The validity and reliability of the Japanese version of RU-SATED

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Abstract:

Objective*:* We developed a Japanese version of RU-SATED (RU-SATED-J), a simple self-rated scale for measurement of multidimensional *sleep health*, and examined its reliability and psychometric validity.

Method*:* The RU-SATED-J was developed by a rigorous reverse translation process. It consists of six questions, each with three Likert-type response options. The total score (range 0-12) was calculated by summing the item scores. Psychometric characteristics were tested in an observational cross-sectional study involving factory workers in Japan (n=177, mean age 42.8±11.6 years, range 19-65 years). The distribution and reliability of the scale scores were examined in terms of Cronbach's alpha coefficient. The convergent and divergent validity of the scale score were assessed by examining the correlations of various factors with the Insomnia Severity Index (ISI) and the Epworth Sleepiness Scale (ESS).

Results*:* The distribution of scores was left-skewed, with a mean of 8.21±2.72 points, and range of 0-12. The internal reliability of the scale was $\alpha = 0.758$. The total score showed a significant negative correlation with the ISS (rs=-0.542, $P<0.001$) and the ESS (rs=-0.178, $P=0.018$). Exploratory factor analysis (EFA) demonstrated a two-factor structure. Confirmatory factor analysis (CFA) showed that the goodness of fit of the higher-order factor model had a Root Mean Square Error of Approximation (RMSEA) of <0.001 and a Comparative Fit Index (CFI) of 1.00, confirming its factorial validity.

Conclusion*:* The RU-SATED is a promising new instrument for measuring multi-dimensional sleep health perception among Japanese adults. Further general population studies using this Japanese version of the questionnaire should be considered.

Keywords: Sleep health; RU-SATED; Reliability; Validity; Japan

1. Introduction

The restorative function of sleep is essential for maintenance of both physical and mental health [1]. *Sleep health* has been defined as "a multidimensional pattern of sleep-wakefulness, adapted to individual, social, and environmental demands, that promotes physical and mental well-being" [2, 3]. The importance of this concept is that sleep health can be characterized as a multidimensional construct comprising different dimensions of sleep and circadian functioning, including satisfaction, sleepiness/alertness, timing, efficiency, duration, regularity, and rhythmicity [2, 3]. These different dimensions can be characterized for every individual at every point in time. Sleep health is also viewed as a positive attribute. These characteristics distinguish sleep health from sleep disorders, which are categorical, tend to be chronic, are present in a minority of individuals, and are viewed as negative attributes.

In recent years, analyses of data from large-scale epidemiological studies have reported associations between sleep health and mortality [2, 4], chronic disorders [5], lower cardiometabolic morbidity [6], poor mental and physical health [7], symptoms and onset of depression [8-10], and health care costs [11].

Although sleep health is an important issue in public health, most of the questionnaires used for sleep medicine research in Japan so far have focused on single sleep characteristics such as insomnia, excessive sleep during the daytime, and morning-type and evening-type sleep. No current assessments evaluate sleep health with multidimensionality in a simple way.

The RU-SATED v2.0 scale is a self-administered instrument for assessment of sleep health, which is composed of multiple dimensions [3]. This questionnaire consists of six questions about sleep and wakefulness, each with one response selected from three Likert-type options. The reliability and validity of the English [12], Portuguese [13], and French [14] versions have been examined based on epidemiological studies.

Here, we conducted a cross-sectional survey among factory workers in Japan using RU-SATED-J. The study aims were to (1) create a Japanese version of RU-SATED (RU-SATED-J),

and (2) examine the reliability and validity of the RU-SATED-J.

2. Methods

2.1. Development of RU-SATED-J

Sleep health was measured using the RU-SATED-J [3]. The measure consists of six items, each assessing one aspect of sleep heath: sleep regularity (bedtime and wake time occurring at the same time, within 1 h, every day), satisfaction, alertness during the day (awake all day without dozing), timing (the middle of sleep being between 2:00 A.M. and 4:00 A.M.), duration (6–8 h per day), and efficiency (wake time of less than 30 min). Items are each rated on a 3-point Likert scale from 0 (Rarely/Never) to 1 (Sometimes) or 2 (Usually/Always), higher scores indicating better sleep health.

In preparing the RU-SATED-J, the following steps were taken to examine the appropriateness of the contents, and six items were determined [15].

(1) After obtaining approval from the original authors of the RU-SATED, a contract was signed with the University of Pittsburgh for preparation of the Japanese version of RU-SATED (v2.0).

(2) RF, YT, and YN in our research group prepared the Japanese translation.

(3) Pilot test: Five Japanese participants aged 20 years or older were surveyed to see whether they could understand the meaning of the questions and answer them smoothly. The results showed that no explanations were required to influence their responses, and were used as a reference for examination of content validity.

(4) The items were determined by examining content validity, and RF, YT, YN, and IT examined whether the translated RU-SATED text reflected the meaning and content of the original text. For content validity, we examined whether the questionnaire items measured subjective sleep, whether the language used was clear, whether there were any technical or unnatural words that subjects could not understand, and whether they were appropriate for Japanese culture.

(5) The RU-SATED-J was finally back-translated into English by a professional translator, and

the semantic content was confirmed by the original author who had developed the English version. All rights related to RU-SATED-J are reserved by the University of Pittsburgh (contact email address: buyssedj@upmc.edu.).

2.2. Study participants and data collection

This cross-sectional survey was carried out in May 2021. Participants were enrolled from among factory workers in Saitama Prefecture, Japan. We calculated that the sample size should be at least 100 people based on the recommendation of Terwee et al. [16], and this factory was included in the study because it had more than 100 employees.

A researcher at the factory distributed a set of questionnaires (explanatory document, consent form, anonymous self-administered questionnaire, and collection envelopes) to all employees. To protect the privacy of the participants, the self-administered questionnaires were anonymized and placed in sealed envelopes.

The inclusion criteria for participants were that they were (1) full-time employees of the company supporting the study, (2) aged 18 years or older, and (3) fully understanding of the study content and able to provide written informed consent to participate.

Exclusion criteria were: (1) a history of intellectual developmental disorder, dementia, drug or alcohol dependence, or major physical or neurological disease; and (2) a conflict of interest with the researcher or the principal investigator.

Ethical considerations

This study was approved by the Kyoto University Medical Ethics Committee, and conducted with due consideration of safety. Subjects were given a full explanation of the study by the researcher, and written consent was obtained from all subjects.

2.3. Procedures

2.3.1. Measures

Insomnia Severity Index (ISI)

We referred to the Japanese version of the Insomnia Severity Index (ISI) [17, 18], which is a 7-item questionnaire with scores ranging from 0 (no insomnia) to 28 (severe insomnia). For interpretation of insomnia severity, the following guidelines have been established: 0-7 points (no insomnia), 8-14 points (subthreshold insomnia), 15-21 points (moderate insomnia), and 22-28 points (severe insomnia) [18]. The first three items are more specific to the nighttime symptoms of insomnia, the fourth item to sleep satisfaction, and the last three items to daytime consequences [14].

Epworth Sleepiness Scale (ESS)

We also referred to the Japanese version of the Epworth Sleepiness Scale (ESS) [19], which is an 8-item questionnaire with scores ranging from 0 (no daytime sleepiness) to 24 (severe daytime sleepiness). For classification of the points scores, the proposed guideline for interpretation is 0-8 (no drowsiness), 9-12 (mild), 13-16 (moderate), and 16 or more (severe) [20].

2.4. Statistical analyses

2.4.1 Descriptive statistics

The distribution of the scores for each item and the distribution of the total and interpretive scores were examined. Statistical normality of the total score distribution was tested using the Kolmogorov-Smirnov test of normality.

Differences in the RU-SATED score according to age categories were compared using the Wilcoxon rank-sum test for continuous variables with skewed distributions. Four age categories were used: 18-29 y, 30-39 y, 40-49 y, and 50-65 y.

2.4.2 Examination of internal consistency reliability

Reliability was examined using Cronbach's alpha coefficient. Relationships between

variables were examined using Spearman's rank correlation coefficient.

2.4.3 Examination of validity

(1) Convergent and divergent validity

Spearman's rank correlation coefficient was used to test the relationships between variables. To examine the scale's convergent validity and divergent validity, RU-SATED responses were compared to the participants' self-rated sleep, as well as their ISI and ESS total scores. Moderate correlation coefficients (≥ 0.30 or ≤ -0.30) indicate convergent validity, and low correlation coefficients (≥ -0.30 or ≤ 0.30), indicate divergent validity.[21, 22]

(2) Factorial validity

The Kaiser-Meyer-Olkin (KMO) test (expected >0.60) and Bartlett's test (expected <0.05) were performed to determine the suitability of this sample for factor analysis [23]. The unique factor structure associated with RU-SATED was examined using exploratory factor analysis (EFA) with principal axis factoring and Promax rotation assuming no *a priori* factor structure.

Next, confirmatory factor analysis (CFA) was performed on the data specifying the factor structure that had emerged via the EFA. To ensure the discriminability of the model, a path from factor 1 to item 1 and a path from factor 2 to item 2 were created, and the model fit indices were χ^2/df, Root Mean Square Error of Approximation (RMSEA), and Comparative Fit Index (CFI). The goodness-of-fit criterion was set at RMSEA; values ≤ 0.05 indicate a very good adjustment, and the CFI; values ≥ 0.95 indicate a very good adjustment.

The results of the study were analyzed using the statistical software packages SPSS 27.0 for Windows and JMP pro15.2.0. Statistical significance was based on a two-tailed test with $P<0.05$ as the criterion.

3. Results

3.1 Descriptive results

A total of 179 workers were recruited and all 179 participated in the complete survey. Two participants were excluded due to missing data related to participation agreement (n=1) or the RU-SATED-J questionnaire (n=1). Therefore, we analyzed data from a final sample of 177 workers (response rate 98.9%). The study sample comprised 161 (91.0%) male and 16 (9.0%) female participants. The mean age of the participants was 42.8±11.6 years, ranging from 19 to 65 years. All of the participants were employed, and 25 (14.1%) were engaged in shift work. Additional descriptive information is presented in **Table 1**.

3.2 Descriptive statistics for RU-SATED-J

The distribution of the RU-SATED-J scores is shown in **Table 2**. The mean total score was 8.21±2.72 points, ranging from a minimum of 0 to a maximum of 12. The lowest mean was found for satisfaction (1.16) and the highest for regularity (1.61). The kurtosis was 0.129 and the skewness was -0.677. A frequency histogram of the RU-SATED-J scores is shown in **Figure 1**. The Kolmogorov-Smirnov test revealed that the total score for RU-SATED-J was not normally distributed. We did not find any significant differences among the age groups (P=0.781).

3.3 Reliability and internal consistency

Cronbach's α and item-total correlations were used to assess the internal consistency of the RU-SATED-J scale. Cronbach's α coefficient for the scale was 0.758, which indicated good internal consistency.

In contrast, the inter-item correlations ranged from 0.211 to 0.443, consistent with a previous study indicating average inter-item correlations of between 0.15 and 0.5 [24] (**Table 3)**.

3.4. Validity

3.4.1 Convergent and divergent validity

Table 3 presents the convergent and the divergent validity. The total score for the ISS was 7.41±5.26, and the correlation of the ISS with the total RU-SATED-J score was rs=-0.542, P<0.001. Moderate correlations between the ISS total score and the total RU-SATED-J score

confirmed convergent validity. The total score for the ESS was 8.44±4.43, and the correlation with the total RU-SATED-J score was rs=-0.178, P=0.018, suggesting divergent validity.

3.4.2 Exploratory factor analysis

The KMO (0.79) and Barlett (P <0.01) tests suggested that the data were suitable for factor analysis. For testing of construct validity, the EFA was performed using the principal factor method (Promax rotation). An item was selected for loading onto a specific factor if it achieved a simple structure, defined as the highest loading eigenvalue exceeding an absolute value of 0.40, with all cross-loadings being at least 0.15 less than the item's highest factor loading. Item loadings for the two factors obtained from the EFA are shown in **Table 4**. Items pertaining to factor 1 (regularity, timing, and efficiency) may best be described as "circadian." Items associated with factor 2 (sleep satisfaction, duration, and alertness) may best be described as "quality and quantity."

CFA was conducted on the two-factor solution obtained from the EFA (**Figure 2**). The two potential constructs were significantly correlated (r = 0.161, P <0.001). The model was finally adopted (χ^2 (df)=4.644 (8), RMSEA<0.001, CFI=1.000, AIC=2109.2). The path from the observed variables (each item) to the temporary factor, factor 1, ranged from 1.0 to 1.22, and to factor 2 ranged from 0.56 to 1.00.

4. Discussion

We translated the original version of the RU-SATED into Japanese and examined its reliability and validity. The content validity of each item of the RU-SATED-J was examined, and the RU-SATED-J was determined to be appropriate for Japanese culture because there were no words that were difficult for respondents to understand. The reliability of the scale was examined and found to be sufficiently high. The results of the factor analysis conducted to examine validity showed results similar to those for the English version, indicating sufficient validity.

The content validity was confirmed by experts by checking the content of items created with reference to preliminary conceptual studies. In this study, the items of the RU-SATED-J were

developed through a preliminary qualitative survey of five Japanese participants and then checked by experts in epidemiological research, psychiatrists, and the original authors. Therefore, the content validity of the RU-SATED-J is considered to be sufficiently high.

In the present study, there were no age-related differences in RU-SATED-J responses, suggesting that age did not seem to have a marked effect. A study examining a wider range of ages has reported differences in the RU-SATED score by age [13]. The distribution of scores was left-skewed. Several previous studies using the English [12] and French [14] versions of RU-SATED found that the distribution of answers was left-skewed. The present results are in agreement with those previous findings.

Cronbach's alpha was 0.758 in this study, indicating that the internal consistency reliability of RU-SATED-J was sufficiently high. In a reliability study using the original version conducted in the USA, Cronbach's alpha was 0.64[12] , suggesting that the value obtained in our study was higher, and that the measurement accuracy of RU-SATED-J was sufficient. For the present scale, the correlation between the items was small (rs=0.211 to 0.443). This suggests that the items measured different constructs. Thus, RU-SATED-J appears to have an appropriate content breadth and is sufficiently reliable.

In this study, we tested correlation coefficient with the ISI and ESS, which are representative sleep disorder assessment scales. Ideally, a multidimensional sleep assessment scale should be used, but since there is no scale that meets these requirements, an internationally standardized assessment scale that is considered to partially overlap in terms of constructs was adopted as the standard. The ISS and the RU-SATED-J total score were moderately correlated. Previous studies have also reported strong correlations between these two questionnaires [12, 25] and have shown similar trends. The correlation between the ESS and the RU-SATED-J total score was weak, a finding similar to that of the previous study [25]. These results suggest that the constructs of RU-SATED-J have convergent validity with the ISS, but divergent validity with the ESS.

The results of the CFA revealed a two-factor structure for this questionnaire, as in the previous American study [12]. However, the items that constituted each factor differed slightly between the two studies. Specifically, Efficiency loaded with Satisfaction and Duration in the previous study, but with Timing and Regularity in the present study. On the other hand, Alertness was loaded with Timing and Regularity in the previous study, but with Satisfaction and Duration in the present study. Thus, the classifications of Efficiency and Alertness were switched across the two studies. Since the results may be affected by the characteristics of the subjects, it will be necessary to examine the results using other samples in the future. It may also be worth noting that the Efficiency dimension had the lowest factor loading in confirmatory factor analysis conducted on an earlier version of this scale [13].

The EFA showed that the fit of the higher-order factor model of RU-SATED-J was sufficiently high by RMSEA and CFI, indicating that the factor validity of RU-SATED is high. The path from each RU-SATED-J questionnaire item to factor 1, a temporary factor, was 1.0 to 1.22, and to factor 2 was 0.56 to 1, which are sufficiently large positive values.

This questionnaire, with only 6 items, is simple and easy to use; the ISI has 7 items and the ESS has 8 items. In clinical practice and epidemiological studies, such a small number of items is important in terms of reducing the burden on the subject and reducing study costs.

There were several limitations to this study. The first was that it was conducted on employees of a single factory, which may have led to sampling bias. In particular, the cohort included only a small number of women. In the future, surveys targeting randomly selected populations with various backgrounds, and more representative of the general population, will be required. Second, the cross-sectional nature of the study design precluded any examination of the test-retest reliability of the RU-SATED-J. Such an examination employing a longitudinal design with repeated measures would make it possible to assess whether sleep health is a relatively stable characteristic or one that changes rapidly over time. Such a study would also allow measurement of the sensitivity of the RU-SATED-J to changes in sleep health due to aging, intervention, or

other causes. Third, the association with objective sleep metrics was not investigated. If the results of all-night polysomnography could be compared with those of actigraphy using portable activity meters that measure daily behavioral sleep-wake states, it would be possible to confirm that the RU-SATED-J is an objectively valid index. However, since there is often a dissociation between subjective evaluation of sleep and the results obtained using objective indices, such characteristics of sleep must be considered when conducting this type of research.

5. Conclusion

This study has confirmed that the reliability and validity of the RU-SATED-J are satisfactory. We conclude that RU-SATED-J is appropriate for widespread use as a simple and useful self-administered questionnaire in epidemiological and clinical studies in Japan.

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Table 1. Participant Characteristics

Variables	N	%
Age		
18-29	26	14.7
30-39	35	19.8
40-49	58	32.8
50-65	58	32.8
Sex		
Men	161	91.0
Women	16	9.0
Live-in		
Alone	46	26.0
Someone	131	74.0
Shiftwork		
No	140	79.1
Yes	25	14.1
Exercise		
not at all/rarely/sometimes	130	73.4
often/every day	47	26.6
Alcohol use		
Never	54	30.5
Sometimes	73	41.2
Everyday	49	27.7
Smoking		
Never	133	75.1
Sometimes	3	1.7
Everyday	41	23.2
Caffeine consumption		
No	14	7.9
Yes	163	92.1
Use of alcohol as aids to sleep		
No	163	92.1
1 /w or more	14	7.9
Hypnotic medication use		
No	172	97.2
1 /w or more	5	2.8

Table 2. Distribution of scores for each questionnaire item.

			0		1		2		Kurtosis	Skewness
	mean	SD	N	%	N	%	N	%		
Regularity	1.61	0.59	10	5.6	49	27.7	118	66.7	0.57	-1.26
Satisfaction	1.16	0.71	32	18.1	84	47.5	61	34.5	-0.98	-0.25
Alertness	1.19	0.69	28	15.8	88	49.7	61	34.5	-0.87	-0.26
Timing	1.50	0.72	24	13.6	41	23.2	112	63.3	-0.26	-1.08
Efficiency	1.33	0.73	27	15.3	65	36.7	85	48.0	-0.90	-0.59
Duration	1.42	0.76	29	16.4	44	24.9	104	58.8	-0.70	-0.88
Total	8.21	2.72							0.13	-0.68

Table3. Spearman's rank correlation coefficient for RU-SATED-J, ISS, and ESS.

	Regularity	Satisfaction	Alertness	Timing	Efficiency	Duration	RUSATED score	ISS	ISI (item1,2,3)	ISI (item4)	ISI (item5,6,7)	ESS
Regularity		.360**	.218**	.397**	.329**	.237**	.573**	-.261**	-.217**	-.198**	-.267**	-0.058
Satisfaction			.356**	.311**	.443**	.397**	.751**	-.618**	-.496**	-.663**	-.559**	-.229**
Alertness				.211**	.211**	.270**	.586**	-.244**	-.171*	-.215**	-.257**	-.273**
Timing					.340**	.242**	.614**	-.171*	-0.136	-.201**	-.156*	0.026
Efficiency						.263**	.662**	-.352**	-.354**	-.287**	-.270**	0.033
Duration							.622**	-.289**	-.214**	-.322**	-.292**	-0.032
RUSATED score								-.542**	-.438**	-.539**	-.503**	-.178*
ISS									.833**	.812**	.906**	.385**
ISI (item1,2,3)										.600**	.565**	.269**
ISI (item4)											.706**	.337**
ISI (item5,6,7)												.399**
ESS												

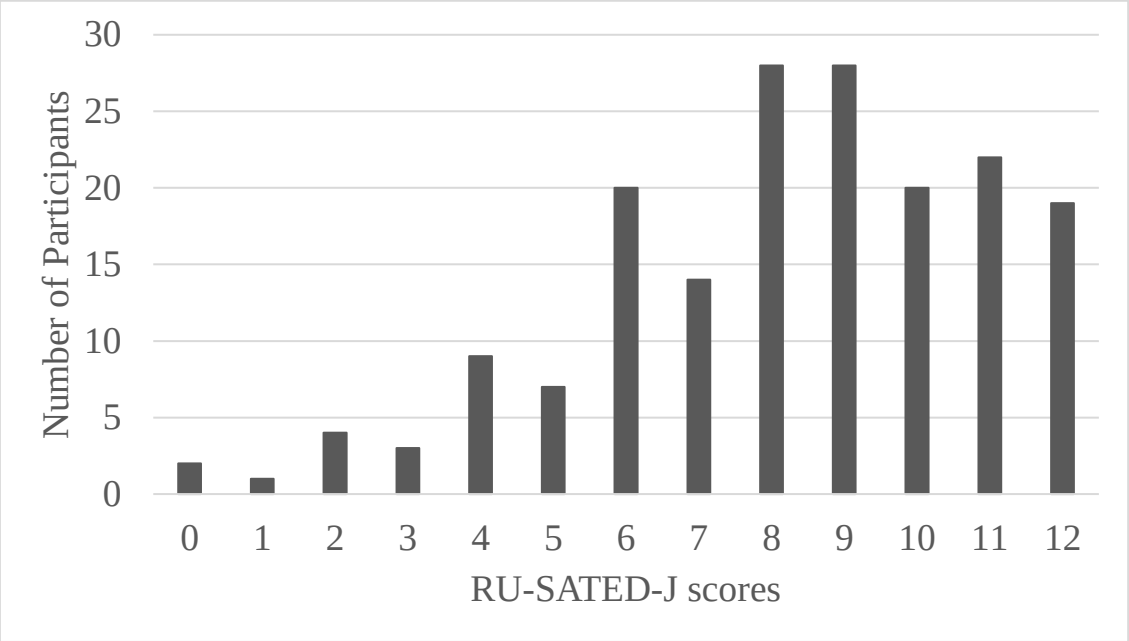
**. Correlation coefficient is significant (two-sided) at the 1% level.

*. Correlation coefficient is significant (two-sided) at the 5% level.

Table 4. Item loadings for the exploratory factor analysis.

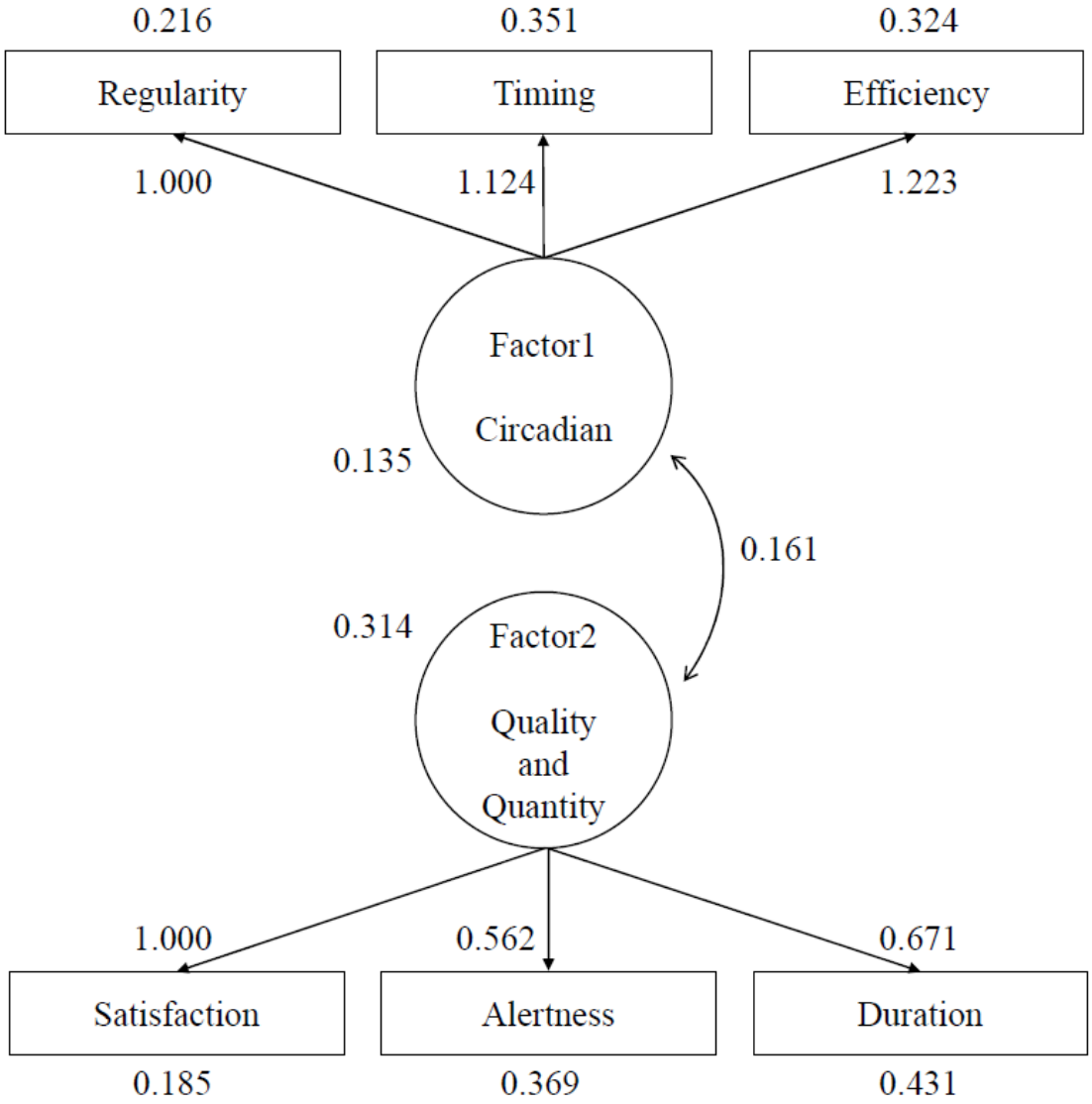
	Factor	
Item	1	2
Timing	0.830	-0.138
Regularity	0.764	-0.014
Efficiency	0.695	0.063
Alertness	-0.117	0.817
Duration	-0.045	0.776
Satisfaction	0.374	0.536

Figure1. Frequency histogram of participants' RU-SATED-J scores.



The distribution of total score of RU-SATED-J was left-skewed, with a mean score of 8.21±2.72, ranging from a minimum of 0 to a maximum of 12 points.

Figure 2. Two-factor model indicated by confirmatory factor analysis with standardized path coefficients between the latent factors (Factor 1 and Factor 2) and the six RU-SATED-J items.



The two potential constructs were significantly correlated. The model was finally adopted.