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分担研究報告書

慢性不眠症に対する認知行動療法の効果
－個人療法と集団療法の比較研究－

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研究要旨

【目的】慢性の不眠症に対する認知行動療法(CBT-I)において、個人療法(個人 CBT-I)と集団療法(集団 CBT-I)の治療効果を比較検討する。

【対象と方法】対象は、精神神経科睡眠障害専門外来を受診し CBT-I を施行した DSM-IV によって診断された原発性不眠症患者である。CBT-I の内容は、両群共に刺激調整法、睡眠時間調整法、認知療法、睡眠衛生教育からなり、同一の治療期間を設定した。施行者は両群共に、睡眠医療を専門とする精神神経科医師であった。個人 CBT-I(計 3 回の個人療法)施行例 20 例と集団 CBT-I(1 グループ 3～5 人、計 2 回の講義形式)施行例 25 例について、施行後 1 ヶ月時点での治療効果を 1)睡眠日誌、2)アクチグラフ(活動計)、3)ピッツバーグ睡眠質問紙(以下 PSQI)、4)睡眠に対する非機能的な信念と態度質問票(以下 DBAS)を用いて比較検討した。両群間で年齢、性別、罹病期間、睡眠薬投与量には差異を認めなかった。

【結果】施行前に比較して施行後 1 ヶ月には、両群共に主観的及び客観的睡眠内容や主観的な睡眠評価に有意な改善が認められた。その中で、1)主観的(睡眠日誌)及び客観的(活動計)入眠潜時、2)客観的(活動計)睡眠効率及び夜間体動時間、3)主観的(PSQI)な睡眠の質及び実睡眠時間、4)DBAS の内、不眠の影響に対する不安、睡眠を制御できない不安、睡眠に対する過剰な期待、眠るための過剰な努力、に関する施行後の改善度が、集団 CBT-I に比較して個人 CBT-I において有意に優れていた。一方で、集団 CBT-I に比較して個人 CBT-I で改善度に有意差を示した評価項目は認められなかった。

【結語】原発性不眠症に対する個人 CBT-I は、同様の内容、期間、施行者による集団 CBT-I に比較して、施行後 1 ヶ月の短期治療成績において、若干ながら優れている可能性が示唆された。

A. 研究背景

本邦一般人口の5人に1人が不眠の訴えを持ち、20人に1人が睡眠薬を使用している。増加の一途を辿って医療経済を圧迫している睡眠薬市場を抑制するために、不眠症に対する非薬物療法の確立と普及は、喫緊の課題である。不眠症の中核は、DSM-Ⅳの原発性不眠症(ICSD-Ⅱの精神生理性不眠症)である。欧米において、原発性不眠症に対する標準的な治療法は、認知行動療法(cognitive behavioral therapy for insomnia; CBT-I)である。CBT-Iによって慢性不眠症患者の70～80%で症状が軽減し、治療終了半年後にも効果が維持され、睡眠薬の減量にも有用であることが実証されている。本邦の『不眠症診断・治療・医療連携ガイドライン』も、治療的初期対応(睡眠衛生指導と適切な薬物療法)で改善が認められない難治例に対して、CBT-Iの導入を推奨している。しかし、その臨床実践は、端緒を開いたに過ぎず、未熟な段階にあると言わざるを得ない。

当院では最近の10年間ほどかけて、慢性の不眠症患者に対してCBT-Iを試行してきた。当初の個人療法のCBT-Iから2009年以降は集団療法に移行させ、同一の内容、施行者、評価時点によって、その治療効果を蓄積してきた。

B. 研究目的

慢性不眠症(DSM-Ⅳの原発性不眠症、ICSD-2の精神生理性不眠症)に対するCBT-Iについて、同一の内容、施行期間、施行者による個人療法(個人CBT-I)と集団療法(集団CBT-I)に関する短期治療効果(施行後1か月)を比較検討する。

C. 研究方法

対象は、東京慈恵会医科大学付属病院精神神経科睡眠障害専門外来を受診し、CBT-I施行を希望した、DSM-IVによって診断された原発性(精神生理性)不眠症患者である。CBT-Iの内容は、両群共に刺激調整法、睡眠時間調整法、認知療法、睡眠衛生教育からなり、同一の治療期間を設定した。施行者は両群共に、睡眠医療を専門とする精神神経科医師であった(表.1)。

表.1　個人あるいは集団CBT-Iプロトコールの概要

	個人CBT-I	集団CBT-I
CBT-Iの内容	睡眠衛生指導　刺激制御療法 睡眠時間制限療法　認知療法	
施行回数	3回 第1セッション：60分 第2・3セッション：15-20分	2回：60-90分 (講義と質疑応答) 1回の個人療法による内容確認（10分）
対象人数	個人	3~5人
施行者	精神神経科 睡眠医療認定医師	
施行後の評価時期	第1セッション後4週	第2セッション後4週

個人CBT-I(計3回の個人療法)施行例20例と集団CBT-I(1グループ3～5人、計2回の講義と討論形式)施行例25例について、施行後1ヶ月時点での治療効果を1)睡眠日誌、2)アクチグラフ(活動計)、3)ピッツバーグ睡眠質問紙(PSQI)、4)睡眠に対する非機能的な信念と態度質問票(DBAS)を用いて比較検討した。両群間で年齢、性別、罹病期間、睡眠薬投与量、不眠症重症度および導入例中の脱落率には差異を認めなかった(表.2)。

表.2　個人CBT-I群と集団CBT-I群の背景因子の比較

	個人CBT-I (N=20)	集団CBT-I (N=25)
年齢（歳，[範囲]）	56.9±12.6　[27-76]	61.7±11.3　[35-81]
性比（男性:女性，[%男性]）	6:14 [30.0]	14:11　[56.0]
罹病期間　（年，[範囲]）	8.9±6.2　[1-22]	8.0±6.4　[0.5-21]
睡眠薬1日投与量 [範囲] (flunitrazepam 1mg=1)	1.6±1.2　[0-4.0]	1.9±1.1　[0.33-4.0]
施行前 global PSQI-J scores [範囲]	12.7±3.0　[6-18]	12.2±2.4　[9-17]
脱落例/導入例（%）	4/24　(16.7)	4/29　(13.8)

mean±SD or N　　Unpaired T test, Chi-square test: N.S.
PSQI-J: the Japanese version of the Pittsburgh Sleep Quality Index

[倫理面への配慮]

本研究の研究計画に関して、本学の倫理委員会において審査され、その実施について承諾されている。

D. 研究結果

施行前に比較して施行後１ヶ月には、両群共に主観的及び客観的睡眠内容や主観的な睡眠評価に関する多くの指標で有意な改善が認められた。

その中で、1)主観的(睡眠日誌)入眠潜時[個人：69.3±8.5→26.3±3.4、集団：46.9±6.0→31.5±2.7。(分)]および客観的(活動計)な入眠潜時[個人：30.4±6.2→7.2±1.0、集団：20.0±2.2→20.1±2.8。(分)]、2)客観的(活動計)な睡眠効率[個人：84.4±1.9→92.1±0.8、集団：85.5±1.7→88.5±1.4。(%)]および夜間体動時間[個人：10.4±1.0→8.4±0.8、集団：8.2±0.9→7.9±0.8。(counts/min)]、3)主観的(PSQI)な睡眠の質(C1)［個人：2.3±0.1→1.2±0.1、集団：2.1±0.1→1.5±0.1。(点)］および実睡眠時間(C3)［個人：2.3±0.2→1.4±0.2、集団：1.8±0.2→1.6±0.1。(点)]、4)DBAS(図.1)の、不眠の影響に対する不安、睡眠を制御できない不安、睡眠に対する過剰な期待、眠るための過剰な努力、に関する施行後の改善度が集団CBT-Iに比較して個人CBT-Iにおいて有意に優れていた。[]内は、両群の施行前後の変化について、平均±標準誤差で表示した。一方で、集団CBT-Iに比較して個人CBT-Iで改善度に有意差を示した評価項目は認められなかった。

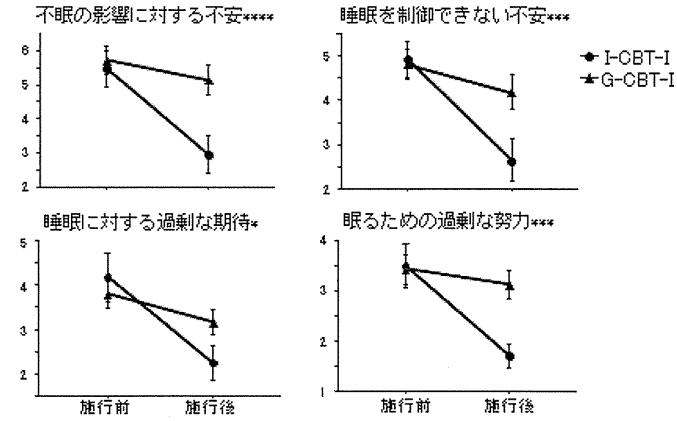

図.1　個人あるいは集団CBT-I施行前後における睡眠に関する認知(DBAS-J)の変化の比較

DBAS-J: Dysfunctional Beliefs and Attitudes about Sleep scale Japanese version
mean±SE, ANOVA with repeated measures,　*: P<0.05, ***: P<0.005, ****: P<0.001

E. 考察

過去に、個人CBT-Iと集団CBT-Iの治療効果を直接的に比較検討した研究は数少ないが、主観的な睡眠評価の改善度には、両者で大きな差異はないと結論付けられている。今回の検討では、原発性不眠症に対する個人CBT-Iは、同様の内容、期間、施行者による集団CBT-Iに比較して、施行後１ヶ月の短期治療成績において、主観的および客観的指標の改善度は若干ながら優れている可能性が示唆された。Edingerらは、個人CBT-Iにおける治療スケジュール設定の柔軟性と患者個別の対応がしやすいこと、集団CBT-Iにおける経済効率を利点として挙げる一方で、集団CBT-Iには実施する上での治療スペースの確保を問題点としている。筆者らは、

集団 CBT-I には他の集団精神療法と同様に、同一疾患患者間で生じる治療的相互作用がありうると想定していたが、結果として明らかにすることができなかった。個人 CBT-I における患者個々の問題に焦点を当てた個人精神療法的アプローチが、特に DBAS などで表現される患者の誤った認知の修正に効果的であったことが示唆された。今後、より多数症例に対する長期間の経過観察による検討が必要であると考える。

F. 結論

不眠症に対する認知行動療法について、自施設における個人療法と集団療法の比較検討を試みた。今後、不眠症に対する精神療法による治療システムが構築され、一般臨床に広く普及することが望まれる。その役割を、CBT-I が担うべきであると考える。なぜならば、重症かつ治療抵抗性の慢性不眠症患者に対する高強度な個人 CBT-I の治療有効性が実証されている上に、より軽症例に対する初期治療あるいは公衆衛生的観点からの不眠症発症予防としての低強度な CBT-I の有用性が期待され、より広範囲な臨床場面で活用され得るからである。ただし、強度の高低に関わらず、施行者には睡眠学全般にわたる正しい知識、つまり、睡眠衛生に関する知識の習得が不可欠である。

G. 健康危険情報

なし

H. 研究発表

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I. 知的財産権の出願・登録状況

なし

Ⅲ. 研究成果の刊行に関する一覧表

1．書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ
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Ⅳ. 研究成果の刊行物・別冊

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Original Article

Validation of the Japanese version of the Ford Insomnia Response to Stress Test and the association of sleep reactivity with trait anxiety and insomnia

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ABSTRACT

Objective: Our study was conducted to validate the Japanese version of the Ford Insomnia Response to Stress Test (FIRST-J) and to clarify the association of the measure with trait anxiety and insomnia in healthy subjects and insomnia patients.
Methods: We studied 161 healthy subjects and 177 insomnia patients who completed the FIRST-J, Pittsburgh Sleep Quality Index (PSQI), Athens Insomnia Scale (AIS), and State-Trait Anxiety Inventory-Trait (STAI). The healthy subjects and the insomnia patients were classified, respectively, into two groups with high FIRST-J and low FIRST-J scores (divided by the median value of healthy subjects).
Results: Cronbach α coefficients of the FIRST-J in the insomnia patients and healthy subjects were 0.89 and 0.87, respectively. Factor analysis revealed that the FIRST-J had a single-factor structure. The FIRST-J score significantly correlated with all other measures in the healthy subjects, though the score only correlated with the score of the STAI in the insomnia patients. The healthy subjects with high FIRST-J scores showed higher scores of the AIS and STAI than those with low FIRST-J scores. Furthermore, insomnia patients had a higher total score of the FIRST-J than the healthy subjects.
Conclusions: The FIRST-J is an important tool for assessing vulnerability to insomnia.

1. Introduction

Insomnia is characterized by difficulty initiating or maintaining sleep, with consequent impairment of daytime functioning. Previous epidemiologic studies have estimated the prevalence of insomnia as approximately 20% of general population in industrialized countries [1–3]. Insomnia also is known to be highly associated with increased risk for depression [4–8] and physical diseases such as cardiovascular disease [9,10] and type 2 diabetes mellitus [11,12], possibly engendering deterioration of health-related quality of life [13–16]. Therefore, it is desirable to identify vulnerability to development of the disorder.

The Ford Insomnia Response to Stress Test (FIRST), a self-administered questionnaire that assesses stress-induced sleep reactivity, provides an indicator of vulnerability to the development of insomnia [17]. The questionnaire includes nine items relevant to situational sleep-disturbing stimuli with a 4-point Likert scale (1, not likely; 4, very likely) [18]. Its total score ranges from 9 to 36. A higher score indicates a higher level of sleep reactivity to the stimuli. The nine items in the original English version of the FIRST were determined based on a consensus agreement of four experts in the field of insomnia research and results of factor analysis of the general population [18]. The questionnaire reportedly has a single-factor structure. Individuals with a higher score on the original version of the FIRST (>20, median score in general population sample) have lower sleep efficiency, longer sleep-onset latency (SOL), and increased percentage of stage 1 sleep on nocturnal polysomnogram (n-PSG) [18]. The reliability of the original version of the FIRST was confirmed by study results showing a Cronbach α coefficient of 0.83 and a test–retest reliability coefficient (r) of 0.92 [18].

Individuals with a higher FIRST score showed a greater number of awakenings on sleep logs and longer SOL on multiple sleep

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latency test [18]. Furthermore, Drake et al. [19] reported that individuals with high FIRST scores (>18, median score of the FIRST of the participants of the study) were likely to show longer SOL on n-PSG after ingestion of caffeine than those with low FIRST scores. Recently, the FIRST has been regarded as having an important genetic and environmental basis [20]. In addition, high FIRST scoring individuals reportedly showed a greater number of arousals and stage transitions and a decreased proportion of rapid eye movement sleep on n-PSG than those with low FIRST scoring individuals under high stress conditions [21].

The results presented above imply that the FIRST can predict the future development of insomnia caused by sleep reactivity related to hyperarousal. Trait anxiety is an important predisposing factor for the development of insomnia [22–26], which implies that trait anxiety contributes to increased sleep reactivity to situational sleep-disrupting stimuli. No validated measure other than the FIRST is available to assess the vulnerability to insomnia caused by stress-induced hyperarousal. Jefferson et al. [27] reported that insomnia patients had a higher FIRST score than healthy participants. However, no report in the relevant literature has confirmed if the FIRST is related to subjective severity of insomnia. Moreover, no Japanese version of the FIRST has been established to date.

The aims of our study were to validate the Japanese version of the FIRST (FIRST-J), to ascertain the association between sleep reactivity and trait anxiety, and to clarify the relation between subjective severity of insomnia and sleep reactivity manifested on the FIRST-J.

2. Methods

2.1. Participants and settings

The Regional Ethical Review Board of the Neuropsychiatric Research Institute in Japan approved our study protocol. After explaining the purpose and the method of our study to all participants, the participants provided written informed consent. Thereafter, the participants were asked to respond to the research questionnaires. Eligible participants were 513 consecutive patients who visited the outpatient clinic of the Japan Somnology Center seeking treatment for insomnia from October 2008 to February 2011 and 310 healthy participants engaged in regular daytime work (Fig. 1).

Patients with insomnia diagnosed by at least two sleep disorders specialist psychiatrists were enrolled in our study if they were age 20 years or older and met criteria for the diagnosis of psychophysiologic insomnia according to the second edition of the [28]. Patients were excluded from our study if they were diagnosed as having sleep disorders other than insomnia or as having insomnia secondary to psychiatric disorders or somatic disorders; they also were excluded if they engaged in shift work or if they habitually ingested alcohol at bedtime. Sleep logs were observed for all the insomnia participants to exclude circadian rhythm sleep disorders. Twenty-six participants (5%) with other suspected sleep disorders (sleep apnea syndrome or periodic limb movement disorder) underwent n-PSGs for differential diagnosis. In all, 231 insomnia patients (129 women [45.0%]; mean age [standard deviation {SD}], 47.9 years [16.2 years]) met all of the criteria; however, 54 patients were excluded as they did not meet the following criteria: 30 min or longer subjective period of wake after sleep onset or SOL, with frequency of three times or more per week based on quantitative criteria for insomnia [29]; or failure to complete the FIRST-J questionnaire. Consequently 177 insomnia patients (101 women [57.1%]; mean age [SD], 46.8 years [15.8 years] proceeded to subsequent analyses.

From employees of three capital sphere-based companies, 310 healthy participants were recruited. Among them, 205 healthy participants answered the questionnaires (72 women [35.1%]; mean age [SD], 50.8 years [10.1 years]). Inclusion criteria of the healthy participants were less than 30 min of wake after sleep onset or SOL in usual nocturnal sleep [29]. The exclusion criteria were the following: (1) previously or currently diagnosed as having a sleep disorder or psychiatric disease, (2) habitually used hypnotics or bedtime alcohol, (3) engaged in shift work, and (4) failed to complete the FIRST-J questionnaire. Consequently 161 healthy participants (53 women [33.1%]; mean age [SD], 51.5 years [9.5 years]) proceeded to subsequent analyses.

2.2. Procedure and measures

The research questionnaires consisted of the FIRST-J, items related to demographic information, questionnaires assessing subjective severity of insomnia (the Pittsburgh Sleep Quality Index [PSQI] [30,31], the Athens Insomnia Scale [AIS] [32,33]) and a questionnaire to assess trait anxiety (State-Trait Anxiety Inventory [STAI]) [34,35]. Details of these questionnaires are described below.

2.2.1. The FIRST-J

The FIRST is a self-rating score measuring the likelihood of the occurrence of sleep disturbances in response to commonly experienced stressful situations [18]. The questionnaire consists of nine items with evaluation according to a 4-point Likert scale (1, not likely; 4, very likely). Therefore, the total score of the FIRST ranges from 9 to 36. The authors developed the FIRST-J after obtaining permission from the last author of the original version of the FIRST. The original version of the FIRST was translated into Japanese and then back-translated into English. Subsequently, the consistency of the back-translated FIRST-J with the original version was confirmed by the last author of the original version.

2.2.2. The PSQI

The PSQI is a measure to assess subjective sleep disturbance [30,31]. This well-validated questionnaire comprises 19 self-rated items with a 4-point Likert scale (0–3) assessing subjective sleep disturbance during a recent 1-month period. The total score of the PSQI ranges from 0 to 21.

2.2.3. The AIS

The AIS was developed as a measure to assess insomnia severity during a previous 1-month period based on the criteria of the ICD, 10th edition [32,33]. The questionnaire comprises eight items evaluated according to a 4-point Likert scale (0, no problem at all; 3, very severe problem). Therefore, the total score of the AIS is ranges from 0 to 24. The first five items of the AIS correspond to sleep conditions. The last three items cover the next-day consequences of insomnia.

2.2.4. The STAI

The STAI assesses state (actual) and trait (stable) anxiety with 20 questionnaire items, respectively, rated with a 4-point intensity scale (1, almost never; 4, almost always). The total score of the STAI ranges from 20 to 80 [34,35]. Trait anxiety can be regarded as a predisposing factor for insomnia [3,26]; therefore, the items for trait anxiety were used for our study.

2.3. Data analysis

According to the validation process of the original version of the FIRST [18], the following analyses were performed using data of healthy participants. Cronbach α coefficients were calculated to

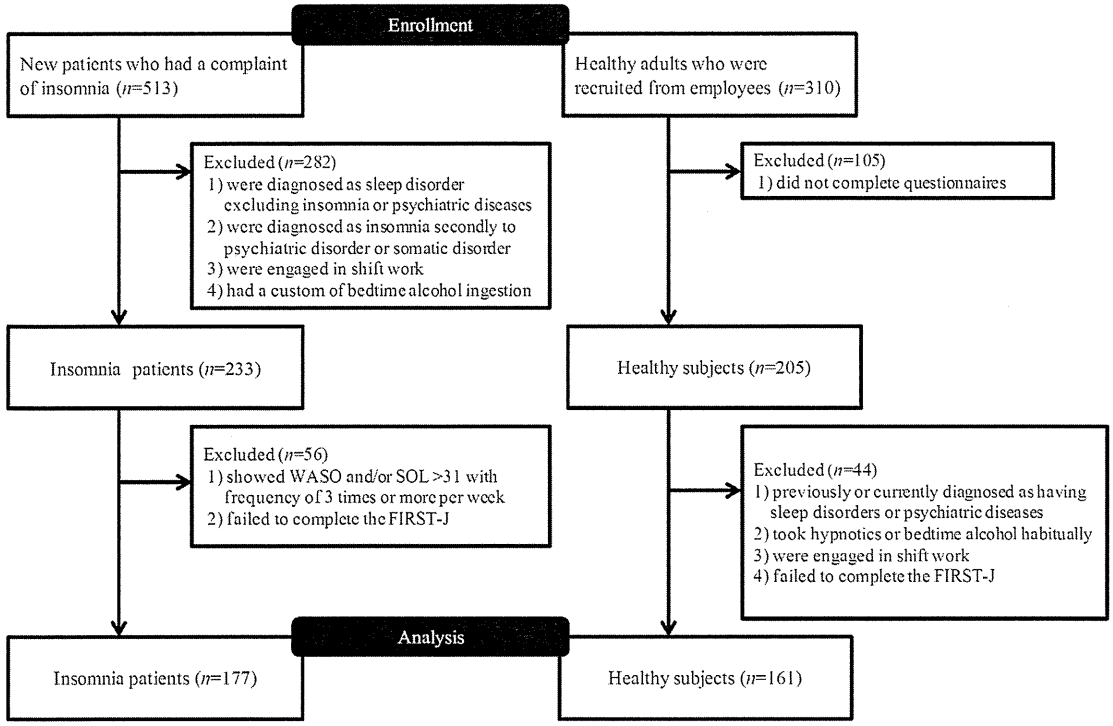

Fig. 1. Participant flow diagram. *Abbreviations:* WASO, wake after sleep onset; SOL, sleep-onset latency; FIRST-J, the Japanese version of the Ford Insomnia Response to Stress Test.

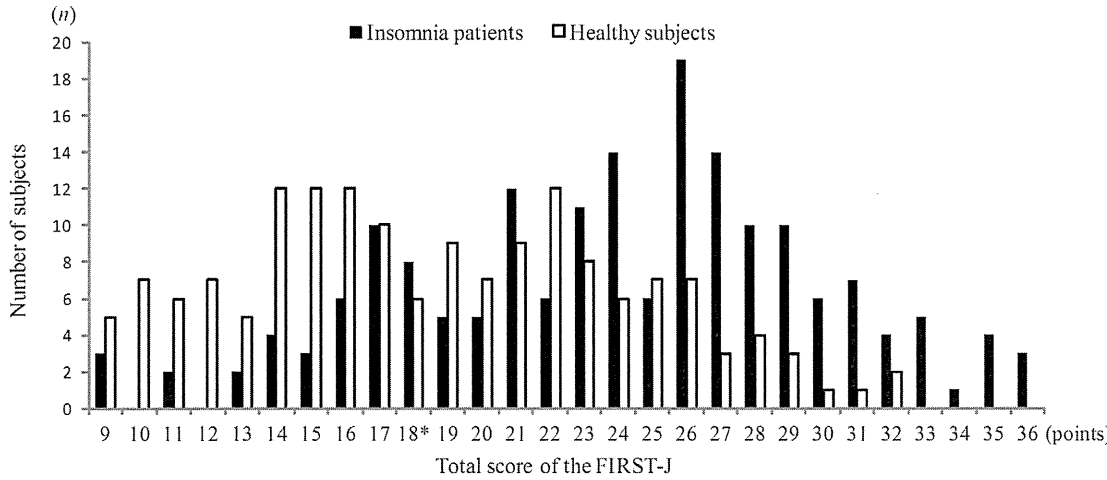

Fig. 2. Distribution of total score of the Japanese version of the Ford Insomnia Response to Stress Test for insomnia patients and healthy subjects. The score of the Japanese version of the Ford Insomnia Response to Stress Test was significantly higher in the insomnia patients than in the healthy subjects ($P < .01$). *Median value in the healthy subjects.

test the internal consistency of the FIRST-J. An exploratory factor analysis using the maximum likelihood method with promax rotation was conducted on the FIRST-J to investigate factorial validity. Before conducting factor analysis, sampling adequacy was verified using the Bartlett spherical test and the Kaiser–Meyer–Olkin measure of sampling adequacy in the groups of insomnia and healthy participants. The Bartlett spherical test is expected to exhibit the propriety of using factor analysis. The Kaiser–Meyer–Olkin values are expected to be greater than 0.70 for making a correlation matrix suitable for factor analysis [36]. Factor loading for the item-inclusion criterion was set at 0.40 according to an earlier study [18]. Severity of insomnia, as evaluated with the PSQI and AIS, was compared among healthy participants and insomnia patients. The measures also were compared among participants with high FIRST-J scores and those with low FIRST-J scores in the respective healthy participants and insomnia patients to test discriminant validity using tests. Because most studies of the FIRST have used the median score of the FIRST in healthy participants to define high and low FIRST groups [18], our also study adopted this standard method.

Additionally, correlation coefficients were calculated among the scores of the FIRST-J, STAI, PSQI, and AIS before and after

controlling for age and gender to identify the association of sleep reactivity with trait anxiety and with severity of insomnia symptoms. Furthermore, the FIRST-J scores of the insomnia patients were compared with those of the healthy participants using tests. Moreover, the quantities of individuals with and without insomnia were compared between the participants with high and low FIRST-J scores in all study populations using χ^2 tests.

In the process explained above, sample sizes differed among respective analyses due to missing data. Data were analyzed using SPSS software version 11.0J (SPSS Inc.), with the significance level set at a 2-tailed α level of 5%. For differences between the two groups, effect sizes were calculated as Cohen [37]. For χ^2 tests, $\varphi(=W)$ was used for estimating the effect size [38]. To clarify the statistical power of the studied samples, post hoc power analyses were performed using G*power 3 [39] on measures representing the difference between the groups: the total score of PSQI for comparison between the groups with insomnia and healthy participants and the FIRST-J score for comparison between the groups with high and low FIRST-J scores.

3. Results

3.1. Reliability (internal consistency)

The internal consistency of the FIRST-J in the insomnia patients and the healthy participants was evaluated using Cronbach α coefficients. Results show that Cronbach α (range of item-deletion α) was 0.89 (0.86–0.88) for the insomnia patients and 0.87 (0.83–0.86) for the healthy participants.

3.2. Factorial validity

From sampling adequacy testing, sphericity in the Bartlett test was significant for the insomnia patients and healthy participants (P<.01). Kaiser–Meyer–Olkin values for the insomnia patients and healthy participants were 0.85 and 0.86, respectively (P<.01). Judging from these results, the following factor analysis was confirmed as appropriate.

The scree plot of the exploratory factor analysis of the healthy participants revealed that the factor structure can be determined as one. After confirming this, exploratory factor analysis was performed with a fixed single factor. The analysis revealed that the FIRST-J has a single-factor structure in which all items showed factor loadings higher than 0.40, except for item 9. A similar result of factor loadings also was observed for insomnia patients. Table 1 presents factor loadings of each item of the FIRST-J for both healthy participants and insomnia patients in our study, referring to the results of the study with the original version of the FIRST on general population [18]. Except for item 9, the factor loadings of each FIRST-J item closely resembled those of the original version. However, we retained item 9 for mutual comparison of the total scores of the original FIRST and our FIRST-J version.

3.3. Discriminant validity

The scores of the FIRST-J and PSQI and AIS were significantly higher in the insomnia patients than in the healthy participants (FIRST-J: $t_{[336]} = 8.35$ [$P < .01$]; PSQI: $t_{[314]} = 30.24$ [$P < .01$]; and AIS: $t_{[335]} = 26.85$ [$P < .01$]). Post hoc power analysis for 2-tailed tests between the insomnia group and the healthy group ($d = 3.42$ [PSQI score], sample size in the healthy adults [score, 161], and sample size in the insomnia group [score, 177]; $\alpha = 0.05$) showed a sufficient power for comparison (1.00). Furthermore, a χ^2 test revealed that the proportion of the insomnia patients was higher in the participants with high FIRST-J scores than in those with low FIRST-J scores ($\chi^2_{[1338]} = 19.81$; $P < .01$; $\varphi = -0.24$ [95% confidence interval {CI}, −0.14 to −0.34]).

The median value of the total score of the FIRST-J in the healthy participants was 18 (Fig. 2). The healthy participants with high FIRST-J scores (FIRST-J score >18) comprised 41 men (51.9%) and 38 women (48.1%), with a mean (SD) age of 49.7 (10.2) years. The healthy participants with low FIRST-J scores (FIRST-J score ⩽18) comprised 67 men (81.7%) and 15 women (18.3%) with mean age of 53.2 (8.4) years. The insomnia patients with a high FIRST-J score (FIRST-J score >18) comprised 57 men (40.7%) and 83 women (59.3%) with mean (SD) age of 47.0 (15.5) years. The insomnia patients with low FIRST-J scores (FIRST-J score ⩽18) comprised 19 men (51.4%) and 18 women (48.6%) with a mean (SD) age of 46.1 (16.8) years. Table 2 presents scores of each measure for all participants with low and high FIRST-J scores.

Comparison of the scores of measures between the healthy participants with low FIRST-J scores and those with high FIRST-J scores revealed that all the scores were significantly higher in the latter group than in the former group (PSQI: $t_{[149]} = -2.12$ [$P = .04$]; AIS: $t_{[159]} = -3.16$ [$P < .01$]; and STAI: $t_{[153]} = -4.23$). Post hoc power analysis for 2-tailed tests between the high-scoring FIRST-J group and the low-scoring FIRST-J group ($d = 3.20$ [FIRST score], sample size in the high-FIRST-J group [score, 79], sample size in the low-FIRST-J group [score, 82], $\alpha = 0.05$) showed sufficient power for comparison (1.00). The healthy participants with high FIRST-J scores were younger and showed a higher proportion of women than those with low FIRST-J scores (age, $t_{[159]} = -19.98$ [$P < .01$]; gender, $\chi^2_{[1161]} = 16.19$ [$P < .01$]).

In the insomnia patients, significant difference was only found in the STAI between the high-scoring FIRST-J group and the low-scoring FIRST-J group ($t_{[129]} = -2.96$ [$P < .01$]). Post hoc power analysis for the 2-tailed test between the high-scoring FIRST-J group and the low-scoring FIRST-J group ($d = 2.78$ [FIRST score], sample size in the high-scoring FIRST-J group [score, 129], sample size in group with low-scoring FIRST-J group [score, 36]; $\alpha = 0.05$) showed sufficient power for comparison (1.00).

3.4. Association of the FIRST-J with the STAI, PSQI and AIS

Table 3 presents correlation coefficients among the scores of the FIRST-J, STAI, PSQI, and AIS in the insomnia patients and healthy participants. In the healthy participants, the FIRST-J score showed significant but weak positive correlations with the scores of all other measures ($P < .01$). However, the FIRST-J correlated neither with the PSQI nor with the AIS in the insomnia patients, it but showed moderate correlation with the STAI ($P < .01$). Additionally, we conducted partial correlation analysis after controlling for age and gender. Consequently, the correlation coefficients between the FIRST-J and each of the PSQI (i.e., the AIS and the STAI) were similar to those before controlling for these factors either in the insomnia patients or in the healthy participants.

To clarify the effect of item 9 on the relation between the FIRST-J and the PSQI, AIS, or STAI, correlation analyses were conducted again using the total score of the FIRST-J after excluding the score of item 9. The result showed that correlation coefficients between the FIRST-J without item 9 and the other three measures were similar to those between the FIRST-J with the score of item 9 and the others.

4. Discussion

The main purposes of our study were to investigate the validity of the FIRST-J and to clarify the association of FIRST-J with trait anxiety and severity of insomnia symptoms in the insomnia patients and healthy participants. Consistent with the results of the