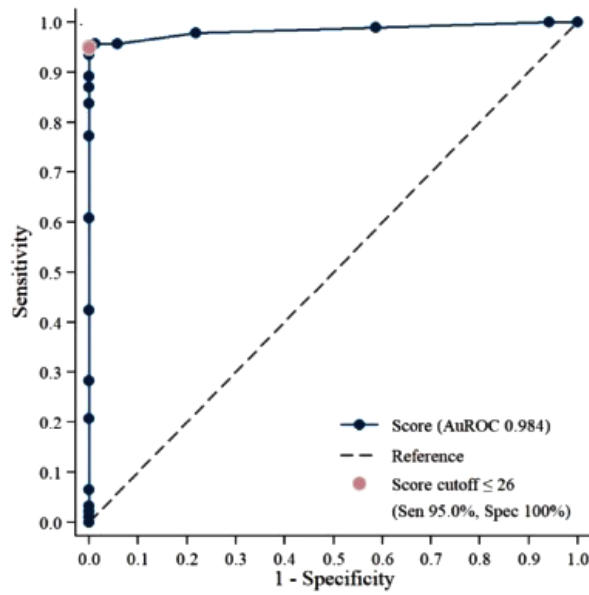
Figure 2 ....

Table 4 Area under the ROC curve of insomnia questionnaire tool for predicting insomnia

Tool	AuROC	SE	95% CI	P
SCI score	0.984	0.010	0.965 1.000	<0.001

It was found that an SCI score of less than or equal to 26 was the best cut-off for diagnosing insomnia with the sensitivity of 94.6% (95%CI: 87.8-98.2), the specificity of 100% (95%CI: 95.8-100), the predicted positive outcome of 100% (95%CI: 95.8-100) and the predicted value of negative outcome 94.6% (95%CI: 87.8-98.2). (Table 5)

Table 5 Diagnostic Test Performance of Insomnia Questionnaire Tool for Predicting Insomnia

Test	Cutoff	Sensitivity	Specificity	PPV	NPV	LR+	LR-
SCI score	≤ 16	28.3	100	100	56.9	NR	0.72
		(19.4-38.6)	(95.8-100)	(86.8-100)	(48.6-64.8)	NR	(0.63-0.82)
SCI score	≤ 26	94.6	100	100	94.6	NR	0.05
		(87.8-98.2)	(95.8-100)	(95.8-100)	(87.8-98.2)	NR	(0.02-0.13)
SCI score	≤ 28	95.7	94.3	94.6	95.3	16.64	0.05
		(89.2-98.8)	(87.1-98.1)	(87.9-98.2)	(88.5-98.7)	(7.1-39.02)	(0.02-0.12)

Secondary outcome finding: Reliable Change Index (RCI)

1. The reliable change index (RCI) to determine clinical improvement

Four weeks after treatments among insomnia patients, there were 52 out of 92 persons who had significantly clinical improvement. The SCI-Thai was re-assessed and found that the average Reliable change index (RCI)'s of 3.81 (95%CI: 3.32-4.30; p-value < 0.001) indicated clinical improvement, as shown in Figure 3 and Table 6.
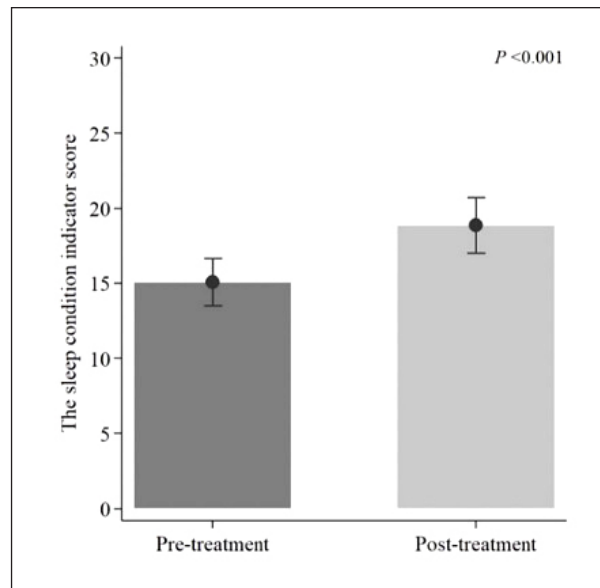
Figure 3 The change of SCI score between pre- and post-treatment

Table 6 Comparison of insomnia assessment before and after 4 weeks of treatment

	Pre-treatment		Post-treatment		Mean difference		t	p-value
	Mean	SD	Mean	SD	Mean	(95%CI)		(<0.05)
Total score from question 1-7	15.08	1.57	18.88	1.84	3.81	(3.32-4.30)	15.596	<0.001*

2. To compare the effectiveness between pharmacological treatment and non-pharmacologicalmedicine treatment.

Total of 92 volunteers 28 individuals were treated by sleep promoting agents, whilst 64 individuals were on non-drug approach. people without medication. The results of the study were as follows:

Demographic characteristics of the insomnia as an experiment group

The study aimed to compare the effectiveness between drug and non-drug treatments. Due to the different general characteristics of both groups, therefore, propensity score analysis was used in the study by Propensity Score Matching (PSM) to calculate propensity score used for a pair of both groups. The experimental group's propensity score was matched to the control group's propensity score by the nearest-neighbor matching ratio of 1:1. The propensity score was calculated by a multiple logistic regression analysis considering the variables analyzed, namely gender, age, body mass index, status, occupation, education, average monthly income, congenital disease, regular medication, tea drinking, coffee drinking, smoking, and alcohol consumption. The results showed that before matching with the propensity score, the participants with medicine and non-medicine treatments had statistically significantly difference in mean propensity scores. with mean values of 0.46±0.25 and 0.24±0.17, respectively, and after matching with the propensity score, the participants with medicine and non-medicine treatments had no statistically significant difference in mean propensity scores with mean values of 0.46±0.25 and 0.38±0.16, respectively.

For the general characteristics of the participants after matching with propensity score, the majority of participants with drug and non-drug treatments were male, 53.6% and 50% male, respectively. They had a mean age of 61.14 (SD17.9) years old and 59.89 (SD 17.2) years old, weight 58.14 (SD13.3) and 58.79 (SD14.1), respectively, and had mean body mass index of 22.09 (SD3.2) and 22.11 (SD3.6), respectively. Most participants with drug and non-drug treatments had a normal body mass index of 60.7% and 64.2%, were domiciled in Bangkok, 67.9% and 67.9%, respectively, were married, 57.1% and 71.4%, were housewives, 25% and 32.1%, respectively, had primary education, 35.7% and 48.9%, respectively, and had monthly incomes of 20,001-30,000 baht, 39.3% and 32.1%, respectively. The participants with drug and non-drug treatments had a co-morbid condition, 67.9% and 64.3%, respectively, including hypercholesterolemia, 50% and 39.3%, hypertension, 35.7% and 35.7%, diabetes, 10.7% and 10.7%, Old CVA, 3.6% and 17.9%, chronic kidney disease 3.6% and 3.6%, and others, 7.1% and 25%, respectively. They took regular medicine, 67.9% and 64.3%, drank tea, 7.1% and 10.7%, drank coffee, 39.3% and 35.7%, smoked, 17.9% and 14.3%, and drank alcohol, 17.9% and 21.4%, respectively (Table 7).

Table 7 General characteristics of the participants classified by exposure to sleeping pills (n = 92)

Characteristic	Before Propensity Score Matching (Full Patient Cohort)				After Propensity Score Matching (Full Patient Cohort)			
	A Group with Sleeping Pills (n = 28)	A Group without Sleeping Pills (n = 64)	p-value	SMD	A Group with Sleeping Pills (n = 28)	A Group without Sleeping Pills (n = 28)	p-value	SMD
	Qty. Pct.	Qty. Pct.			Qty. Pct.	Qty. Pct.		
Propensity Score, Mean±SD	0.46±0.25	0.24±0.17	<0.001*		0.46±0.25	0.38±0.16	0.134	
Gender								
Male	15 (53.6)	40 (62.5)	0.422	0.182	15 (53.6)	14 (50.0)	0.789	0.072
Female	13 (46.4)	24 (37.5)			13 (46.4)	14 (50.0)		
Age (Year), Mean±SD	61.14±17.93	59.38±16.69	0.324	0.102	61.14±17.93	59.89±17.23	0.791	0.071
Weight (kg), Mean±SD	58.14±13.32	66.89±14.35	0.004*	-0.632	58.14±13.32	58.79±14.06	0.861	-0.047
Body Mass Index (kg/m2), Mean±SD	22.09±3.24	24.66±4.00	0.002*	-0.706	22.09±3.24	22.11±3.62	0.984	-0.005
Normal	17 (60.7)	21 (32.8)	0.003*	0.880	17 (60.7)	18 (64.2)	0.543	0.299
Overweight	8 (28.6)	13 (20.3)			8 (28.6)	5 (17.9)		
Obese	3 (10.7)	30 (46.9)			3 (10.7)	5 (17.9)		
Domicile								
Bangkok	19 (67.9)	42 (65.6)	0.521	0.368	19 (67.9)	19 (67.9)	0.589	0.278
Other province	9 (32.1)	18 (28.1)			9 (32.1)	8 (28.6)		
Not specified	0 (0.0)	4 (6.3)			0 (0.0)	1 (3.5)		
Status								
Married	16 (57.1)	47 (73.4)	0.241	0.362	16 (57.1)	20 (71.4)	0.241	0.302
Single	9 (32.1)	14 (21.9)			9 (32.1)	6 (21.4)		
Divorced	3 (10.7)	3 (4.7)			3 (10.7)	2 (7.14)		
Occupation								
General employee	6 (21.4)	9 (14.1)	0.380	0.533	6 (21.4)	5 (17.9)	0.427	0.665
Housewife	7 (25.0)	15 (23.4)			7 (25.0)	9 (32.1)		
Merchant	4 (14.3)	9 (14.1)			4 (14.3)	3 (10.7)		
Retired/Pensioner	6 (21.4)	19 (29.7)			6 (21.4)	5 (17.9)		
Government officer	2 (7.1)	10 (15.6)			2 (7.1)	6 (21.4)		
Employee	1 (3.6)	2 (3.1)			1 (3.6)	0 (0.0)		
Other	2 (7.1)	0 (0.0)			2 (7.1)	0 (0.0)		

Table 7 General Characteristics of the Participants Classified by Exposure to Sleeping Pills (n = 92)

Characteristic	Before Propensity Score Matching (Full Patient Cohort)									After Propensity Score Matching (Full Patient Cohort)								
	A Group with Sleeping Pills (n = 28)		A Group without Sleeping Pills (n = 64)		p-value	SMD	A Group with Sleeping Pills (n = 28)		A Group without Sleeping Pills (n = 28)		p-value	SMD
	Qty.	Pct.	Qty.	Pct.			Qty.	Pct.	Qty.	Pct.		
Education												
None	0	(0.0)	1	(1.6)	0.714	0.362	0	(0.0)	0	(0.0)	0.633	0.363
Primary	10	(35.7)	19	(29.7)			10	(35.7)	12	(48.9)		
Secondary or Equivalent	10	(35.7)	31	(48.4)			10	(35.7)	7	(25.0)		
Bachelor's degree	7	(25.0)	10	(15.6)			7	(25.0)	6	(21.4)		
Master's degree	1	(3.6)	3	(4.7)			1	(3.6)	3	(10.7)		
Average Monthly Income												
<10,000 Baht	9	(32.1)	13	(20.3)	0.558	0.473	9	(32.1)	9	(32.1)	0.804	0.428
10,001-20,000 Baht	5	(17.9)	12	(18.8)			5	(17.9)	4	(14.3)		
20,001-30,000 Baht	11	(39.3)	27	(42.2)			11	(39.3)	9	(32.1)		
30,001-50,000 Baht	0	(0.0)	5	(7.8)			0	(0.0)	2	(7.1)		
50,001-100,000 Baht	3	(10.7)	7	(10.9)			3	(10.7)	4	(14.3)		
Congenital disease	19	(67.9)	45	(70.3)	0.814	0.053	19	(67.9)	18	(64.3)	0.778	0.075
Dyslipidemia	14	(50.0)	34	(53.1)	0.782	0.063	14	(50.0)	11	(39.3)	0.420	0.217
Hypertension	10	(35.7)	30	(46.9)	0.320	0.228	10	(35.7)	10	(35.7)	1.000	0.000
Diabetes	3	(10.7)	10	(15.6)	0.747	0.146	3	(10.7)	3	(10.7)	1.000	0.000
Previous stroke	1	(3.6)	6	(9.4)	0.671	0.234	1	(3.6)	5	(17.9)	0.193	0.475
Chronic kidney disease	1	(3.6)	1	(1.6)	0.518	0.127	1	(3.6)	1	(3.6)	1.000	0.000
Other	2	(7.1)	15	(23.4)	0.064	0.464	2	(7.1)	7	(25.0)	0.143	0.501
Regularly Taken Medicine	19	(67.9)	43	(67.2)	0.950	0.014	19	(67.9)	18	(64.3)	0.778	0.075
Tea	2	(7.1)	10	(15.6)	0.333	0.269	2	(7.1)	3	(10.7)	1.000	0.125
Coffee	11	(39.3)	25	(39.1)	0.984	0.005	11	(39.3)	10	(35.7)	0.783	0.074
Smoking	5	(17.9)	10	(15.6)	0.768	0.060	5	(17.9)	4	(14.3)	1.000	0.097
Alcohol	5	(17.9)	16	(25.0)	0.453	0.175	5	(17.9)	6	(21.4)	0.737	0.090
Initial symptom	0	(0.0)	0	(0.0)	NA	-	0	(0.0)	0	(0.0)	NA	-

Abbreviations: NA, data not applicable; SMD, standard mean difference

Data are presented as number (%), mean±standard deviation or median (interquartile range).

P-value corresponds to independent samples t-test, Mann-Whitney U test, Chi-square test or Fisher's exact

Comparison of insomnia assessment results between pharmacological treatment group and non-medicine treatment group

Before treatment, participants with medicine and non-medicine treatments had differences in the mean SCI scores of 15.32±1.22 and 16.43±2.69, respectively, with no statistical significance. After 1 month of treatment, participants with medicine and non-medicine treatments had differences in the mean SCI scores of 18.86±1.96 and 18.43±2.04, respectively, with no statistical significance. However, participants with medicine treatment had a 1.53 score difference in the SCI scores between pre and post-treatment over participants with non-medicine treatment (95%CI: 0.34, 2.73) with statistical significance. The difference between before and after treatment of mean SCI scores was 3.54±1.71 and 2.00±2.64, respectively (Table 8).

A comparison of clinical results between the medicine and non-medicine treated groups demonstrated that both groups had statistically significantly different treatment outcomes. 100% of the medicine-treated participants showed improvement in clinical results, while only 50% of the non-medicine-treated participants showed clinical improvement (Table 9).

Table 8 Comparison of Insomnia Assessment Results between medicine and non-medicine treatment

Insomnia Assessment Results Sleep condition indicator (SCI)	Sedative-treated Group	Non-sedative-treated Groups	Mean difference (95%CI)		p-value[a]
	Mean±SD	Mean±SD			
Before treatment	15.32±1.22	16.43±2.69	-1.12	(-2.22, 0.01)	0.052
After 1 month of treatment	18.86±1.96	18.43±2.04	0.43	(-0.70, 1.35)	0.427
Difference before and after treatment	3.54±1.71	2.00±2.64	1.53	(0.34, 2.73)	0.013*

[a] Independent samples t-test.

* Significant at p-value < 0.05

Table 9 Comparison of Clinical Results between the Sedative-treated and Non-sedative-treated Groups

อาการทางคลินิก	Total (n = 92)		Medicine-treated Group		Non-medicine-treated Group		p-value[a]
	Qty.	Pct.	Qty.	Pct.	Qty.	Pct.	
Clinical Result							<0.001*
Worsen	3	(5.4)	0	(0.0)	3	(10.7)	
Not improved	11	(19.6)	0	(0.0)	11	(39.3)	
Better	42	(75.0)	28	(100)	14	(50.0)	

[a] Fisher's exact test.

* Significant at p-value < 0.05

Discussion

Our significantly different characteristics between two groups were body mass index (23.88±3.95 vs. 21.34±3.64; p<0.001), married (68.5% vs. 49.4%; p<0.001) and underlining diseases (69.6% vs. 31%; p<0.001), that would be risk factors of insomnia. As for the marital status, there may not be any clearly explained support. Compared to other previous studies, it was found that insomnia was associated with age over 60 and more common in women than men.

To choose the cut-off for diagnosis insomnia, our threshold 16 provided 100% specificity (95%CI: 95.8-100), while only 28.3% sensitivity, (95%CI: 19.4-38.6), positive predictive value 100% (95%CI: 86.8-100) and negative predictive value of 56.9% (95%CI: 48.6-64.8). By contrast, it was found that the best cut-off point was at 26 since it increases

sensitivity to 94.6% (95%CI: 87.8-98.2) and specificity off 100% (95%CI: 95.8-100).

To identify the score change representing clinical improvement, Colin et al,[9] reported that the reliable change index (RCI) of 7 point or greater was the most parsimonious value for using in clinical and research practice that represented clinical improvement in insomnia disorder. Our study showed that average RCI of Thai version SCI at 3.81 (95%: 3.32-4.3; p value<0.001) indicated the significant clinical improvement after 4-week insomnia treatment.

For comparison of insomnia assessment results between sedative-treated and non-sedative-treated groups, before treatment, participants with medicine and non-medicine treatments had differences in the mean SCI scores of 15.32±1.22 and 16.43±2.69, respectively, with no statistical significance. After 1 month of treatment, participants

with medicine and non-medicine treatments had differences in the mean SCI scores of 18.86±1.96 and 18.43±2.04, respectively, with no statistical significance. However, participants with medicine treatment had a 1.53 score difference in the SCI scores between pre- and post-treatment over participants with non-medicine treatment (95%CI: 0.34, 2.73) with statistical significance. The difference between before and after treatment of mean SCI scores was 3.54±1.71 and 2.00±2.64, respectively.

A comparison of clinical results between the sedative-treated and non-sedative-treated groups demonstrated that both groups had statistically significantly different treatment outcomes. One hundred percent of the sedative-treated participants showed improvement in clinical results, while only 50% of the non-sedative-treated participants showed clinical improvement.

Our research had some limitations which were 1) the number and demographic characteristic between insomnia group and non-insomnia group were inhomogeneous and 2) the SCI is a self-questionnaire, so there would be some misunderstanding related to individuals' back-ground knowledge or experience especially in case of different in culture, level of education and location of residency.

Conclusion

We concluded that the Thai version of the SCI score was an effective tool to diagnose and follow up insomnia. A diagnostic cut-off of 26 was employed. The reliable change index (RCI) of 4 indicates an improved clinical symptom which was found higher RDI among volunteers with sleep enhancing agents' group than non-sleep enhancing agents' group.

References

1.   Singleton N, Bumpstead R, O'Brien M, Lee A, Meltzer H. Psychiatric morbidity among adults living in private households, 2000. Int Rev Psychiatry 2003;15:65-73.

2.   Khan MS, Aouad R. The effects of insomnia and sleep loss on cardiovascular disease. Sleep Med Clin 2017; 12:167-77.

3.   American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. American Psychiatric Association, Washington, DC, 2013.

4.   Espie CA, Kyle SD, Hames P, et al. The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. BMJ Open 2014;4:e004183. doi:10.1136/ bmjopen-2013-004183.

5.   Bayard S, Lebrun C, Maudarbocus KH, et al. Validation of a French version of the sleep condition indicator: a clinical screening tool for insomnia disorder according to DSM-5 criteria. J Sleep Res 2017;26:702-8.

6.   Palagini L, Ragno G, Caccavale L, et al. Italian validation of the sleep condition indicator: a clinical screening tool to evaluate insomnia disorder according to DSM-5 criteria. Int J Psychophysiol 2015;98:435-40.

7.   Voinescu B, Szentagotai A. Categorical and dimensional assessment of insomnia in the general population. J Cogn Behav Psychother 2013;13:197-209.

8.   Wong ML, Lau KNT. Espie CA, et al. Psychometric properties of the sleep condition indicator and insomnia severity index in the evaluation of insomnia disoerder. Sleep Med 2017;33:76-81.

9.   Colin E, Machado F, Jenna R. et al. The sleep condition indicator: reference values derived from a sample of 200 000 adults. European Sleep Research socity. J Sleep Res 2018;27:1-7 . DOI: 10.1111/jsr.12643