



Development and Validity of the Japanese Version of the Pre-Sleep Arousal Scale

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Hyperarousal, defined as increased levels of cortical activity and cognitive-emotional reactivity induced by stress, is suggested to be a key factor in insomnia. In particular, pre-sleep arousal constitutes one of the major features of insomnia. The Pre-Sleep Arousal Scale is the best-known measure used to evaluate pre-sleep arousal. However, a well-validated Japanese version of the scale (PSAS-J) has not yet been established. The aim of this research was to develop and validate such a scale. A cross-sectional questionnaire-based study was conducted via the internet. In total, 237 of 300 participants (mean age 43.28 ± 11.19 years) completely responded to the questionnaires as followed: the PSAS-J, the Insomnia Severity Index, Ford Insomnia Response to Stress Test, and Dysfunctional Beliefs and Attitudes about Sleep Scale. In addition, the participants were divided into two groups: insomniacs and normal sleepers. As a result, the PSAS-J had a two-factor structure similar to that of the original version, i.e., somatic and cognitive arousal subscales. The internal consistency ($\alpha = 0.85$ to 0.90) and test-retest reliability ($r = 0.67$ to 0.78) were high. Correlations between the PSAS-J and the above-mentioned scales ranged from 0.35 to 0.53 . Discriminant validity showed that the PSAS-J was distinct from the Ford Insomnia Response to Stress Test and Dysfunctional Beliefs and Attitudes about Sleep Scale. The PSAS-J scores were significantly higher in insomniacs than in normal sleepers. Our results suggest that the PSAS-J has high reliability and validity and that this scale is adequate for assessing pre-sleep arousal.

Keywords: hyperarousal; pre-sleep arousal; precipitating; predisposing; vulnerability

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Introduction

Nearly 20% of the general adult population in Japan has been reported to have symptoms related to insomnia (Kim et al. 2000; Okajima et al. 2012). It is also known that 5%-19% of individuals have insomnia that follows a chronic course (Ohayon 2002; Riemann et al. 2017). Chronic insomnia disorder is diagnosed when nocturnal sleep problems (e.g., difficulty initial and/or maintaining sleep) and associated daytime symptoms (e.g., fatigue and depressive mood) occur for three months or more (American Academy of Sleep Medicine 2014).

Spielman's 3P model suggested that insomnia is the end result of predisposing, precipitating, and perpetuating

factors (Spielman and Glovinsky 1986; Spielman et al. 1987). According to Spielman and Glovinsky (1986), predisposing factors are conditions that set the stage or determine the threshold for insomnia. A weak sleep-generating system may be a predisposing factor. A history of recurrent depression, the predilection to stay up late and sleep late, or a susceptibility to anxiety states may also predispose to insomnia. Precipitating factors include stressful events. Perpetuating factors are generally not present during the inception of insomnia but make their appearance as a consequence of coping with the problem. They include both mental states and behavioral practices such as excessive amounts of time spent in bed, pre-sleep arousal, and dysfunctional beliefs and attitudes about sleep (Morin and

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Espie 2004).

It has been suggested that hyperarousal may be a key cause of insomnia (Riemann et al. 2010; Palagini et al. 2016). Hyperarousal is defined as increased levels of cortical activity and cognitive-emotional reactivity (e.g., pre-sleep rumination and worry) induced by stress (Kalmbach et al. 2018). It is recently suggested that hyperarousal includes a trait predisposition toward excess arousal (i.e., trait arousal) and pre-sleep-state-dependent hyperarousal (i.e., state arousal; Palagini et al. 2016). Trait arousal, such as sleep reactivity to stressful events, refers to the individual differences in predisposition toward arousal that are to be expected when performing various tasks and in the presence of environmental stressors (Drake et al. 2004). State arousal, such as pre-sleep arousal, is considered to be a state-dependent construct that refers specifically to cognitive and somatic hyperarousal when attempting to fall asleep in the pre-sleep period (Riemann et al. 2010). Puzino et al. (2019) showed that sleep reactivity is a risk factor for increased pre-sleep cognitive and somatic arousal.

The following insomnia-related scales have been developed: the Ford Insomnia Response to Stress Test (FIRST), which measures predisposing trait hyperarousal, the Pre-Sleep Arousal Scale (PSAS), which measures perpetuating cognitive and somatic state hyperarousal, and the Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS), which identifies a perpetuating cognitive factor. The FIRST and DBAS have been translated into Japanese and confirmed to have high validity and reliability (Munezawa et al. 2009b; Nakajima et al. 2014). However, there has been no Japanese version of the PSAS.

The PSAS is the most frequently used subjective state arousal measurement tool (Nicassio et al. 1985) and measures the intensity of physiological/somatic and cognitive symptoms of arousal as a subject falls asleep based on theory and research on the nature of psychophysiological arousal and related states (Nicassio et al. 1985). In a validation study, the items and subscales of the PSAS were shown to have good reliability ($\alpha = 0.79\text{--}0.81$; test-retest $r = 0.72\text{--}0.76$), to have high concurrent validity with anxiety and depression scales, and to discriminate persons with insomnia from normal sleepers (Nicassio et al. 1985).

This scale is available in Portuguese, Swedish, and Pakistani versions (Jansson-Fröjmark and Norell-Clarke 2012; Shahzadi and Ijaz 2014; Ruivo Marques et al. 2018), all of which have been confirmed to have good reliability and validity. However, the Swedish version takes the form of a 13-item short version and uses explanatory factor analysis, although all original and translated versions of the PSAS measure two factors, that is, somatic and cognitive arousal. Therefore, the Swedish version can be used in the general population whereas the other versions have been used in university students or patients with insomnia.

Given the potential role of hyperarousal in chronic insomnia, a considerable amount of research has focused on the development and psychometric validation of measures

that assess physiological and cognitive arousal. However, a well-validated Japanese version of this scale has not yet been established. Furthermore, based on the 3P and hyperarousal models of insomnia (Spielman et al. 1987; Riemann et al. 2010), it has been suggested that the FIRST, PSAS, and DBAS measured different factors but this has not been confirmed in a formal study. If these measures could be statistically discriminated against different factors, it would be useful for testing the assumption of the model for onset and maintenance of insomnia.

Therefore, this research aimed to develop a Japanese version of the PSAS and to assess its reliability and validity by using an internal consistency, test-retest reliability and structural, current, discriminant, and predictive validity.

Materials and Methods

The study was approved by the Ethics Committee of Waseda University. All study participants provided informed consent.

Study participants

The data analyzed in this study, known as the Japan Validation of Insomnia-related scales Project (JVIP), were collected on September 21, 2017 (time 1), and October 11, 2017 (time 2). The study participants were recruited by Rakuten Research Inc., an online marketing research company that holds the contact details of approximately 2.3 million Japanese survey respondents. An e-mail containing a link to an online questionnaire was randomly sent to individuals stratified by sex and age throughout Japan. The participants ranged in age from 20 years to 65 years. Individuals receiving pharmacological or psychological treatment for a mental, physical, or sleep disorder were excluded.

The study analyzed the responses to 900 of the completed JVIP questionnaires (time 1) and subsequently analyzed a further 300 completed responses (time 2). Questionnaires were not used if data input error was suspected (e.g., average total sleep time for a month was more than 13 hours). Finally, data for 237 individuals (116 men, 121 women) of mean age 43.21 years ($SD = 11.02$) were included in the analyses (Fig. 1). The mean age [SD] was the same at times 1 and 2.

Measures

Assessment of insomnia-related symptoms: Based on the diagnostic criteria for chronic insomnia disorders outlined in the ICSD-3 (American Academy of Sleep Medicine 2014), the respondents answered questions related to sleep disturbance (difficulty initiating sleep, difficulty maintaining sleep, and waking up earlier than desired) and associated daytime symptoms (fatigue, attention or concentration impairment, daytime sleepiness, mood disturbance). Participants responded whether sleep disturbances and associated daytime symptoms occurred at least three times per week and have been present for at least 3 months.

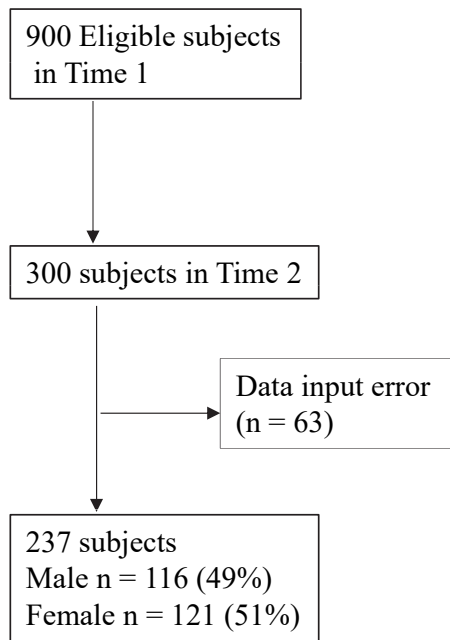


Fig. 1. Flowchart showing the study enrolment process.

Japanese version of the Pre-Sleep Arousal Scale: The PSAS-J is a validated 16-item self-reported questionnaire that assesses pre-sleep arousal. The original version of the PSAS was constructed with two-factor somatic (i.e., physiological) arousal (8 items) and cognitive arousal (8 items) subscales. The score for each subscale is summed (range, 8-40), with higher scores indicating a state of more pre-sleep arousal. In a validation study of the original PSAS, the items and subscales were shown to have good reliability ($\alpha = 0.79-0.81$; test-retest $r = 0.72-0.76$), to have high concurrent validity with anxiety and depression scales, and to discriminate individuals with insomnia from normal sleepers (Nicassio et al. 1985). This type of scale is available in other countries and has been confirmed to have good reliability and validity (Jansson-Fröjmark and Norell-Clarke 2012; Shahzadi and Ijaz 2014; Ruivo Marques et al. 2018). Moreover, the pathological cut-off values on the PSAS-somatic and PSAS-cognitive subscales were estimated to be ≥ 14 and ≥ 20 , respectively (Puzino et al. 2019).

Japanese version of the Insomnia Severity Index: The Insomnia Severity Index (ISI) is a validated 7-item self-reported questionnaire that assesses the severity of insomnia. A summed score is calculated (range, 0-28), with higher scores indicating more symptoms of insomnia (Bastien et al. 2001). The Japanese version of this scale has been confirmed to have high internal consistency and validity (Munezawa et al. 2009a).

Japanese version of the Ford Insomnia Response to Stress Test: FIRST is a validated 9-item self-report questionnaire that assesses sleep reactivity to stress (i.e., hyper-

arousal caused by a stressful event). It has been suggested that sleep reactivity is a vulnerability factor in the onset of insomnia and depression (Drake et al. 2014). A summed score is calculated (range, 9-36), with higher scores indicating more sleep reactivity (Drake et al. 2004). The Japanese version of the scale has been confirmed to have high internal consistency and validity (Nakajima et al. 2014).

Dysfunctional Beliefs and Attitudes about Sleep-16: The DBAS-16 scale is a validated 16-item self-reported questionnaire that assesses dysfunctional beliefs and attitudes about sleep. A summed score is calculated (range, 0-160), with higher scores indicating more dysfunctional beliefs about sleep (Morin et al. 2007). The Japanese version of the scale has been confirmed to have high internal consistency and validity (Munezawa et al. 2009b).

Procedure

The study was conducted and reported in accordance with the recommendations of the International Society for Pharmacoeconomics and Outcomes Research Task Force (Wild et al. 2005). We developed the PSAS-J after obtaining permission from the first and corresponding author of the article describing the original version of the PSAS (Nicassio et al. 1985). A back-translation procedure was used to ensure equivalence between the original English version and the translated Japanese version. First, the scale was front-translated from English into Japanese independently by two clinical psychologists working in a sleep clinic. Three clinical psychologists and a physician with expertise in sleep research and sleep medicine then confirmed the suitability of the translation in Japanese. A tentative version of the scale was completed. Second, the scale was back-translated from Japanese into English independently by two native speakers of both Japanese and English. Two back-translations were reviewed and confirmed to be acceptable by the original author.

Statistical analysis

Descriptive statistics were computed by using R statistical software version 3.6.3 (R Project for Statistical Computing, Vienna, Austria). To account for cultural differences, the structural validity of the PSAS-J was evaluated by exploratory factor analysis (EFA) utilizing a maximum likelihood solution method with promax rotation. Factors were determined by setting eigenvalues to ≥ 1 and the shape of the scree plot. In addition, confirmatory factor analysis (CFA) was performed to evaluate the goodness of fit of the model. We conducted CFA using the “lavaan” package (Rosseel 2012) and evaluated the following fit indices: chi-square (χ^2), Adjusted Goodness of Fit Index (AGFI), Comparative Fit Index (CFI), Standardized Root Mean Square Residual (SRMR), and Root Mean Square Error of Approximation (RMSEA). These were absolute fit indices, and it is suggested that at a minimum these indices should be reported (Hooper et al. 2008; Kline 2015).

A good model fit of χ^2 would provide an insignificant result at a 0.05 threshold. However, when large samples are used, the χ^2 statistic is in essence a statistical significance test that is sensitive to sample size, meaning that the χ^2 statistic nearly always rejects the model (Hooper et al. 2008). AGFI and CFI can range between 0 and 1, and the closer the values are to 1, the better the model fits. When the SRMR and RMSEA values are ≤ 0.08 , the indices indicate that the model fits well (Hooper et al. 2008; Kline 2015).

The internal consistency for each subscale of the PSAS-J was evaluated using Cronbach's alpha. The test-retest reliability of each subscale between time 1 and time 2 was evaluated using the intraclass correlation coefficient (ICC). An ICC of < 0.5 indicates poor reliability, an ICC of 0.5-0.75 indicates moderate reliability, an ICC of 0.75-0.9 indicates good reliability, and an ICC of > 0.90 indicates excellent reliability (Koo and Li 2016).

Concurrent validity was evaluated by correlation analysis of the PSAS-J with the ISI, FIRST, and DBAS. Furthermore, predictive validity was evaluated by multiple regression analysis with the ISI score at time 2 as a dependent variable and the PSAS-J subscales (somatic and cognitive) at time 1 as independent variables. Discriminant validity was assessed in an exploratory factor analysis of all items on the PSAS-J, FIRST, and DBAS simultaneously and whether they converged to each scale.

We also compared differences in the PSAS-J scores, including the somatic and cognitive arousal subscale scores, between the insomnia group and the normal sleeper group using the unpaired two-tailed *t*-test. Participants who responded that sleep disturbances and associated daytime symptoms occurred at least three times per week and have been present for at least 3 months were classified as the insomnia group and the others as the normal sleeper group. We estimated the effect sizes of scales within and between groups using Hedges' *g*. In general, an absolute *g* value of ≥ 0.2 indicates a small effect size whereas a value around 0.5 indicates a moderate effect size, and a value ≥ 0.8 indicates a large effect size (Cohen 1988).

Furthermore, we used the pathological cut-off values for the PSAS-somatic subscale (≥ 14) and the cognitive subscale (≥ 20) to compare differences in the ISI scores between the high pre-sleep arousal group and the low pre-sleep arousal group (Puzino et al. 2019). The data were compared using an unpaired two-tailed *t*-test.

Results

Demographic characteristics

The demographic characteristics (age, sex, and occupation of participants) and descriptive statistics for all measurements (PSAS-J, ISI, FIRST, and DBAS-16) at times 1 and 2 are presented in Table 1. The most common occupation of the respondents was workers (57%), followed by home keepers (18%), part-time jobs (14%), unemployed (6%), and students (2%; Table 1).

Structural validity

Table 2 shows a result of EFA utilizing a maximum likelihood solution method with promax rotation. EFA showed that the PSAS-J has the same two-factor structure as that of the original PSAS: "somatic arousal" (PSAS-J-somatic, items 1-8) and "cognitive arousal" (PSAS-J-cognitive, items 9-16). Factor loadings for both factors were generally good. The correlation coefficient (*r*) between these factors was 0.72 (Table 2). In addition, CFA showed that the two-factor model had a relatively good fit ($\chi^2_{103} = 289.34$, $p < 0.001$, AGFI = 0.824, CFI = 0.909, SRMR = 0.067, RMSEA = 0.087).

Reliability

Cronbach's alpha values for factor 1 (PSAS-J-somatic) and factor 2 (PSAS-J-cognitive) were high (α [95% CI] = 0.85 [0.82, 0.88] and 0.90 [0.89, 0.92], respectively). The ICC values for each factor were also moderate to good (ICC = 0.67 [0.60, 0.74] and 0.78 [0.74, 0.84], respectively).

Concurrent, discriminant, and predictive validities

The correlation analysis showed a significant positive correlation (*r*) between the PSAS-J-somatic subscale and the ISI (*r* [95% CI] = 0.43 [0.32, 0.53]), FIRST (*r* = 0.38 [0.27, 0.49]), and DBAS-16 (*r* = 0.35 [0.24, 0.46]) (all $p <$

Table 1. Demographic characteristics and descriptive statistics of all measures.

	Time 1	Time 2
Age (years), mean (SD) ¹	43.28 (11.19)	
Sex (M/F), n (%)	M = 116 (49), F = 121 (51)	
Occupation		
Workers, n (%)	136 (57)	
Students, n (%)	4 (2)	
Home keepers, n (%)	43 (18)	
Part-time job, n (%)	34 (14)	
Unemployed, n (%)	15 (6)	
Others, n (%)	5 (2)	
Measures		
ISI, mean (SD)	7.86 (5.12)	8.08 (5.31)
PSAS-J-som, mean (SD)	14.19 (5.48)	14.82 (6.25)
PSAS-J-cog, mean (SD)	17.45 (6.85)	17.53 (7.45)
FIRST, mean (SD)	21.13 (5.66)	21.10 (6.02)
DBAS-16, mean (SD)	66.78 (25.24)	66.76 (28.23)

The data indicates characteristics of the participants and descriptive statistics of all measures at baseline (time 1) and after 3 weeks (time 2).

DBAS, Dysfunctional Beliefs and Attitudes about Sleep; F, female; FIRST, Ford Insomnia Response to Stress Test; ISI, Insomnia Severity Index; M, male; n, number of participants; PSAS-cog, cognitive subscale of the Pre-Sleep Arousal Scale; PSAS-som, somatic subscale of the Pre-Sleep Arousal Scale; SD, standard deviation; %, percent of total participants.

¹The mean age (SD) was the same at times 1 and 2.

Table 2. Results of exploratory factor analysis of the PSAS-J.

Items	Contents	Factor loadings ¹	
		PSAS-cog	PSAS-som
<i>Factor 1: Cognitive arousal</i>			
13.	Being mentally alert, active	0.94	−0.12
12.	Worry about problems other than sleep	0.93	−0.08
15.	Thoughts keep racing through your head	0.91	−0.12
10.	Review or ponder events of the day	0.91	−0.14
14.	Can't shut off your thoughts	0.64	0.18
11.	Depressing or anxious thoughts	0.62	0.00
9.	Worry about falling asleep	0.45	0.26
16.	Being distracted by sounds, noise in the environment	0.37	0.19
<i>Factor 2: Somatic arousal</i>			
2.	A jittery, nervous feeling in your body	−0.16	0.97
4.	A tight, tense feeling in your muscles	−0.13	0.88
3.	Shortness of breath or labored breathing	−0.14	0.87
1.	Heating racing, pounding, or beating irregularly	−0.05	0.72
6.	Have stomach upset	0.12	0.47
7.	Perspiration in the palms of your hands or other parts of your body	0.18	0.45
8.	Dry feeling in your mouth or throat.	0.21	0.44
5.	Cold feeling in your hands, feet or your body	0.13	0.38
Factor Correlation (<i>r</i>)		PSAS-cog	PSAS-som
PSAS-cog		1.00	0.72
PSAS-som			1.00

The data indicates the results of exploratory factor analysis utilizing a maximum likelihood solution method with promax rotation.

PSAS-cog, cognitive subscale of the Pre-Sleep Arousal Scale; PSAS-som, somatic subscale of the Pre-Sleep Arousal Scale.

¹The numbers in bold represent the factor loadings for each item in each factor.

0.001) and between the PSAS-J-cognitive subscale and the ISI ($r = 0.52$ [0.42, 0.61]), FIRST ($r = 0.53$ [0.43, 0.61]), and DBAS-16 ($r = 0.44$ [0.33, 0.53]) (all $p < 0.001$).

EFA on all the items of the PSAS-J, FIRST, and DBAS showed a three-factor structure, namely, PSAS-J (factor loadings: 0.47-0.78), FIRST (factor loadings: 0.22-0.89), and DBAS (factor loadings: 0.41-0.77).

The multiple regression analysis showed that the subscales of the PSAS-J at time 1 were significantly associated with aggravation of symptoms of insomnia at time 2 (somatic: $B = 0.16$, $p = 0.03$, and cognitive: $B = 0.30$, $p < 0.001$; $adj. R^2 = 0.25$, $p < 0.001$).

Hypothesis testing: Comparison of all scales between groups

The means and standard deviations for the scale scores in the insomnia group ($n = 48$) and the normal sleeper group ($n = 126$) are presented in Table 3. The results of t -tests showed that total scores for all scales were significantly higher in the insomnia group than in the normal sleeper group ($p < 0.001$). The effect sizes were large for

PSAS-J-somatic (Mean score [SD]: 16.92 [6.52] vs. 12.87 [4.39]; g [95% CI] = 0.80 [0.45-1.14]), PSAS-J-cognitive (Mean score [SD]: 22.46 [7.36] vs. 15.13 [5.42]; $g = 1.22$ [0.86-1.58]), and ISI (Mean score [SD]: 13.38 [5.03] vs. 5.33 [3.72]; $g = 1.95$ [1.55-2.34]) but moderate for FIRST (Mean score [SD]: 23.58 [6.52] vs. 20.02 [5.07]; $g = 0.65$ [0.31-0.99]), and DBAS-16 (Mean score [SD]: 81.73 [24.49] vs. 64.80 [24.85]; $g = 0.68$ [0.34-1.02]).

Furthermore, the ISI scores were significantly greater in the high pre-sleep somatic arousal group (≥ 14 for PSAS-somatic subscale; $n = 114$, mean score [SD] = 9.38[5.42]) than in the low pre-sleep somatic arousal group (< 14 ; $n = 123$, mean score [SD] = 6.45[4.40]; $t(217) = -4.55$, $p < 0.001$). Similarly, the ISI scores were significantly greater in the high pre-sleep cognitive arousal group (≥ 20 for PSAS-cognitive subscale; $n = 81$, mean score [SD] = 10.49[5.53]) than in the low pre-sleep cognitive arousal group (< 20 ; $n = 156$, mean score [SD] = 6.49[4.31]; $t(131) = -5.68$, $p < 0.001$).

Table 3. Comparison of all scales between the two study groups.

Measures	Normal sleepers (n = 126), mean (SD)	Insomnia (n = 48), mean (SD)	<i>t</i> value[<i>df</i>]	Hedges' <i>g</i> [95% CI] ¹
PSAS-J-som	12.87 (4.39)	16.92 (6.52)	3.97 [63] ***	0.80 [0.45-1.14]
PSAS-J-cog	15.13 (5.42)	22.46 (7.36)	6.28 [67] ***	1.22 [0.86-1.58]
ISI	5.33 (3.72)	13.38 (5.03)	10.09 [67] ***	1.95 [1.55-2.34]
FIRST	20.02 (5.07)	23.58 (6.52)	3.49 [71] ***	0.65 [0.31-0.99]
DBAS-16	64.80 (24.85)	81.73 (24.49)	4.06 [86] ***	0.68 [0.34-1.02]

The data indicates mean score and SD of all measures in each group, the result of *t*-test, and effect sizes between groups for each scale. CI, confidence interval; DBAS, Dysfunctional Beliefs and Attitudes about Sleep; *df*, degree of freedom; FIRST, Ford Insomnia Response to Stress Test; ISI, Insomnia Severity Index; *n*, number of participants; PSAS-cog, cognitive subscale of the Pre-Sleep Arousal Scale; PSAS-som, somatic subscale of the Pre-Sleep Arousal Scale; SD, standard deviation.

*** $p < 0.001$.

¹Hedges' *g* indicates that an absolute *g* value of ≥ 0.2 indicates a small effect size whereas a value around 0.5 indicates a moderate effect size, and a value ≥ 0.8 indicates a large effect size (Cohen 1988).

Discussion

This research aimed to develop a Japanese version of the PSAS and to examine its reliability and validity. The results show that the PSAS-J has a two-factor structure (somatic and cognitive arousal), which is consistent with that of the original PSAS (Nicassio et al. 1985). We also confirmed that the PSAS-J has high internal consistency (somatic factor: $\alpha = 0.85$, cognitive factor: $\alpha = 0.90$) and good test-retest reliability (somatic factor: ICC = 0.67, cognitive factor: ICC = 0.78) similar to that of the original scale (somatic: $\alpha = 0.79$ to 0.84, ICC = 0.76 and cognitive: $\alpha = 0.67$ to 0.88, ICC = 0.72) (Nicassio et al. 1985). Therefore, the results of this study are consistent with those of a previous study of the PSAS (Nicassio et al. 1985; Ruivo Marques et al. 2018).

With regard to concurrent, predictive, and discriminant validity, the PSAS-J showed a significant positive correlation with the insomnia-related scales. The PSAS-somatic and PSAS-cognitive subscales showed a moderate to large correlation with the insomnia-related measures ($r = 0.35$ – 0.53), similar to that found with the original scale (Puzino et al. 2019, 2020). Moreover, as pointed out in previous studies (e.g., Schwartz and Carney 2012), a higher PSAS score predicted subsequent worsening of symptoms of insomnia. Moreover, this is the first time that finding that revealed to be a distinctively different concept for PSAS-J, FIRST, and DBAS.

Of note is that despite the moderate to large correlation between scales, it is possible to distinguish the PSAS-J from other scales. Both the PSAS (i.e., state arousal) as a perpetuating component and FIRST (i.e., trait arousal) as a predisposing component measure arousal status (Riemann et al. 2010; Palagini et al. 2016), while both the PSAS and the DBAS-16 measured the perpetuating cognitive component (Morin and Espie 2004). Sleep reactivity measured by FIRST is a vulnerability factor in the onset of insomnia and depression (Drake et al. 2014). A high FIRST score predicts a high PSAS-cognitive score in patients with insomnia

($\beta = 0.29$) (Puzino et al. 2020) and high cognitive and somatic arousal scores in young adults ($\beta = 0.17$ and $\beta = 0.12$, respectively) (Puzino et al. 2019).

Therefore, sleep reactivity might involve trait hyperarousal as a predisposing factor and pre-sleep arousal may be a perpetuating factor at the time of onset of insomnia. Although there have been a number of treatment outcome studies on cognitive behavioral therapy for insomnia (Morin et al. 1999), few have investigated the mechanism underlying the improvement in insomnia in individuals treated with this method (Morin et al. 2002; Jansson-Fröjmark and Linton 2008). Future research should examine the differences in the effect of the two hyperarousal measures on the onset, maintenance, and recurrence of insomnia and whether or not improvement in insomnia is mediated by a reduction in pre-sleep arousal, sleep reactivity, or sleep-related dysfunctional beliefs using pharmacological and non-pharmacological (i.e., CBT-I) strategies.

The result of our comparison of PSAS-J between people with and without insomnia indicates that the PSAS-J can discriminate between a pathological and non-pathological pre-sleep arousal status. Moreover, the pathological cut-offs on the original PSAS subscales suggested previously (Puzino et al. 2019) can be used in the PSAS-J. This finding is consistent with both the theory and the evidence for the hyperarousal model of insomnia (Riemann et al. 2010). Our results suggest that the PSAS-J has high reliability and validity and that the scale is adequate for assessing pre-sleep arousal.

There are some limitations to this study. First, the study participants might not be representative of the general population in Japan because the study was conducted as an internet-based survey. Second, the participants were middle-aged. Third, it is not clear whether the participants in the insomnia group would be diagnosed with chronic insomnia disorder by a physician, although they were classified based on a criterion for insomnia on the ICSD-3 (American Academy of Sleep Medicine 2014). Therefore, further research is needed to determine whether the same

results would be obtained in a population sample that includes all age groups and in patients with insomnia. Finally, we did not examine the relationship between anxiety, depression, and pre-sleep arousal. This would be necessary in the future, given the reported association of trait and state arousal with symptoms of anxiety and depression (Palagini et al. 2016).

In the future, research that includes new psychometrics (e.g., item response theory) may help to refine the PSAS-J now that it has been confirmed to have high reliability and validity.

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Conflict of Interest

The authors declare no conflict of interest. On the other hand, I.O. has received grants from NEC Solution Innovators and personal fees from Otsuka Pharmaceutical, Merck Sharp & Dohme, Eisai, and Takeda Pharmaceuticals for projects unrelated to the submitted work.

References

- American Academy of Sleep Medicine (2014) *International classification of sleep disorders*, 3rd ed., American Academy of Sleep Medicine, Darien, IL, USA.
- Bastien, C.H., Vallières, A. & Morin, C.M. (2001) Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Med.*, **2**, 297-307.
- Cohen J. (1988) *Statistical power analysis for the behavioral sciences*, 2nd ed., Erlbaum Associates, Hillsdale, NJ, USA.
- Drake, C., Richardson, G., Roehrs, T., Scofield, H. & Roth, T. (2004) Vulnerability to stress-related sleep disturbance and hyperarousal. *Sleep*, **27**, 285-291.
- Drake, C.L., Pillai, V. & Roth, T. (2014) Stress and sleep reactivity: a prospective investigation of the stress-diathesis model of insomnia. *Sleep*, **37**, 1295-1304.
- Hooper, D., Coughlan, J. & Mullen, M.R. (2008) Structural equation modelling: guidelines for determining model fit. *Electron. J. Bus. Res. Methods*, **6**, 53-60.
- Jansson-Fröjmark, M. & Linton, S.J. (2008) The role of sleep-related beliefs to improvement in early cognitive behavioral therapy for insomnia. *Cogn. Behav. Ther.*, **37**, 5-13.
- Jansson-Fröjmark, M. & Norell-Clarke, A. (2012) Psychometric properties of the Pre-Sleep Arousal Scale in a large community sample. *J. Psychosom. Res.*, **72**, 103-110.
- Kalmbach, D.A., Cuamatzi-Castelan, A.S., Tonnu, C.V., Tran, K.M., Anderson, J.R., Roth, T. & Drake, C.L. (2018) Hyperarousal and sleep reactivity in insomnia: current insights. *Nat. Sci. Sleep*, **10**, 193-201.
- Kim, K., Uchiyama, M., Okawa, M., Liu, X. & Ogihara, R. (2000) An epidemiological study of insomnia among the Japanese general population. *Sleep*, **23**, 41-47.
- Kline, R.B. (2015) *Principles and practice of structural equation modeling*, 4th ed., Guilford Press, NY, USA.
- Koo, T.K. & Li, M.Y. (2016) A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *J. Chiropr. Med.*, **15**, 155-163.
- Morin, C.M., Blais, F. & Savard, J. (2002) Are changes in beliefs and attitudes about sleep related to sleep improvements in the treatment of insomnia? *Behav. Res. Ther.*, **40**, 741-752.
- Morin, C.M., Colecchi, C., Stone, J., Sood, R. & Brink, D. (1999) Behavioral and pharmacological therapies for late-life insomnia: a randomized controlled trial. *JAMA*, **281**, 991-999.
- Morin, C.M. & Espie, C.A. (2004) *Insomnia: A clinical guide to assessment and treatment*, Springer Science & Business Media, NY, USA.
- Morin, C.M., Vallières, A. & Ivers, H. (2007) Dysfunctional beliefs and attitudes about sleep (DBAS): validation of a brief version (DBAS-16). *Sleep*, **30**, 1547-1554.
- Munezawa, T., Morin, C.M., Inoue, Y. & Nedate, K. (2009a) Development of the Japanese version of Insomnia Severity Index (ISI-J). *Jpn. J. Psychiatric Treat.*, **24**, 219-225 (in Japanese).
- Munezawa, T., Morin, C.M., Inoue, Y. & Nedate, K. (2009b) Development of the Japanese version of Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS-J). *Jpn. J. Sleep Med.*, **3**, 396-403 (in Japanese).
- Nakajima, S., Okajima, I., Sasai, T., Kobayashi, M., Furudate, N., Drake, C.L., Roth, T. & Inoue, Y. (2014) Validation of the Japanese version of the Ford Insomnia Response to Stress Test and the association of sleep reactivity with trait anxiety and insomnia. *Sleep Med.*, **15**, 196-202.
- Nicassio, P.M., Mendlowitz, D.R., Fussell, J.J. & Petras, L. (1985) The phenomenology of the pre-sleep state: the development of the pre-sleep arousal scale. *Behav. Res. Ther.*, **23**, 263-271.
- Ohayon, M.M. (2002) Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med. Rev.*, **6**, 97-111.
- Okajima, I., Komada, Y., Nomura, T., Nakashima, K. & Inoue, Y. (2012) Insomnia as a risk for depression: a longitudinal epidemiologic study on a Japanese rural cohort. *J. Clin. Psychiatry*, **73**, 377-383.
- Palagini, L., Mauri, M., Dell'Osso, L., Riemann, D. & Drake, C.L. (2016) Trait- and pre-sleep-state-dependent arousal in insomnia disorders: what role may sleep reactivity and sleep-related metacognitions play? A pilot study. *Sleep Med.*, **25**, 42-48.
- Puzino, K., Amatrudo, G., Sullivan, A., Vgontzas, A.N. & Fernandez-Mendoza, J. (2020) Clinical significance and cut-off scores for the Pre-Sleep Arousal Scale in chronic insomnia disorder: a replication in a clinical sample. *Behav. Sleep Med.*, **18**, 705-718.
- Puzino, K., Frye, S.S., LaGrotte, C.A., Vgontzas, A.N. & Fernandez-Mendoza, J. (2019) Am I (hyper)aroused or anxious? Clinical significance of pre-sleep somatic arousal in young adults. *J. Sleep Res.*, **28**, e12829.
- Riemann, D., Baglioni, C., Bassetti, C., Bjorvatn, B., Dolenc Groselj, L., Ellis, J.G., Espie, C.A., Garcia-Borreguero, D., Gjerstad, M., Gonçalves, M., Hertenstein, E., Jansson-Fröjmark, M., Jennum, P.J., Leger, D., Nissen, C., et al. (2017) European guideline for the diagnosis and treatment of insomnia. *J. Sleep Res.*, **26**, 675-700.
- Riemann, D., Spiegelhalter, K., Feige, B., Voderholzer, U., Berger, M., Perlis, M. & Nissen, C. (2010) The hyperarousal model of insomnia: a review of the concept and its evidence. *Sleep Med. Rev.*, **14**, 19-31.
- Rosseel, Y. (2012) Lavaan: an R package for structural equation modeling. *J. Stat. Softw.*, **48**, 1-36.
- Ruivo Marques, D., Allen Gomes, A., Nicassio, P.M. & Azevedo, M.H.P. (2018) Pre-Sleep Arousal Scale (PSAS): psychometric study of a European Portuguese version. *Sleep Med.*, **43**, 60-65.
- Schwartz, D.R. & Carney, C.E. (2012) Mediators of cognitive-behavioral therapy for insomnia: a review of randomized controlled trials and secondary analysis studies. *Clin. Psychol. Rev.*, **32**, 664-675.
- Shahzadi, N. & Ijaz, T. (2014) Reliability and validity of pre-sleep arousal scale for Pakistani University students. *FWU J. Soc. Sciences*, **8**, 78-82.

- Spielman, A.J., Caruso, L.S. & Glovinsky, P.B. (1987) A behavioral perspective on insomnia treatment. *Psychiatr. Clin. North Am.*, **10**, 541-553.
- Spielman, A.J. & Glovinsky, P. (1986) The varied nature of insomnia. In *Case studies in insomnia*, edited by Hauri, P.J., Plenum Publishing, Philadelphia, PA, pp. 1-15.
- Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A. & Erikson, P.; ISPOR Task Force for Translation and Cultural Adaptation (2005) Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value Health*, **8**, 94-104.
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