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ORIGINAL RESEARCH

Disease Awareness, Care-Seeking Behavior, and Symptom Burden Among Japanese Patients with Generalized Anxiety Disorder: Results from a Web-Based Questionnaire of Clinical Trial Participants

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Purpose: This study was conducted among Japanese patients with generalized anxiety disorder (GAD) who had participated in a clinical trial to investigate their level of disease awareness, past medical care-seeking behavior and diagnoses, symptoms and impact on daily life, perceptions of diagnosis and clinical assessment, and changes after trial participation. The patients' first-hand experiences related to symptoms and disease burden were collected through open-ended responses.

Patients and Methods: This was a quantitative (descriptive observational) study using a web-based questionnaire conducted from April 23 to May 25, 2025. Patients diagnosed with GAD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, and previously enrolled in Study B2411367, a clinical trial of venlafaxine, a serotonin-norepinephrine reuptake inhibitor, were eligible.

Results: Data from 98 respondents were analyzed. The most frequently reported GAD symptoms at trial entry included excessive anxiety or worry (99.0%), becoming fatigued easily (86.7%), and sleep problems (82.7%). Over half of respondents (53.1%) identified work or studying as the most affected area of daily life, describing impaired concentration, reduced efficiency, and physical strain. Regarding disease awareness, 72.4% of respondents had never heard of GAD and 71.4% attributed their anxiety to their personality. Only 11.2% had sought medical care before trial participation, with depression being the most frequent diagnosis (36.4%) and only 9.1% having been diagnosed with GAD.

Conclusion: Many patients with GAD were unaware of the disease name before trial entry and had symptoms that impacted daily life. The patients' first-hand accounts provided deeper insight into their burden. The findings highlight the unmet needs among Japanese patients with GAD who participated in a clinical trial and the situation of low public disease awareness and limited recognition in clinical settings. Efforts to increase awareness of GAD may help facilitate earlier diagnosis and broaden access to appropriate treatment.

Clinical Trial Registration: UMIN000057689.

Keywords: generalized anxiety disorder, awareness, Japan, questionnaire, patient, burden

Introduction

Generalized anxiety disorder (GAD) is characterized by chronic, excessive, uncontrollable anxiety and worry about various aspects of daily life, such as finances, family, health, and the future.[1] The disorder is often associated with nonspecific mental and physical symptoms,[1] which impair the patient's health-related quality of life (HRQoL) and daily functioning.[2,3] GAD is primarily diagnosed according to the criteria provided in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR), which specifies excessive anxiety and worry lasting ≥ 6 months, along with symptoms

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such as fatigue, difficulty concentrating, and sleep disturbance.[1,4,5] The functional impact of these symptoms is a core feature of the disorder, as reflected in diagnostic criteria that specify significant difficulties in social activities, work, or other major areas of life.[5] Previous studies have shown that individuals with GAD frequently experience reduced work productivity, impaired social functioning, and difficulties in daily life, even in the absence of overt psychiatric comorbidity.[2,6,7]

The lifetime prevalence of GAD is estimated to be 3.7% worldwide and 2.6% in Japan.[6,8] According to a patient survey conducted by the Japanese Ministry of Health, Labour and Welfare, the number of Japanese patients being treated for GAD in 2023 was estimated to be 170,000.[9] Considering that over 3,000,000 Japanese people may have GAD based on the prevalence in Japan (2.6%), the estimate provided by the Japanese Ministry of Health, Labour and Welfare suggests that only a very small percentage of Japanese patients with GAD are being diagnosed and treated for the disease.

Limited awareness of GAD is likely a factor in its under-diagnosis and low rates of care-seeking in Japan.[2,7] A recent study of patients with probable GAD in Japan showed that many patients do not recognize that their condition constitutes an illness, and when they did seek medical care, the psychiatric diagnoses they had received were depression (26.9%), panic disorder (8.8%), and social anxiety disorder (5.4%), with only 4.0% being diagnosed with GAD.[2] These data suggest limited awareness of GAD by Japanese patients and healthcare providers, which may limit opportunities for GAD patients to receive appropriate care.

Beyond awareness and diagnosis, relatively little is known about how Japanese patients with GAD perceive their symptoms, functional burden, and diagnostic experiences, particularly among patients participating in clinical trials. While symptom severity and treatment efficacy are commonly assessed in such trials, fewer studies have examined patients' perspectives regarding symptom impact on daily functioning, motivations for participating in clinical research, or perceptions of diagnostic evaluation and clinical assessment. Similarly, patient-reported changes following trial participation, including symptoms, behaviors, and satisfaction with the trial, remain underexplored.

European guidelines and a US clinical review on the management of GAD recommend psychotherapy (eg, cognitive behavioral therapy) and pharmacological treatment with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) as first-line treatment.[10,11] Venlafaxine is an SNRI approved in Japan for the treatment of depression. To evaluate its efficacy and safety as a potential treatment for GAD, a multicenter, randomized, double-blind, placebo-controlled Phase 3 study (study identifier: B2411367; hereafter "Study B2411367") of Japanese patients diagnosed with GAD according to the DSM-5 criteria was initiated in 2022. This trial was completed in 2024 after enrolling 357 Japanese patients treated at outpatient clinics.[12]

Study B2411367 demonstrated the efficacy and safety of venlafaxine, supporting its treatment potential in Japan. However, addressing the limited awareness of GAD in Japan would aid in expanding the real-world benefits of treatment. Gaining insight into how patients perceive their own symptoms, burden, and path to receiving treatment may help raise awareness among patients and healthcare providers by informing strategies to support earlier diagnosis and treatment. Furthermore, understanding patients' medical care-seeking behavior could guide the establishment of support systems to help patients seek medical care and receive appropriate diagnosis and treatment.

Thus, the present study was conducted as a quantitative assessment of Japanese patients with GAD enrolled in Study B2411367 to investigate their motivation for trial participation, awareness of GAD, medical care-seeking behavior and past diagnoses, symptoms present at trial entry and their impact on daily life, perceptions of diagnosis and assessment, changes after trial participation including their physical and mental symptoms, behavior, and challenges, and satisfaction with the clinical trial. This study has a robust scientific rationale in that it collected data directly from patients with a confirmed diagnosis of GAD based on DSM-5 criteria using a structured diagnostic interview, ensuring that the obtained insights are derived from well-characterized cases.

Materials and Methods

Study Design

This was a quantitative (descriptive observational) study using a web-based questionnaire. Participants were patients with GAD who had been enrolled through a clinical trial information website maintained by 3H Medi Solution Inc. (Seikatsu-Kojo WEB) in Study B2411367, a multicenter, randomized, double-blind, placebo-controlled study of the efficacy and

safety of venlafaxine conducted from August 2022 to July 2024. 3H Medi Solution Inc. recruited the participants for the present study, and consenting patients completed a web-based questionnaire online. The study period was from April 23 to May 25, 2025.

Study Population

Japanese patients with GAD who had participated in Study B2411367 and who voluntarily gave electronic informed consent were eligible for this study; no exclusion criteria were specified. To participate in Study B2411367, patients were required to have been diagnosed with GAD according to the DSM-5 diagnostic criteria and to have a Hamilton Anxiety Rating[13] score of ≥ 20 and a Generalized Anxiety Disorder 7-Item (GAD-7) scale[14] score of ≥ 10. Based on the number of patients with GAD who participated in Study B2411367 through a clinical trial information website, the maximum anticipated sample size was 219. Respondents in this study included those who completed treatment in Study B2411367 and rolled over to an open-label, long-term extension study lasting 52 weeks. Respondents were compensated for their participation in this study.

Study Variables

This study collected data on the following variables: patients' awareness of GAD and medical care-seeking behavior before diagnosis (motivation for trial participation, awareness of GAD, awareness of symptoms, past medical care-seeking behavior and diagnoses), symptoms of GAD that were present at trial entry and their impacts on daily life, perceptions of diagnosis and assessment (feelings upon being diagnosed, burden of responding to the GAD-7), changes observed due to trial participation (degree of improvement in symptoms and their impacts on daily life, satisfaction with trial participation rated on a scale of 0 [poorly satisfied] to 10 [highly satisfied]), resistance to medical care and care experiences (resistance to visit/experiences visiting a psychiatric or psychosomatic medicine department), and perceived need for patient support groups.

Data Collection

Patients who wished to take part in this study were directed to a designated website and given an online explanation of the study to support their understanding prior to consent. The online explanation described the study objectives, procedures, expected time required to complete the questionnaire, and data handling. Those who gave voluntary consent on the electronic informed consent form proceeded to complete the web-based questionnaire. The questionnaire was developed by the researchers for this study and consisted of 44 single-choice, multiple-choice, or open-ended questions estimated to take between 30 and 40 minutes to complete; the questionnaire was self-completed by participants online using their own electronic devices. The questionnaire used in the study was written in Japanese; the English translation is provided in Supplementary Figure 1.

To support the accuracy and integrity of responses, participants completed the questionnaire independently and without interviewer involvement. Responses were submitted electronically and stored in a secure system managed by the survey administrator (3H Medi Solution Inc.). No personally identifiable information was included in the dataset used for analysis.

The web-based questionnaire was conducted after completion of Study B2411367. Survey responses were collected in a de-identified manner and could not be linked to treatment assignments in Study B2411367. Accordingly, analyses stratified by randomized treatment assignment were not performed. Due to the double-blind design, participants were not aware of their original treatment allocation in Study B2411367.

Statistical Analyses

Data from patients who completed the questionnaire were included in the analysis. Prespecified criteria for invalid responses were those with mutually contradictory answers to questionnaire items, nonsensical free text, or response patterns indicating non-engagement. Responses from patients whose total response time was less than 2 minutes were also regarded as invalid. The 2-minute threshold was prespecified as a quality-control criterion to flag potentially non-credible responses, such as rapid click-through behavior, based on internal completion time checks and prior experience

of the survey administrator. Exclusions of invalid responses were adjudicated by the survey administrator. If a question was answered multiple times, the first response was used in the analysis. Data on categorical variables were summarized as the number and percentage of patients in each category. Data on continuous variables were summarized as descriptive statistics (number, mean, standard deviation [SD], minimum, median, quartiles, and maximum).

Results

Patient Characteristics

A total of 219 patients were eligible for this study, and the questionnaire was distributed to 215 patients after excluding 4 who could not be reached. Valid responses were obtained from 98 patients, all of whom were included in the analysis set (ie, no responses were excluded for inconsistency, lack of coherence, response time, or other quality-control reasons). The patients had a mean (SD) age of 44.5 (11.0) years, and 50 patients (51.0%) were male (Table 1). The most frequently observed duration from onset of GAD symptoms to trial entry was ≥ 5 years (34.7%), followed by ≥ 2 to < 5 years (31.6%) and ≥ 1 to < 2 years (21.4%).

Table 1 Patient Characteristics (N = 98)

Characteristic	
Sex, n (%)	
Male	50 (51.0)
Female	48 (49.0)
Age	
Mean (SD)	44.5 (11.0)
Median [IQR]	46.0 [36.0, 53.3]
Range (min, max)	22, 64
Age group, n (%)	
18 to 29 years old	14 (14.3)
30 to 39 years old	20 (20.4)
40 to 49 years old	27 (27.6)
50 to 59 years old	29 (29.6)
60 years old or above	8 (8.2)
Occupation (at trial entry), n (%)	
Company or government employee	45 (45.9)
Temporary or contract employee	11 (11.2)
Freelancer, licensed professional, or self-employed	9 (9.2)
Part-time worker	19 (19.4)
Homemaker	7 (7.1)
University student (junior college, four-year college, or graduate school)	2 (2.0)
Unemployed (including retired early or at official retirement age) or domestic helper	5 (5.1)
Highest level of education completed, n (%)	
Junior high school	1 (1.0)
High school or technical college	15 (15.3)
Junior college	19 (19.4)
Vocational school	12 (12.2)
University	43 (43.9)
Graduate school	8 (8.2)

(*Continued*)

Table 1 (Continued).

Characteristic	
Household family members (multiple answers allowed), n (%)	
Spouse or partner	49 (50.0)
Children	40 (40.8)
Parents	16 (16.3)
Siblings	6 (6.1)
Grandparents	0 (0.0)
Grandchildren	1 (1.0)
Other	2 (2.0)
No cohabitants (living alone)	28 (28.6)
Cohabitant status, n (%)	
With cohabitants	70 (71.4)
Without cohabitants	28 (28.6)
History of mental disorders among first-degree relatives (multiple answers allowed), n (%)	
Depression	8 (8.2)
Obsessive-compulsive disorder	3 (3.1)
Generalized anxiety disorder	1 (1.0)
Panic disorder	1 (1.0)
Social anxiety disorder	1 (1.0)
Bipolar disorder	1 (1.0)
Schizophrenia	1 (1.0)
Post-traumatic stress disorder	0 (0.0)
Other mental disorder	1 (1.0)
Do not know	13 (13.3)
None of the above apply	71 (72.4)
Duration from symptom onset to trial entry, n (%)	
< 1 year	12 (12.2)
≥ 1 to < 2 years	21 (21.4)
≥ 2 to < 5 years	31 (31.6)
≥ 5 years	34 (34.7)
Completion of clinical trial (lasting 11 weeks), n (%)	
Completed the clinical trial	95 (96.9)
Did not complete the clinical trial	3 (3.1)
Participation in long-term study[a] (lasting approximately 1 year),[b] n (%)	
Participated (completed)	45 (47.4)
Participated (discontinued)	2 (2.1)
Did not participate	48 (50.5)

Notes: [a]Participants of Study B2411367 who completed treatment in the trial were given the option to roll over to an open-label, long-term extension study lasting 52 weeks. [b]Among patients who completed the initial 11-week clinical trial period, n = 95.
Abbreviations: IQR, interquartile range; SD, standard deviation.

Because survey responses were de-identified and could not be linked to randomized treatment assignment, analyses stratified by treatment group were not feasible, and reported post-trial changes reflect participants' self-reported experiences rather than treatment effects.

Patients' Awareness of GAD and Medical Care-Seeking Behavior Before Diagnosis

The greatest motivation to participate in the clinical trial was that patients identified with the eligibility criteria, such as "feeling anxious or worried about small things in daily life", which was reported by 93.9% of patients (Table 2). Before

Table 2 Patients' Awareness of GAD and Medical Care-Seeking Behavior Before Diagnosis (N = 98)

Questionnaire Item	n (%)
Motivation for wanting to participate in the clinical trial (multiple answers allowed)	
Saw the clinical trial information and felt that the criteria, such as "feeling anxious or worried about small things in daily life", applied to myself	92 (93.9)
Was interested in clinical trials and wanted to contribute to the development of new medications and help others suffering from the same symptoms	44 (44.9)
Because the clinical trial targeted GAD, it seemed like an opportunity to understand my health condition and a part of treatment	43 (43.9)
The clinical trial offered financial compensation and access to free treatment and medications	43 (43.9)
Recommended by family or acquaintances	4 (4.1)
Extent of knowledge about GAD	
Awareness of GAD before seeing information about the clinical trial	
Had never heard of it	71 (72.4)
Had heard of it	27 (27.6)
Extent of knowledge about the disease	
Knew the disease characteristics and treatment methods in detail	5 (18.5)
Had a general understanding of what the disease is	14 (51.9)
Had only heard the name of the disease	8 (29.6)
Whether the patient considered their anxiety problem to be an illness or a personality trait	
Considered it a personality trait	70 (71.4)
Considered it an illness	12 (12.2)
Neither	4 (4.1)
Did not know	12 (12.2)
Experience of seeking medical care before trial entry	
Yes	11 (11.2)
Medical departments visited (multiple answers allowed)[a]	
Psychiatry or psychosomatic medicine	9 (81.8)
Internal medicine	1 (9.1)
Other medical department	1 (9.1)
Do not know/do not remember	1 (9.1)
Mental disorders previously diagnosed (multiple answers allowed)[a]	
Depression	4 (36.4)
Social anxiety disorder	2 (18.2)
GAD	1 (9.1)
Insomnia	1 (9.1)
Panic disorder	0 (0.0)
Somatic symptom disorder/somatoform disorder	0 (0.0)
Other mental disorder	1 (9.1)
Was not diagnosed with any mental disorder	4 (36.4)
Do not remember	1 (9.1)
No	87 (88.8)
Reasons for not seeking medical care before trial entry (multiple answers allowed)[b]	
Did not think it was an illness	58 (66.7)
Did not know which hospital or department to visit	30 (34.5)
Was reluctant to go to a psychiatric department	30 (34.5)
Did not think going to a hospital would cure my condition	28 (32.2)
Could not afford it	19 (21.8)
Thought I could solve my problems on my own	19 (21.8)
Did not have enough time	12 (13.8)
Other	2 (2.3)

Notes: [a]Among patients who had experience of seeking medical care before trial entry, n = 11. [b]Among patients who did not have experience of seeking medical care before trial entry, n = 87.

Abbreviation: GAD, generalized anxiety disorder.

trial entry, the majority of patients (72.4%) had never heard of GAD. Among those who had heard of it, 18.5% had detailed knowledge of the disease characteristics and treatment, 51.9% had a general understanding, and 29.6% had only heard the disease name. When asked whether they had perceived their anxiety as an illness or a personality trait, most patients (71.4%) had considered it a personality trait, while only 12.2% had regarded it as an illness.

Only 11 patients (11.2%) reported having sought medical care before trial entry, while the majority (88.8%) had not (Table 2). Among those who sought medical care, most had visited psychosomatic medicine or psychiatry departments (n=9; 81.8%). With respect to previous diagnoses of mental disorders, depression was the most frequent (36.4%), followed by social anxiety disorder (18.2%), GAD (9.1%), and insomnia (9.1%).

Among the 87 patients who had not sought medical care prior to trial entry, the most frequently cited reason was the perception that their condition was not an illness (66.7%). Other frequently cited reasons included not knowing which hospital or department to visit (34.5%), reluctance to visit a psychiatric department (34.5%), the belief that seeking medical care would not cure their condition (32.2%), and thinking they could solve the problems on their own (21.8%). Practical barriers were also reported, including financial constraints (21.8%) and lack of time (13.8%).

Symptoms of GAD Present at Trial Entry and Impact on Daily Life

The symptoms of GAD present at trial entry, their impact on daily life, and summaries of representative patient comments illustrating their specific experiences are presented in Table 3. The original verbatim responses (in Japanese) of patients describing their experiences are presented in Supplementary Tables, along with the English translations (Supplementary Table 1, symptoms present at trial entry; Supplementary Table 2, impact on daily life).

At trial entry, nearly all patients (99.0%) reported experiencing excessive anxiety or worry. Becoming fatigued easily (86.7%) and sleep problems (82.7%) were also frequently reported. Other frequently reported symptoms included tension

Table 3 Symptoms of GAD Present at Trial Entry and Impact on Daily Life (N = 98)

Symptom	Present at Trial Entry,[a] n (%)	Selected as the Most Distressing Symptom, n (%)	Specific Experiences/Examples
Excessive anxiety or worry about various things	97 (99.0)	60 (61.2)	"I felt so overcome with anxiety that even the smallest things seemed like the end of the world". "I was afraid of going out (felt like I was being watched) and of the night (not of anything specific). I would get anxious when people were talking, feeling as though they were talking about me". "I became anxious that unlikely accidents, incidents, or other distressing events might occur".
Becoming fatigued easily	85 (86.7)	9 (9.2)	"I became anxious from overthinking and worrying too much, and it left me feeling exhausted". "I was mentally and physically exhausted, and even sleep didn't help me recover". "I felt exhausted just from doing daily household tasks".
Sleep problems (eg, difficulty falling asleep, waking up in the middle of the night, light sleep)	81 (82.7)	11 (11.2)	"It would take me a long time to fall asleep, and I often woke up in the middle of the night, so I wasn't getting enough sleep both in terms of quality or quantity". "I would wake up many times at night worrying if I would be able to get up the next morning. Anxious thoughts made it difficult for me to go to sleep". "I couldn't fall asleep because I had so many thoughts running through my mind at bedtime".
Feelings of tension or emotional agitation	73 (74.5)	7 (7.1)	"Once I would get anxious about something, even just a small thing, I couldn't get it out of my head and couldn't relax". "As I went about my daily life, I often felt anxious and tense about various things, which made everyday life difficult". "I would cry easily at work when my boss gave me negative feedback".
Irritability or being quick to anger	67 (68.4)	6 (6.1)	"I would always feel unsettled. I had huge mood swings, and I would get irritated and shout even about the smallest things". "I felt bothered by trivial things in daily life, which triggered feelings of anger and caused me stress".

(*Continued*)

Table 3 (Continued).

Symptom	Present at Trial Entry,[a] n (%)	Selected as the Most Distressing Symptom, n (%)	Specific Experiences/Examples
Muscle tension (eg, stiff shoulders)	62 (63.3)	2 (2.0)	"I was always tense, probably from nervousness. The nervousness made me stiff and unable to relax".
Difficulty concentrating	59 (60.2)	1 (1.0)	"I had trouble concentrating, and sometimes, I felt as though my mind was going blank even in the middle of speaking". "I was easily distracted by even the smallest things and had difficulty staying focused". "I was unable to concentrate or think clearly, which interfered with my work and daily life". "I would constantly feel vaguely anxious and nervous for no reason, which made it difficult for me to focus on work and impaired my concentration".
Restlessness or difficulty sitting still	31 (31.6)	0 (0.0)	"I was constantly anxious and never felt at peace. I repeatedly checked my schedule and couldn't stay still". "Even the smallest things made me anxious, and I felt so restless that I couldn't stay still or calm down". "My mind was always agitated and unsettled, and I was never able to feel at ease".
Other physical symptoms (eg, headache, stomach pain, back pain)	50 (51.0)	2 (2.0)	"I would feel so nervous that my breathing became erratic". "I took medication for daily headaches". "I often had a sensitive stomach". "Even small things in daily life made my heart race and my hands sweat. I would become momentarily paralyzed and needed time to proceed to the next task". "My anxiety intensified, leading to heart palpitations, and persistent worries constantly occupied my mind". "Even the smallest things would overwhelm me with anxiety all over and give me stomach pain". "When my anxiety worsened, it triggered symptoms such as heart palpitations and dizziness".
Areas of Daily Life	**Areas Greatly Impacted,[a] n (%)**	**Areas with the Greatest Impact, n (%)**	**Specific Experiences/Examples**
Work/studying	83 (84.7)	52 (53.1)	"I couldn't get enough sleep and was always tense and caught up in obsessive thoughts, so I had to deal with work while struggling to concentrate". "Because of anxiety and nervousness, I often couldn't focus on my work the way I wanted to, and I sometimes felt nauseous and couldn't eat. My hands would get cold, my heart would race, and I couldn't concentrate. These symptoms reduced my work performance". "I was always nervous and anxious at work, so my body always felt tense. Because I was so anxious, I tried to do my work overly carefully, which made me less efficient". "I made frequent mistakes at work, and my efficiency didn't improve".
Social relationships	82 (83.7)	23 (23.5)	"Interacting with others became burdensome, and my irritability often surfaced, negatively affecting my relationships". "I couldn't socialize much because I felt it would only increase my worrying". "I found it difficult to get a job because I was afraid of having negative interpersonal experiences. I had difficulty trusting others, which often resulted in social isolation. I also had difficulty making new friends and felt it was hard to go to social gatherings".
Everyday outings	57 (58.2)	6 (6.1)	"I wasn't able to go out, not even for shopping". "Spending extended time in crowded environments, such as on trains, caused stress that accumulated and led to persistent fatigue". "I felt uneasy about leaving the house unattended, so I disliked going out and tried to avoid it".
Leisure activities/hobbies	45 (45.9)	4 (4.1)	"I lost interest in things". "I could no longer fully enjoy my hobbies as I used to. Sometimes, a sudden anxious thought would cross my mind and ruin my good mood".

(*Continued*)

Table 3 (Continued).

Areas of Daily Life	Areas Greatly Impacted,[a] n (%)	Areas with the Greatest Impact, n (%)	Specific Experiences/Examples
Household tasks/childcare	41 (41.8)	12 (12.2)	"At night, while putting my child to sleep, I often felt drowsy myself but was unable to fall asleep. When my child wanted to play, I struggled to move my body as I wished, which made things emotionally and physically exhausting". "I wanted to do all my household tasks perfectly, and even while doing one task, I kept thinking of other things I also needed to do. However, I could only complete about half of the tasks I came up with. As these unfinished tasks piled up, I became more anxious".
None apply/not sure	1 (1.0)	1 (1.0)	–

Note: [a]Multiple answers allowed.
Abbreviation: GAD, generalized anxiety disorder.

or agitation (74.5%), irritability (68.4%), muscle tension (63.3%), and difficulty concentrating (60.2%). The most distressing symptom among those present at trial entry was excessive anxiety or worry (61.2%), caused by constant anxious thoughts and fears about everyday situations. This was followed by sleep problems (11.2%) and fatigue (9.2%), with patients noting difficulty sleeping due to racing thoughts and exhaustion from overthinking.

Symptoms that were present at trial entry substantially interfered with the daily lives of patients. The most frequently reported areas of impact were work or studying (84.7%) and social relationships (83.7%), followed by everyday outings (58.2%). When asked to identify the single most impacted domain of daily life, over half of patients (53.1%) reported work or studying, often describing impaired concentration, reduced efficiency, and physical strain. Social relationships (23.5%) were also frequently reported, with patients citing experiences of withdrawal, mistrust, and irritability, followed by household tasks/childcare (12.2%), caused by exhaustion and feeling overwhelmed.

Perceptions of Diagnosis and Assessment

More than half of patients reported feeling some relief upon receiving a GAD diagnosis, with a total of 54.1% feeling relieved or a little relieved (Table 4). A small proportion reported increased anxiety (12.2%). A majority of patients indicated having positive feelings after diagnosis, with 72.4% noting that they learned their symptoms could be treated, 48.0% that others shared the same symptoms, and 28.6% that treatment might restore their previous well-being. About a quarter (24.5%) felt reassured that the diagnosis was preferable to another disorder, such as depression. Negative reactions were also reported: 52.0% expressed resistance to taking medication, 32.7% felt treatment would be a hassle, 23.5% feared prejudice, and 21.4% felt depressed about having a disorder.

Regarding answering the GAD-7, most patients did not perceive it as burdensome, with 76.8% reporting little to no burden, while 17.9% experienced a greater degree of burden. The majority (88.4%) felt the GAD-7 accurately reflected their symptoms at the time of completing it.

Changes Observed Due to Trial Participation

Overall, 70.4% of patients reported some degree of improvement in GAD symptoms following participation in the clinical trial, with 7.1% (n=7) improving and 63.3% (n=62) improving somewhat. In contrast, 26.5% (n=26) reported no change, 3.1% (n=3) experienced a slight worsening, and none reported worsening of symptoms.

The areas of daily life that improved after trial participation, along with summaries of representative patient comments illustrating their specific experiences, are presented in Table 5. The original Japanese verbatim responses and their English translations are shown in Supplementary Table 3. Treatment benefits were most often observed in work or studying (45.9%), with patients describing having better concentration, less fatigue, and greater emotional stability. Improvements were also noted in social relationships (35.7%), everyday outings (29.6%), leisure activities (24.5%), and household tasks or childcare (17.3%).

Table 4 Perceptions of Diagnosis and Assessment (N = 98)

Questionnaire Item	n (%)
Feelings on being diagnosed with GAD	
Felt relieved	12 (12.2)
Felt a little relieved	41 (41.8)
Cannot say either way	32 (32.7)
Felt slightly more anxious	10 (10.2)
Felt more anxious	2 (2.0)
Do not remember	1 (1.0)
Feelings after receiving a diagnosis of GAD (multiple answers allowed)	
Positive feelings	
Learned that my symptoms can be treated	71 (72.4)
Learned that others also have the same symptoms	47 (48.0)
Thought that treatment would bring my old self back	28 (28.6)
Thought it was better than being diagnosed with another mental disorder like depression	24 (24.5)
Felt something positive other than the above	3 (3.1)
Negative feelings	
Felt resistance toward taking medication	51 (52.0)
Felt that seeing a doctor or getting treatment would be a hassle	32 (32.7)
Felt that others might view me with prejudice	23 (23.5)
Was depressed to learn I have a disease/mental disorder	21 (21.4)
Felt something negative other than the above	2 (2.0)
None of the above apply	3 (3.1)
Burden of answering the GAD-7 during the clinical trial[a]	
Did not feel any burden	32 (33.7)
Did not feel much burden	41 (43.2)
Neutral	5 (5.3)
Felt some burden	15 (15.8)
Felt a burden	2 (2.1)
Whether the contents of the GAD-7 accurately aligned with the symptoms present at the time of answering the questionnaire[a]	
Yes	84 (88.4)
Neutral	9 (9.5)
No	2 (2.1)

Notes: [a]Among patients who remembered answering the GAD-7 during the clinical trial, n = 95.
Abbreviations: GAD, generalized anxiety disorder; GAD-7, Generalized Anxiety Disorder 7-Item.

Table 5 Improvements in the Daily Life of Patients After Trial Participation (N = 98)

Area of Daily Life	Improved After Receiving Treatment in the Clinical Trial,[a] n (%)	Specific Experiences/Examples
Work/studying	45 (45.9)	"I've been able to approach my tasks at work more calmly. I can sense that my feeling of panic has started to ease". "I started to feel less tired when working or doing other things". "My concentration improved, and I became able to work more efficiently. I started to feel a little more emotionally stable and less depressed about social relationships".
Social relationships	35 (35.7)	"Communicating with others, both at work and in my personal life, became less burdensome, and I was able to go outside and exercise instead of staying home all the time". "I used to feel anxious over small things, but now I can stay calmer and let things pass". "I started wanting to see my friends". "I became able to listen to others calmly and with composure, and I no longer felt frustrated in my mind".
Everyday outings	29 (29.6)	"I became able to live a normal life without fear. I also started going out more often". "I feel that the physical symptoms I used to experience when feeling anxious while out (like heart palpitations, shortness of breath, or dizziness) have become less frequent". "I started being able to go out in my free time before and after work".

(*Continued*)

Table 5 (Continued).

Area of Daily Life	Improved After Receiving Treatment in the Clinical Trial,[a] n (%)	Specific Experiences/Examples
Leisure activities/hobbies	24 (24.5)	"I became able to set aside time to spend on my hobbies. I started being able to retain what I read in books". "I became able to enjoy outdoor hobbies again, and I also found hobbies I can do at home". "I was able to go to an event at the community center, be in crowded places, and go to lunch with friends".
Household tasks/childcare	17 (17.3)	"Being able to sleep a little better gave me some peace of mind. I can interact with my child in a calm manner". "I can now focus while doing household tasks and have found that putting on videos or the radio in the background helps distract me from emotional distress". "I am able to move and act a bit more efficiently".
Other	2 (2.0)	–
Did not experience any improvements from treatment	24 (24.5)	–

Note: [a]Multiple answers allowed.

Satisfaction with the clinical trial was high, with a mean (SD) score of 7.3 (2.0) and a median of 8.0 [interquartile range, 6.0–9.0] on a scale from 0 to 10. The number and percentage of patients who gave each score were as follows: 0, n=1 (1.0%); 1, n=1 (1.0%); 2, n=0 (0.0%); 3, n=1 (1.0%); 4, n=2 (2.0%); 5, n=11 (11.2%); 6, n=18 (18.4%); 7, n=11 (11.2%); 8, n=28 (28.6%); 9, n=8 (8.2%); and 10, n=17 (17.3%). Overall, most patients rated their satisfaction between 6 and 10.

Resistance to Medical Care, Care Experiences, and Need for Support Groups

Most patients reported feeling at least some resistance to visiting a psychiatric or psychosomatic medicine department for the clinical trial, with 53.1% (n=52) feeling some resistance and 19.4% (n=19) feeling resistance; 27.6% (n=27) reported feeling no resistance. For most patients, the clinical trial represented their first time receiving care at such a medical department (n=73, 74.5%), while one quarter (n=25, 25.5%) had previous experience.

Regarding the need for patient groups, nearly half of the patients (n=48, 49.0%) thought such a group would be helpful and 26.5% (n=26) thought it would be very helpful, while a small proportion expressed negative views ("Do not think it would be very helpful", n= 7, 7.1%; "Do not think it would be helpful at all", n=0, 0.0%). Interest in participation was also high, with 64.3% (n=63) indicating they would be interested in participating, while 30.6% (n=30) indicated they would not be very interested and 5.1% (n=5) indicated no interest.

Discussion

This study of Japanese patients with GAD who had participated in a clinical trial for venlafaxine investigated patients' disease awareness, past medical care-seeking behavior and diagnoses, symptoms and impact on daily life, perceptions of diagnosis and clinical assessment, and changes after trial participation.

This study found that most patients enrolled in the clinical trial had been experiencing anxiety symptoms for years that impaired their activities in areas of daily life such as work/studying and social relationships but had not sought medical care. This study also found that many of them were not aware of GAD and had construed their anxiety problems as personality traits, with only a small percentage considering their symptoms an illness. This finding is in line with the results of a previous study that investigated disease awareness in patients with probable GAD in Japan, in which a large proportion of participants also considered their symptoms to be personality-related; the authors of the study likewise reported that 76.5% of the study participants had no knowledge of GAD, and only 3.9% had detailed knowledge of it.[2] These observations support the notion that limited disease awareness remains a major barrier to recognition and diagnosis of GAD in Japan. Furthermore, in the aforementioned study,[2] over half of participants had never visited a medical institution for anxiety or other mental issues. These findings align with the results of our study, in which the majority of participants had never sought medical care. The findings from our study and previous literature indicate a very low level of public awareness of GAD in Japan and suggest that

GAD may be highly underdiagnosed and undertreated in the Japanese population. Thus, raising public awareness of GAD and its treatability may help individuals with GAD receive appropriate diagnosis and treatment.

This study obtained first-hand accounts of the symptoms and burden on daily life of patients with GAD, which provide important insights for clinicians to better understand the patient experience. Patients frequently described difficulties in daily functioning due to anxiety, tension, and sleep problems, which affected their work, household responsibilities, and social relationships. These findings align with those of previous studies on the functional impact of GAD symptoms[2,6,7] and help characterize the impact on daily life at the time of trial entry. Reported changes after trial participation included feeling calmer and more focused when working or doing household tasks, greater emotional stability and reduced distress in interpersonal relationships, and an increased ability to leave the house. These patient-reported changes contextualize participants' experiences following trial participation and offer insights beyond traditional clinical endpoints. These findings suggest that appropriate diagnosis and treatment can be associated with improvements not only in symptoms but also in daily functioning among patients with GAD. In Study B2411367, treatment with venlafaxine led to significant improvements in both anxiety symptoms and functioning. Interpreted together with the present findings, these results highlight the clinical importance of diagnosing and treating GAD, underscoring the potential for meaningful improvements in patients' daily lives.

The patients enrolled in the clinical trial generally reported a high level of satisfaction with their participation. Although this observation reflects participants' experiences during trial participation, it does not imply treatment efficacy or causal mechanisms. Satisfaction with trial participation may have been influenced by multiple factors, including access to specialist care, structured follow-up, and increased attention to symptoms, and should therefore be interpreted cautiously.

Most patients reported little or no burden associated with completing the GAD-7 and felt that the questionnaire accurately reflected their symptoms. The GAD-7 is well known as a useful diagnostic tool for GAD, as it takes only a few minutes to complete and imposes a negligible burden upon patients.[14,15] The Japanese version of the GAD-7 has been fully validated by Muramatsu et al.[16] The results of this study suggest that the Japanese version of the GAD-7 may be useful not only for screening but also for measurement-based care.

Regarding patient groups, many patients expressed a favorable opinion for the availability of such groups, indicating a high level of need. Among the patients' reflections on receiving a GAD diagnosis, close to half of patients felt encouraged to hear that others had the same symptoms, suggesting that patients with GAD may receive emotional support from the presence of other patients. Mutual support among patients with a mental health disorder, such as through communication in patient groups, has been shown to contribute to symptomatic recovery, empowerment, and coping with the disease.[17,18] Given the low level of awareness of GAD in Japan, patient groups for GAD are expected to provide direct support to patients and foster understanding, hopefully contributing to improving public awareness of the disease.

This study has several limitations. First, the study relied on the patients' recollections of their experiences at the time of trial participation (up to about 3 years before this study), and thus the possibility of recall bias cannot be excluded. Their current clinical state and overall trial experience may have influenced how they retrospectively reported their awareness of GAD, symptom severity, and disease burden at trial entry. Although participants were instructed to recall their experiences at the time of trial entry, the potential influence of active treatment effects, placebo response, and trial-related care or attention cannot be excluded. Second, because this study included patients who were previously enrolled in a clinical trial, there is a risk of selection bias, where patients with more severe symptoms or greater distress may have been overrepresented; thus, caution should be used when generalizing the findings. Third, the clinical trial involved compensation and a level of care that may have been more attentive than in routine practice, and these factors may have influenced patient satisfaction. The findings of this study should be interpreted in light of these limitations.

Conclusion

The present study showed that Japanese patients with GAD who had participated in Study B2411367 had limited awareness of GAD as a medical condition but experienced substantial disease burden. Patients reported mental and physical symptoms that impaired functioning in various areas of daily life. Despite this burden, most had never sought medical care before trial entry, and among those who did seek medical care, only a few were diagnosed with GAD.

The present findings should be interpreted in light of the study's limitations, including its retrospective design and restriction to individuals who had participated in a clinical trial, which may limit generalizability. Nonetheless, the findings of this study highlight the unmet needs among Japanese patients with GAD who participated in a clinical trial, including low disease awareness and limited recognition in clinical settings. Efforts to increase awareness of GAD may help facilitate earlier diagnosis and broaden access to appropriate treatment.

Future research should extend these findings by examining broader populations, using prospective designs to reduce recall bias, and evaluating pathways that link symptom recognition to timely diagnosis and treatment. Studies assessing the impact of educational or awareness-based interventions on care-seeking behavior may further inform strategies to address unmet needs related to GAD in Japan.

Abbreviations

DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; DSM-5-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision; GAD, generalized anxiety disorder; GAD-7, Generalized Anxiety Disorder 7-Item Scale; HRQoL, health-related quality of life; IQR, interquartile range; SD, standard deviation; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; UMIN-CTR, University Hospital Medical Information Network Clinical Trial Registry; US, United States.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request and with the approval of Viatris Inc.

Ethics Approval and Informed Consent

This study was conducted in compliance with the Declaration of Helsinki and notifications related to the Ethical Guidelines for Medical and Biological Research Involving Human Subjects. The study protocol (protocol ID: VENL-CAZ-7f 002) was approved on April 16, 2025 (approval no. CRE10845), by the Medical Corporation TOUKEIKAI Kitamachi Clinic Ethics Review Board, an independent review board registered with the ethics review board reporting system of the Japanese Ministry of Health, Labour and Welfare (registration no. 11001110). Prior to initiation, this study was registered in the University Hospital Medical Information Network Clinical Trial Registry (identifier: UMIN000057689).

The Act on the Protection of Personal Information and applicable privacy guidelines in Japan were followed in handling the personal and sensitive personal information of patients in this study. After completion of the web-based questionnaire, all responses were anonymized and submitted for analysis as data that could not identify individual patients. All participants provided informed consent for the use of their questionnaire responses in the publication of study results in academic settings, including medical journals. Participants were anonymized (de-identified so that individuals could not be identified), and only de-identified data, including open-ended responses, were used for analysis and publication.

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Author Contributions

All authors made a significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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References

1. Munir S, Takov V. *Generalized Anxiety Disorder*. StatPearls. StatPearls Publishing LLC.; 2025.
2. Matsuyama S, Otsubo T, Nomoto K, Higa S, Takashio O. Prevalence of generalized anxiety disorder in Japan: a general population survey. *Neuropsychiatr Dis Treat*. 2024;20:1355–1366. doi:10.2147/ndt.S456272
3. Locke AB, Kirst N, Shultz CG. Diagnosis and management of generalized anxiety disorder and panic disorder in adults. *Am Fam Physician*. 2015;91(9):617–624.
4. Mishra AK, Varma AR. A comprehensive review of the generalized anxiety disorder. *Cureus*. 2023;15(9):e46115. doi:10.7759/cureus.46115
5. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders: DSM-5-TR*. American Psychiatric Association Publishing; 2022.
6. Ruscio AM, Hallion LS, Lim CCW, et al. Cross-sectional comparison of the epidemiology of DSM-5 generalized anxiety disorder across the globe. *JAMA Psychiatry*. 2017;74(5):465–475. doi:10.1001/jamapsychiatry.2017.0056
7. Keller MB. The long-term clinical course of generalized anxiety disorder. *J Clin Psychiatry*. 2002;63(Suppl 8):11–16.
8. Ishikawa H, Kawakami N, Kessler RC. Lifetime and 12-month prevalence, severity and unmet need for treatment of common mental disorders in Japan: results from the final dataset of World Mental Health Japan Survey. *Epidemiol Psychiatr Sci*. 2016;25(3):217–229. doi:10.1017/s2045796015000566
9. Portal Site of Official Statistics of Japan. e-Stat (Portal Site of Official Statistics of Japan). Available from: https://www.e-stat.go.jp/. Accessed February 16, 2026. (in Japanese).
10. DeGeorge KC, Grover M, Streeter GS. Generalized anxiety disorder and panic disorder in adults. *Am Fam Physician*. 2022;106(2):157–164.
11. National Institute for Health and Care Excellence. Generalised anxiety disorder and panic disorder in adults: management. National Institute for Health and Care Excellence: guidelines. National Institute for Health and Care Excellence (NICE); 2019.
12. Otsubo T, Watanabe K, Inoue T, et al. A randomized, double-blinded, placebo-controlled study to evaluate the efficacy and safety of venlafaxine extended release in Japanese patients with generalized anxiety disorder. *Psychiatry Clin Neurosci*. 2025;79(12):849–858. doi:10.1111/pcn.13907
13. Matza LS, Morlock R, Sexton C, Malley K, Feltner D. Identifying HAM-A cutoffs for mild, moderate, and severe generalized anxiety disorder. *Int J Methods Psychiatr Res*. 2010;19(4):223–232. doi:10.1002/mpr.323
14. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166(10):1092–1097. doi:10.1001/archinte.166.10.1092
15. Mossman SA, Luft MJ, Schroeder HK, et al. The Generalized Anxiety Disorder 7-item scale in adolescents with generalized anxiety disorder: signal detection and validation. *Ann Clin Psychiatry*. 2017;29(4):227–234a. doi:10.1177/104012371702900404
16. Muramatsu K, Miyaoka H, Kamijima K, et al. [Validity and usefulness of the Japanese version of the Generalized Anxiety Disorder 7-Item (GAD-7) scale] (meeting proceedings). *Jpn J Psychosom Med*. 2010;50:592. (in Japanese).
17. Smit D, Miguel C, Vrijsen JN, Groeneweg B, Spijker J, Cuijpers P. The effectiveness of peer support for individuals with mental illness: systematic review and meta-analysis. *Psychol Med*. 2023;53(11):5332–5341. doi:10.1017/s0033291722002422
18. Fortuna KL, Solomon P, Rivera J. An update of peer support/peer provided services underlying processes, benefits, and critical ingredients. *Psychiatr Q*. 2022;93(2):571–586. doi:10.1007/s11126-022-09971-w