

# Pilot Validation Study of the Japanese Translation of the Brief Negative Symptoms Scale (BNSS)

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**Purpose:** The brief negative symptoms scale (BNSS) is a concise instrument used to assess negative symptoms of subjects with schizophrenia covering five domains of negative symptoms and is suitable for use in clinical, experimental, and epidemiological settings. The original and translated version of BNSS has thus far been shown to have adequate psychometric properties. This study aimed to examine internal consistency, inter-rater and test-retest reliability, discriminant and convergent validity, and factor structure of the Japanese version of BNSS.

**Patients and methods:** The assessment was performed by 11 raters using interview videos of nine subjects. Reliability was calculated with Cronbach's alpha for internal consistency and intra class correlation coefficient (ICC) for inter-rater reliability. Pearson's correlation coefficients were calculated to estimate the test-retest reliability. In addition to BNSS, Scale for assessment of negative symptoms (SANS) and scale for assessment of positive symptoms (SAPS) was obtained to assess the convergent and discriminant validity. Factor structure was assessed using principle factor analysis.

**Results:** The Japanese BNSS showed excellent internal consistency (Cronbach's alpha=0.95), inter-rater reliability (intra class correlation coefficient=0.97), and test-retest reliability ( $r=0.94$ ,  $p<0.001$ ). The convergent validity shown by correlation with SANS total score ( $r=0.87$ ,  $p<0.001$ ) and discriminant validity shown by correlation with SAPS total score ( $r=0.17$ ,  $p=-0.68$ ) were also good. Principal factor analysis revealed a two-factor structure of BNSS, although the loading of each item differed from that in the literature.

**Conclusion:** Our pilot study demonstrated that Japanese BNSS had good psychometric properties which were achieved with relatively brief training. Further studies with more subjects and raters with various backgrounds recruited from multiple sites are warranted.

**Keywords:** negative symptom, schizophrenia, scale, factor structure

## Introduction

Negative symptoms of schizophrenia are the core symptoms of this disease, underscored by "emotional dullness" and "weakening of volitional impulse" as reported by Kraepelin in 1919.<sup>1</sup> The concept of negative symptoms was developed in the 1970s to 1980s, whereby patients who exhibited severe negative symptoms were reported to have poor function,<sup>2-4</sup> although there has been considerable debate as to which aspects of psychopathology should be included in negative symptoms.

According to a consensus statement of the National Institute of Mental Health (NIMH), negative symptoms comprise five domains, such as blunted affect, alogia, asociality, anhedonia, and avolition.<sup>5</sup> The need for a new instrument which includes these five domains has been raised. Two gold standard scales for negative

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symptoms, the Scale for Assessment of Negative Symptoms (SANS)<sup>6</sup> and Positive and Negative Symptom Scale (PANSS)<sup>7</sup> exist. SANS is considered superior to PANSS because it contains multiple domains regarding negative symptoms and multiple items for each domain.<sup>8</sup> However, SANS has several weaknesses as follows: 1) several items such as attentional impairment were inappropriate for a negative symptom scale; 2) it does not distinguish anticipatory and consummatory aspects of anhedonia; and 3) assessments are only made from behavioral aspects, and subjective experiences or desires are ignored.<sup>5,8,9</sup>

After the NIMH Consensus about negative symptoms, two new instruments considering these issues were developed: Clinical Assessment Interview for Negative Symptoms (CAINS)<sup>10</sup> and the Brief Negative Symptom Scale (BNSS).<sup>11</sup> These two instrument was created with distinct characteristics to full fill the diverse need in the field. CAINS was developed to create empirically based psychometric scale whereas the BNSS was developed pursuing the rapid dissemination of a shorter measure.<sup>12</sup> CAINS, as well as BNSS mentioned below, is well validated<sup>13</sup> and translated in many languages,<sup>14</sup> and used in clinical researches.<sup>15,16</sup>

The BNSS was designed to fulfil seven principles: 1) conciseness, 2) coverage of five domains, 3) reliable assessment across cultures, 4) suitable for use in clinical, experimental, and epidemiological settings, 5) assessing anticipatory and consummatory aspects of anhedonia differently, 6) assessing internal experience and behavior differently, 7) exclusion of items which do not reflect core aspects of negative symptoms.<sup>5,17</sup> Validation studies of BNSS demonstrated strong inter-rater reliability, internal consistency, stability, and convergent/discriminant validity.<sup>11,17</sup> These validation studies also demonstrated that the BNSS has a two-factor structure reflecting Emotional Expressivity, and Motivation and Pleasure domains.<sup>11,18</sup> It has also demonstrated good sensitivity to treatment effects,<sup>19</sup> high cross-cultural validity,<sup>20</sup> utility for patients with clinically high risk of psychosis,<sup>21</sup> and utility in experimental settings.<sup>22,23</sup> To date, the BNSS has been translated and validated in many languages.<sup>9,24–30</sup> Collectively, these studies provide evidence of adequate psychometric properties and a two-factor structure of BNSS in these languages.

In the current study, we aimed to explore the inter-rater reliability, convergent/discriminant validity, and factor structure of the Japanese version of BNSS. We

hypothesized that the Japanese version of BNSS would exhibit good psychometric properties and have a two-factor structure as per BNSS in other languages.

## Methods

### Participants

The Hokkaido University Hospital Ethics Committee approved all study procedures (017–0008). The study was conducted in accordance with the tenets of the Declaration of Helsinki. Before beginning the study, all participants received a description of the study and provided written informed consent.

Ten subjects (six male, four female) who met the DSM-5 diagnostic criteria for schizophrenia were recruited from Hokkaido University Hospital. The diagnosis was made by treating psychiatrists with 5 or more years of clinical experience. We excluded patients who had a history of head injury, seizure disorders, dementia, diabetes mellitus, or other severe physical disease. None of the patients had a history of substance misuse, including alcohol abuse. We also excluded currently suicidal patients.

The demographic background of 10 subjects is shown in Table 1. The subjects had an average age (SD) of 37.9 (9.7) years, 15.9 (9.6) years of duration of disease, and were prescribed 824.5 (439.1) mg of chlorpromazine equivalent antipsychotics. Seven subjects were outpatients, and three were inpatients.

### Instruments

#### BNSS

The BNSS contains a manual, score sheet, and workbook.<sup>11</sup> It comprises 13 items, organized into six subscales (anhedonia, distress, asociality, avolition, blunted affect, and alogia). The manual defines the terms used in the scale, provides anchors for each item, and gives instructions for a semi-structured interview including suggested questions. The workbook extracts the suggested questions and anchors and is designed for the rater's reference during administration.

All 13 items have possible scores ranging from 0 to 6. Higher scores are associated with greater impairment of symptoms. A scale total score is calculated by summing the 13 individual items. Subscale scores are obtained by summing the items within each subscale. The distress subscale has only one item, which quantifies the absence of distress, but is otherwise treated similar to other

**Table 1** Demographic Characteristics of Subjects

	Age (Years)	Sex	Duration of Disease (Years)	Inpatient/Outpatient	Daily Dose of Antipsychotics <sup>a</sup>
Case 1	33	M	8	Outpatient	1200
Case 2	47	M	30	Inpatient	1200
Case 3	36	F	12	Outpatient	1255
Case 4	41	M	18	Inpatient	1230
Case 5	22	F	9	Outpatient	160
Case 6	44	M	24	Outpatient	1000
Case 7	24	M	2	Outpatient	600
Case 8	44	F	10	Outpatient	300
Case 9	36	F	13	Outpatient	1000
Case 10	52	M	30	Inpatient	300
	37.9 (9.7) <sup>b</sup>	M:F=6:4	15.6 (9.6) <sup>b</sup>	In:Out=3:7	824.5 (439.1) <sup>b</sup>

**Notes:** <sup>a</sup>Chlorpromazine equivalent (mg), <sup>b</sup>Mean (standard deviation), Case 1 was used for rater training, and cases 2 to 10 were used for validation analysis.

subscales. The BNSS has possible total scores ranging from 0 to 78.

The Japanese version of the BNSS was developed using the translation/back-translation method. The manual, workbook, and score sheet were translated into Japanese by five psychiatrists (NH, OM, OR, HN, and KI). Then, the Japanese version BNSS was back-translated into Japanese by a translation company. The back-translated version was reviewed and approved by one of the original developers of the scale (Prof. Brian Kirkpatrick).

#### Scale for Assessment of Negative Symptoms (SANS) and Scale for Assessment of Positive Symptoms (SAPS)

The SANS provides a comprehensive assessment of negative symptoms of schizophrenia; it contains 24 items that are summarized in global ratings such as flattened affect, alogia, avolition apathy, anhedonia/asociality, and attention.<sup>6</sup> Conversely, the SAPS is used to assess positive symptoms of schizophrenia; it contains 35 items that are summarized in four global ratings such as hallucinations, delusions, bizarre behavior, and positive formal thought disorder.<sup>31</sup> Both scales are rated from 0 (absent) to 5 (severe). In Japan, SANS had already been translated and validated in 1984.<sup>32</sup> We, therefore, adopted these scales as standards of symptom assessment in this study.

#### Procedure

Ten patients were interviewed by a psychiatrist (NH) or postdoctoral fellow (AM) who had more than 10 years of experience in clinical interviews. We administered SANS,

SAPS, and BNSS in that order. These interviews were videotaped for subsequent rating. After 1 week, BNSS was administered and videotaped again to examine the test-retest reliability. The second set of data from each subject was used for the assessment of inter-rater reliability and test-retest reliability.

Prior to conducting the ratings, the raters participated in a 3 hr training workshop on the instrument that focused on inter-rater reliability. In the workshop, author NH explained to the raters how to use the instruments and assess each item by assessing the videotaped interview of one patient. After rater training, the 18 remaining videotaped interviews (2 × 9 patients) were rated independently by nine psychiatrists and one postdoctoral fellow, all of whom had more than 5 years of experience in conducting patient symptom interviews in clinical or research settings.

#### Statistical Analyses

Reliability was calculated with Cronbach's alpha for internal consistency and intra class correlation coefficient (ICC) for inter-rater reliability. Pearson's correlation coefficient was calculated to estimate the test-retest reliability of BNSS scores measured during two interviews separated by 1 week. To calculate correlations for convergent and discriminant validity, Pearson's correlation coefficient was computed. Convergent validity of BNSS was evaluated by examining the association with SANS. Discriminant validity of BNSS was evaluated by examining the association with SAPS.

For exploratory factor analysis, the factors were extracted by principle axis factoring, and promax oblique rotation was performed to take into account the possible

correlations among factors.<sup>9,18</sup> The optimal number of factors was determined via eigenvalue > 1.0 and screen plot criteria. Items with high loading (>0.40) were used to interpret factors.<sup>18</sup>

All analyses were conducted using the psych package 1.8.12. (<https://CRAN.R-project.org/package=psych>) running on R statistics 3.1.2 (<https://www.r-project.org>).

## Results

### Descriptive Statistics, Distributions of Score, and Internal Consistency

Descriptive statistics of the BNSS items and subscale are displayed in Table 2. For all BNSS items, the scores were evenly distributed among the patients, with no skewness higher than 1.

The internal consistency of BNSS was analyzed by Cronbach's alpha. The alpha value for the 13 items of

the BNSS was 0.95, indicating that the items measured a single latent construct of negative symptoms. The alpha coefficients ranged from 0.95 to 0.96 when each item was omitted individually, suggesting no benefit from excluding any individual item.

### Inter-Rater Reliability and Test-Retest Reliability

For inter-rater reliability, ICCs were calculated for the BNSS total score and each subscale. The ICC was higher than 0.8 for each item and subscale and 0.97 for the BNSS as a whole, which indicated excellent reliability (Table 3).

Pearson's correlation coefficients were calculated to estimate the test-retest reliability of the BNSS scores measured during two interviews separated by 1 week. The BNSS total score had high temporal stability with  $r=0.94$  ( $p<0.001$ ) for each subscale ranging from avolition

**Table 2** Descriptive Statistics and Cronbach's Alpha

	Mean	SD	Skew	Kurtosis	Cronbach Alpha if Item Deleted
I. Anhedonia					
1. Intensity of pleasure during activities	2.70	1.65	0.34	-1.09	0.95
2. Frequency of pleasurable activities	2.70	1.59	0.29	-0.90	0.95
3. Intensity of future pleasure	2.57	1.69	0.38	-1.00	0.95
Total subscale	7.96	4.78	0.36	-0.95	
II. Distress					
4. Lack of normal distress	2.28	1.35	0.18	-1.23	0.95
Total subscale	2.28	1.35	0.18	-1.23	
III. Asociality subscale					
5. Asociality:behavior	3.22	1.28	-0.18	-0.64	0.95
6. Asociality:inner-experience	3.14	1.55	-0.15	-1.24	0.96
Total subscale	6.36	2.53	-0.37	-0.82	
IV. Avolition subscale					
7. Avolition: behavior	2.17	1.16	0.33	-0.50	0.95
8. Avolition: inner-experience	2.43	1.30	0.05	-1.07	0.95
Total subscale	4.61	2.33	0.03	-1.04	
V. Blunted affect subscale					
9. Facial expression	2.74	1.42	0.34	-1.07	0.95
10. Vocal expression	2.30	1.59	0.52	-1.05	0.95
11. Expressive gesture	2.76	1.53	0.19	-1.13	0.95
Total subscale	7.80	4.23	0.38	-1.08	
VI. Alogia subscale					
12. Quantity of speech	1.70	1.19	0.99	0.47	0.95
13. Spontaneous elaboration	2.17	1.54	0.71	-0.72	0.95
Total subscale	3.87	2.53	0.79	-0.35	0.95
Total	32.88	15.18	0.20	-0.92	0.95

**Abbreviation:** SD, standard deviation.

**Table 3** Inter-Rater and Test-Retest Reliability

	Inter-Rater Reliability		Test-Retest Reliability	
	ICC <sup>a</sup>	p	r <sup>b</sup>	p
I. Anhedonia				
1.Intensity of pleasure during activities	0.97	<0.001	0.85	<0.001
2.Frequency of pleasurable activities	0.97	<0.001	0.77	<0.001
3.Intensity of future pleasure	0.98	<0.001	0.86	<0.001
Total subscale	0.98	<0.001	0.86	<0.001
II. Distress				
4. Lack of normal distress	0.96	<0.001	0.80	<0.001
Total subscale	0.96	<0.001	0.80	<0.001
III. Asociality subscale				
5. Asociality: behavior	0.96	<0.001	0.80	<0.001
6. Asociality: inner-experience	0.98	<0.001	0.75	<0.001
Total subscale	0.98	<0.001	0.81	<0.001
IV. Avolition subscale				
7. Avolition: behavior	0.96	<0.001	0.73	<0.001
8. Avolition: inner-experience	0.96	<0.001	0.78	<0.001
Total subscale	0.96	<0.001	0.79	<0.001
V. Blunted affect subscale				
9. Facial expression	0.96	<0.001	0.90	<0.001
10. Vocal expression	0.95	<0.001	0.91	<0.001
11. Expressive gesture	0.96	<0.001	0.90	<0.001
Total subscale	0.97	<0.001	0.94	<0.001
VI. Alogia subscale				
12. Quantity of speech	0.94	<0.001	0.82	<0.001
13. Spontaneous elaboration	0.90	<0.001	0.85	<0.001
Total subscale	0.93	<0.001	0.87	<0.001
Total	0.97	<0.001	0.94	<0.001

Notes: <sup>a</sup>ICC: Intra class correlation coefficient, <sup>b</sup>r: Pearson's correlation coefficient.

( $r=0.79$ ,  $p<0.001$ ) to blunted affect ( $r=0.94$ ,  $p<0.001$ ) and for each item.

## Convergent and Discriminant Validity

Comparison of the correlations among the BNSS total/subscale scores, SANS total/subscale scores, and SAPS total score was performed to assess convergent and discriminant validity (Table 4). The BNSS total score was highly correlated with SANS total score, as well as the score of each subscale of BNSS. The correlation between SANS Attention subscale and BNSS subscales were generally low. The correlations between SANS Attention and BNSS Asociality or Alogia subscales were not significant. The BNSS total score was not correlated with the SAPS

total score. For the score of each subscale, correlation coefficients ranged from  $r=0.35$  for Avolition ( $p<0.001$ ) to  $r<0.01$  for Blunted Affect ( $p=0.85$ ). As a whole, the BNSS total score and score of each subscale showed good convergent and discriminant validity.

## Factor Structure

Principle axis factoring of the BNSS scores extracted two factors after three iterations, explaining 66.6% of the variance in the whole sample. As shown in Table 5, the first factor was interpreted as “Emotion Expressivity and Asociality,” consisting of items in Asociality, Blunted Affect, and Alogia. Conversely, the second factor was interpreted as “Avolition,” consisting of items in Anhedonia and Avolition.

## Discussion

The present study examined the internal consistency, inter-rater reliability, test-retest reliability, convergent and discriminant validity, and factor structure of the Japanese version of BNSS. Overall, the BNSS showed good psychometric properties, which mostly replicated the results of validation studies in the original and several other language versions of BNSS.<sup>9,11,17,24–30</sup>

The total BNSS score in this study was slightly higher than those of previously reported.<sup>11,17,26</sup> This may be because three of ten of our subjects were inpatients who were stable but had more severe negative symptoms than did outpatient subjects. Both the inter-rater reliability and test-retest reliability were high, indicating excellent agreement between researchers even after a brief training. This suggested that this instrument is adequate for clinical use. However, it should be noted that several factors in this study, which included assessments using videotaped interviews and relatively uniform rater backgrounds, may render these psychometric properties higher to an extent. Convergent validity shown by a strong correlation with SANS and discriminant validity shown by no correlation with SAPS were also concordant with previous studies,<sup>9,11,17,24,26</sup> which confirms the assumption of a common and established construct for negative symptoms. Each subscale of BNSS showed high correlation with its corresponding subscale of SANS (BNSS Anhedonia, BNSS Asociality, and SANS Asociality/Anhedonia; BNSS Avolition and SANS Avolition, BNSS Blunted Affect, and SANS Blunted Affect; BNSS Alogia and SANS Alogia). The convergent validity of each subscale of BNSS was also validated. The correlation between

**Table 4** Convergent and Discriminant Validity of BNSS

BNSS	SANS Total		SANS Avolition/Apathy		SANS Asociality/Anhedonia		SANS Blunted Affect		SANS Alogia		SANS Attention		SAPS Total	
	R <sup>a</sup>	p	R <sup>a</sup>	p	R <sup>a</sup>	p	R <sup>a</sup>	p	R <sup>a</sup>	p	R <sup>a</sup>	p	R <sup>a</sup>	p
Total	0.87	<0.001	0.80	<0.001	0.72	<0.001	0.83	<0.001	0.74	<0.001	0.46	<0.001	0.17	0.678
Anhedonia	0.80	<0.001	0.75	<0.001	0.74	<0.001	0.67	<0.001	0.67	<0.001	0.49	<0.001	0.29	0.004
Distress	0.76	<0.001	0.70	<0.001	0.54	<0.001	0.73	<0.001	0.62	<0.001	0.47	<0.001	0.20	0.053
Asociality	0.66	<0.001	0.69	<0.001	0.59	<0.001	0.62	<0.001	0.52	<0.001	0.23	0.101	0.15	0.159
Avolition	0.77	<0.001	0.83	<0.001	0.76	<0.001	0.58	<0.001	0.61	<0.001	0.47	<0.001	0.35	<0.001
Blunted Affect	0.79	<0.001	0.64	<0.001	0.55	<0.001	0.85	<0.001	0.68	<0.001	0.38	0.002	<0.01	0.851
Alogia	0.65	<0.001	0.51	<0.001	0.41	0.001	0.73	<0.001	0.64	<0.001	0.25	0.101	<0.01	0.281

Note: <sup>a</sup>Pearson's correlation coefficient.

Abbreviations: BNSS, brief negative symptoms scale; SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms.

**Table 5** Factor Analysis

		Factors	
		1	2
<b>I. Anhedonia</b>			
	1.Intensity of pleasure during activities	-0.05	<b>0.99</b>
	2.Frequency of pleasurable activities	0.02	<b>0.92</b>
	3.Intensity of future pleasure	-0.12	<b>1.00</b>
<b>II. Distress</b>			
	4. Lack of normal distress	<b>0.60</b>	0.25
<b>III. Asociality subscale</b>			
	5. Asociality: behavior	<b>0.54</b>	0.33
	6. Asociality: inner-experience	<b>0.63</b>	-0.04
<b>IV. Avolition subscale</b>			
	7. Avolition: behavior	0.07	<b>0.75</b>
	8. Avolition: inner-experience	0.14	<b>0.73</b>
<b>V. Blunted affect subscale</b>			
	9. Facial expression	<b>0.91</b>	-0.01
	10. Vocal expression	<b>0.58</b>	0.34
	11. Expressive gesture	<b>0.96</b>	-0.04
<b>VI. Alogia subscale</b>			
	12. Quantity of speech	<b>0.87</b>	-0.09
	13. Spontaneous elaboration	<b>0.71</b>	0.06
Eigenvalue		7.97	1.21
% of variance		61.28	9.30

Note: Items loading on the factor are in bold.

SANS Attention subscale and BNSS subscales were generally low, which is probably due to the fact that attention is not a component of negative symptoms.<sup>5,8</sup>

Factor analysis revealed two-factor solutions, which were concordant with previous studies.<sup>9,18,24,26,27</sup> However, our result is unique in that items 5 and 6 in the Asociality subscale loaded to the same factor as items in Blunted Affect and Alogia subscales, and not Anhedonia and Avolition subscales. Although the items in Anhedonia, Avolition, and Asociality subscales loaded to the same factor in a previous factor analysis in BNSS<sup>9,18,24,26,27</sup> and CAINS,<sup>13</sup> recent studies revealed that five or more factor models fit better than two-factor models in BNSS and CAINS.<sup>28,33-35</sup> This is in line with the following idea in the original NIMH report: “The five domains may have separate neurobiological substrates and may represent separate therapeutic targets.”<sup>5</sup> Some of the neurobiological tasks exploring the biological basis specific to the each of the five domains have been adopted in clinical studies.<sup>34</sup> In a biological study using computerized tasks assessing effort-cost computations, the score of the task was associated with Anhedonia and Avolition scores, and not with Asociality scores.<sup>36</sup> These studies indicated that the two-factor model of BNSS in which the items in Avolition, Anhedonia, and Asociality subscale load on the same factor is not as robust as initially thought. Further studies with sufficient sample size are warranted to confirm the factor structure of BNSS.

A relatively uniform background of raters is a major limitation of our study. All of our raters had long clinical experiences (7–20 years); 10 out of the 11 raters were psychiatrists, and all raters belonged to the same institution. The assessment using videotaped interviews of 10 patients was another methodological limitation of our study. The small sample size restricted the generalizability of our results and raises the question of the stability of the factor structure.<sup>11</sup> The third limitation is that all the rating scales were completed by the same rater. Based on the

results of the current study, we have just launched another study, in which we are examining negative symptoms using BNSS, as well as neurocognitive impairment and social cognitive impairment and social function to explore the relationship of these factors (The Hokkaido University Hospital Ethics Committee has already approved this study (017-0098)). We are recruiting more than hundred of schizophrenia subjects in this study and raters are with various backgrounds and clinical experiences. We are expecting that this new study will reinforce the result of the current study.

## Conclusion

Our pilot study demonstrated that the Japanese version of BNSS has good inter-rater, test-retest, convergent, and discriminant reliability, which were achieved with a relatively brief training. A two-factor structure was observed similar to other versions, although the precise factor structure was not typical. Further studies with a sufficient number of subjects and raters with various backgrounds recruited from multiple sites are warranted.

## Abbreviations

BNSS, Brief negative symptoms scale; ICC, Intra class correlation coefficient; NIMH, National Institute of Mental Health; PANSS, Positive and Negative Symptom Scale; SANS, Scale for Assessment of Negative Symptoms; SAPS, Scale for Assessment of Positive Symptoms.

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## Author Contributions

NH, MO, RO, HN, and KI translated the BNSS. NH and AM implemented and recorded the interviews. NH, MO, KT, HN, KK, NU, TM, SW, YO, AM, and KI rated the patients. NH and AM analyzed the data. NH wrote the initial draft. All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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## Disclosure

Dr Naoki Hashimoto reports personal fees from Janssen Pharmaceutical, Yoshitomiyakuhin, Otsuka Pharmaceutical, Dainippon Sumitomo Pharma, Novartis Pharma, and Meiji Seika Pharma, outside the submitted work. Dr Atsushi Toyomaki reports personal fees from Otsuka Pharmaceutical, Dainippon Sumitomo Pharma and Meiji Seika Pharma, outside the submitted work. Dr Matsuhiko Oka reports grants from Novartis Research Grants, outside the submitted work. Dr Keisuke Takanobu reports personal fees from Otsuka Pharmaceutical Co., Ltd., Seiwa Shoten Publishers, Japan Medical Herb Association, and Tsumura & Co., outside the submitted work. Dr Hisashi Narita reports grants from JSPS KAKENHI Grant Numbers 18H0608108, outside the submitted work. Dr Kan Kitagawa reports personal fees from Otsuka Pharmaceutical, outside the submitted work. Dr Niki Udo reports personal fees from Japan Medi-Physics and Tanabe Mitsubishi Pharma, outside the submitted work. Dr Koki Ito reports personal fees from Janssen Pharmaceutical, Mitsubishi Tanabe Pharma, Otsuka Pharmaceutical, Dainippon Sumitomo Pharma, Meiji Seika Pharma, and Eli Lilly, outside the submitted work. Prof. Dr. Ichiro Kusumi reports grants, personal fees from Astellas, Daiichi Sankyo, Dainippon Sumitomo Pharma, Eisai, Eli Lilly, Janssen Pharmaceutical, Kyowa Hakko Kirin, Lundbeck, personal fees from Meiji Seika Pharma, Mochida Pharmaceutical, MSD, Mylan, Novartis Pharma, Ono Pharmaceutical, Otsuka Pharmaceutical, Pfizer, Shionogi, Shire, Taisho Toyama Pharmaceutical, Takeda Pharmaceutical, Tanabe Mitsubishi Pharma, Tsumura, and Yoshitomiyakuhin, outside the submitted work. The authors report no other conflicts of interest in relation to the subject of this study.

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