Validation of the Japanese version of the Social Functioning in Dementia scale and COVID-19 pandemic's impact on social function in mild cognitive impairment and mild dementia

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ABSTRACT

Objectives: We aimed to psychometrically evaluate and validate a Japanese version of the Social Functioning in Dementia scale (SF-DEM-J) and investigate changes in social function in people with dementia during the coronavirus disease-19 (COVID-19) pandemic.

Design: We interviewed people with mild cognitive impairment (MCI) and mild dementia and their caregivers during June 2020-March 2021 to validate patient- and caregiver-rated SF-DEM-J and compared their scores at baseline (April 2020 to May 2020) and at 6-8 months (January 2021 to March 2021) during a time of tighter COVID-19 restrictions.

Setting: The neuropsychology clinic in the Department of Psychiatry at Osaka University Hospital and outpatient clinic in the Department of Psychiatry and Neurology at Daini Osaka Police Hospital, Japan.

Participants: 103 dyads of patients and caregivers.

Measurements: SF-DEM-J, Mini-Mental State Examination, Neuropsychiatric Inventory, UCLA Loneliness Scale, and Apathy Evaluation Scale.

Results: The scale's interrater reliability was excellent and test-retest reliability was substantial. Content validity was confirmed for the caregiver-rated SF-DEM-J, and convergent validity was moderate. Caregiver-rated SF-DEM-J was associated with apathy, irritability, loneliness, and cognitive impairment. The total score of caregiver-rated SF-DEM-J and the score of Section 2, "communication with others," significantly improved at 6-8 months of follow-up.

Conclusions: The SF-DEM-J is acceptable as a measure of social function in MCI and mild dementia. Our results show that the social functioning of people with dementia, especially communicating with others, improved during the COVID-19 pandemic, probably as a result of adaptation to the restrictive life.

Key words: social functioning, assessment tool, validity, reliability, mild cognitive impairment, mild dementia, COVID-19, behavioral and psychological symptoms

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Introduction

A decline in social function, defined as "how individuals associate and interact, both in society

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at large and their own personal environment (Tyrer and Casey, 1993)," is a hallmark of dementia (World Health Organization, 2019), caused by cognitive impairment (Dyer et al., 2021) and behavioral and psychological symptoms (BPSD) (Henry et al., 2009). Declining social functioning may exacerbate cognitive impairment (Kuiper et al., 2015) and BPSD (Manini et al., 2021) and increase family caregiver burden (Spitzer et al., 2019). Therefore, it is important to be able to evaluate social function as an important factor influencing quality of life and prognosis of people with dementia. If psychological and cognitive factors associated with social functioning could be identified, then the early detection of changes in these variables and early intervention to promote social functioning may be possible.

The coronavirus disease-19 (COVID-19) pandemic has highlighted the importance of social functioning, especially in the most vulnerable people, such as people with dementia (Suárez-González et al., 2021). As in other countries, the COVID-19 outbreak has been ongoing in Japan since 2020. The government repeatedly declared states of emergency and encouraged Japanese people to implement measures to prevent infection spread (Office for COVID-19 and Other Emerging Infectious Disease Control, 2020; 2021). The guidelines included refraining from going out unnecessarily, washing hands and gargling frequently, wearing a mask whenever going out, and ventilating rooms regularly. These requests limited social interaction in people with dementia because of the cessation of home visits by care specialists, visits by family and friends, and day care attendance. The reduction in social interaction precipitated social isolation (Wang et al., 2020) and worsened cognitive impairment and BPSD, such as anxiety, depression, and irritability (Cagnin et al., 2020) in people with dementia. They found it particularly difficult to live their daily lives with discontinuation of recreational activities and disruption of daily habits (Keng et al., 2020). Previously, we reported COVID-19's impact on people with dementia and mild cognitive impairment (MCI) (Hashimoto et al., 2020; Suzuki et al., 2020). However, longitudinal changes in social functioning of people with dementia during the COVID-19 pandemic remain unclear.

As it is important to evaluate the social functioning of people with dementia with valid and reliable instruments to measure social function in these patients, Sommerlad *et al.* (2017) developed a scale of social functioning in dementia (SF-DEM) for people with mild dementia. The SF-DEM is an English-language scale for older patients with dementia, which has already been evaluated for reliability and validity and has been found to

quantify three aspects of social function. Since social functioning is highly context-dependent, the characteristics of social functioning are expected to vary across cultures and international comparisons are desirable; this requires identical scales to be created to allow cultural differences to be explored. So appropriate scales that have been validated as equivalent in each country should be developed, taking into account cultural differences. However, no such scale exists in Japan. Therefore, in the present study, we aimed to (1) translate the SF-DEM into Japanese (SF-DEM-J); (2) test the factor structure, reliability, and validity of the scale; (3) evaluate the longitudinal changes in the social function of people with MCI and mild dementia during the COVID-19 pandemic; and (4) explore the association between social function and psychometric and cognitive variables in people with MCI and mild dementia.

Methods

Original SF-DEM and SF-DEM Japanese Version (SF-DEM-J)

The original SF-DEM is a structured questionnaire comprising 20 questions regarding patients' social interactions with family, friends, and the community. It has separate patient- and caregiver-report forms enquiring about the same social functioning domains, with the caregivers' version being a rephrasing of the patients' version for a proxy response. The SF-DEM includes 17 core questions scored from 0 to 3 and three unscored summary questions. The 17 scored questions cover the following three domains: Section "Introduction"comprises seven questions regarding "spending time with other people," Section "Methods" comprises six questions regarding "communication with other people," and Section "Results" comprises four questions regarding "sensitivity to other people" (Budgett et al., 2019). Higher scores indicate better social functioning; the maximum possible total score is 51. The three unscored summary questions assess the overall impression of current social functioning, past changes, and possible future lifestyle changes.

The original version was administered to 30 English-speaking patients with mild dementia, diagnosed with any subtype of dementia and scoring ≥ 20 on the Mini-Mental State Examination (MMSE), and their caregivers. Both patient- and caregiver-rated SF-DEM are acceptable, internally consistent, and have interrater and test-retest reliability as well as content, concurrent, and convergent validity. To ensure conceptual equivalence with the origin, we translated SF-DEM into

Japanese (SF-DEM-J) in accord with the International Society of Pharmacoeconomics and Outcomes Research task force guidelines (Wild *et al.*, 2005), carefully considering cultural differences between the UK and Japan. The cultural adaptations included changing the questions about "religious meetings" in the original version to "gatherings for neighborhood" and about "Social club" to "gatherings for hobbies" (see Table A1). The scale is intervieweradministered and rated by a person with dementia (patient-rated) or by a caregiver (caregiver-rated).

Participants

Participants were older patients with MCI or mild dementia and their family caregivers who visited the neuropsychology clinic in the Department of Psychiatry at Osaka University Hospital and outpatient clinic in the Department of Psychiatry and Neurology at Daini Osaka Police Hospital. We used the following inclusion criteria: (1) aged ≥ 65 years, (2) fulfilling Petersen's MCI criteria (Petersen et al., 1999) or the National Institute on Aging and Alzheimer's Association (NIA-AA) dementia criteria (McKhann et al., 2011) with an MMSE score higher than 20, (3) meeting the diagnostic criteria of possible and probable Alzheimer's disease (AD) dementia (McKhann et al., 2011) or possible and probable dementia with Lewy bodies (DLB) (McKeith et al., 2017) if the patients met the NIA-AA criteria of dementia, and (4) having a reliable family caregiver. The diagnosis was made by psychiatrists specializing in dementia who were in charge of the outpatient clinics for dementia at each facility and diagnose dementia based on clinical assessment and against standardized diagnostic criteria. Family caregivers' inclusion criteria were: (1) aged ≥ 20 years and (2) seeing their relative with dementia at least once weekly. We excluded participants with severe physical or other psychiatric disorders and those who could not provide informed consent. Written informed consent was obtained from both patients and caregivers for the patient-rated SF-DEM-J and from caregivers for the carer-rated SF-DEM-J. All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and the Helsinki Declaration of 1975, as revised in 2008. The Research Ethical Committee of Osaka University Hospital (Study Number 200305, Suita, Japan) and Daini Osaka Police Hospital (Study Number 1018) approved this study.

Procedure

At baseline, all patients were evaluated using the MMSE (Folstein *et al.*, 1975) to measure general

cognition, Clinical Dementia Rating (CDR) scale (Hughes et al., 1982) for dementia severity, Japanese version of the University of California, Los Angeles Loneliness Scale (UCLA-LS) (Masuda et al., 2012), 12-item version of Neuropsychiatric Inventory (NPI-12) (Cummings, 1997), and informant version of the Apathy Evaluation Scale (AES) (Kasai et al., 2014). Further, we collected the patients' demographic characteristics, including age, education duration, employment status, living arrangements, diagnosis, comorbidities, medicine taken internally, level of care needed for the Japanese long-term care insurance system, and type of care services they use. The SF-DEM-J interview was administered to patients and family caregivers individually and faceto-face by one of the 12 evaluators, each of them being a neuropsychiatrist or neuropsychologist specializing in the diagnosis and assessment of dementia. Each interview was audio-recorded and lasted for 15-20 minutes. After one evaluator audio-recorded the questions, another evaluator played, listened to, and scored the questions to assess interrater reliability. We repeated the SF-DEM-J interviews with some participants and caregivers approximately 5 weeks after the baseline to assess test-retest reliability. Some participants were also re-evaluated after 6 to 8 months to assess the SF-DEM-J's responsiveness to change - together with the "Community Affairs" domain of CDR (Hughes et al., 1982).

The data collection period was from June to October 2020. A subset of participants participated in the follow-up data collection to assess responsiveness from January to March 2021. We collected data in the Osaka Prefecture, where the first state of emergency in response to COVID-19 was declared from April 2020 to May 2020, and the second from January 2021 to February 2021. The first declaration had tighter restrictions, and many facilities with a large capacity such as department stores, amusement parks, and even schools were forced to be closed. However, people were still allowed to go out for necessities. The second one had certain restrictions such as limiting the number of customers and operating at shorter hours but did not require a suspension of business.

Sample size setting

We set the sample size to 100, according to the recommendation of the Consensus-based Standards for the Selection of Health Measurement Instruments checklist, which is a standardized tool for assessing the methodological quality of studies on measurement properties (Mokkink *et al.*, 2010a; 2010b; Terwee *et al.*, 2012), as this is an adequate number to evaluate internal consistency, validity, and interrater reliability. The sample size was set to 30 for test-retest reliability and responsiveness

testing, as this is considered sufficient to rate them as fair. To account for dropouts, we planned to recruit the first 31 participants for the responsiveness evaluation.

Analysis for reliability and validity of SF-DEM-J

Unless otherwise noted, both patient- and caregiverrated data were used in our analyses of reliability and validity, but only caregiver-rated data were used for "Additional investigation."

Internal consistency was assessed using Cronbach's α of total and subtotal (section), and item per section correlation using Spearman's rank coefficient. The total SF-DEM-J scores' interrater and test-retest reliabilities were evaluated using the intraclass correlation coefficient (ICC), employing the (2, 1) and (1,1) models, respectively (Rousson, 2011). Interrater and test-retest agreements for individual questions were tested using Cohen's quadratic-weighted κ .

To examine convergent validity, the results from patient- and caregiver-rated SF-DEM-J were compared using Cohen's quadratic-weighted κ for each item's score and ICC (2, 1) for the total score. In addition, we compared the total score and the score of each section between patient- and caregiver-rated versions using Wilcoxon signed rank test. For criterion validity testing, we divided patients into two groups according to whether or not they performed community activities (such as working, shopping, and going to functions outside of the home) independently, based on the score obtained on "community affairs" in CDR (independent: 0 or 0.5, dependent: 1 or more), which is considered the psychometrically acceptable existing measure of social function against SF-DEM-J; thereafter, we compared the total score of caregiver-rated SF-DEM-J using Mann-Whitney U test. Social function is affected by cultural differences, particularly in Sections "Introduction" and "Methods" of the SF-DEM-J questions; hence, we expected to observe differences in factors between the UK and Japan. Therefore, we performed principal component analysis for structural validity verification with 17 scored items on the caregiver-rated SF-DEM-J using the principal component method with promax rotation. In this analysis, components with eigenvalues greater than 1.0 were adopted. We considered Cronbach's $\alpha > 0.6$ (Nunnally, 1967; Nunnally and Bernstein, 1994) and Cohen's quadratic-weighted $\kappa > 0.4$ (Landis and Koch, 1977) as acceptable level.

Evaluation of SF-DEM-J's responsiveness during the covid-19 pandemic

To assess responsiveness to changes in social function of people with MCI and mild dementia

during the COVID-19 pandemic, we compared the scores obtained on the caregiver-rated SF-DEM-J at baseline with those obtained after 6–8 months using Wilcoxon signed rank test. We hypothesized that the social function of patients and caregivers would change owing to the COVID-19 outbreak and, therefore, decided to utilize this change to confirm the SF-DEM-J's responsiveness.

Additional investigation to assess the association between social function and other psychometric instruments

To identify the variables associated with patients' social function, we performed multiple regression analysis using the SF-DEM-J's total caregiver-rated score or Section scores as dependent variables, and sex and the scores of measures as independent variables.

All analyses were performed using SPSS for Windows, version 28 (IBM Corp., Armonk, NY, USA). The statistical significance level was set at two-tailed p < 0.05.

Results

Participant characteristics

We recruited 104 dyads of patients and caregivers, of which 103 were finally included (one withdrew from the study). Table 1 summarizes the demographic characteristics of the 103 patients with MCI or mild dementia and their family caregivers, respectively. The patients' mean age was 78.5 years (SD = 6.0); of these, 61 (59.2%) were female, 74 (71.8%) were living with their families, and 29 (28.2%) were living alone. Overall, 54 patients (52.4%) had MCI, 34 (33.0%) exhibited mild AD dementia, and 15 (14.6%) exhibited mild DLB (Table 1). Further, 30 patients for test-retest reliability and 31 patients for responsiveness were included in this study. After the 6-8 months of follow-up, 11 (35.5%) patients started or increased the dose of anti-dementia medication and 10 (32.3%) patients received new social welfare services because of an application of long-term care insurance at the first time or change of grade. None of the 31 patients who participated in the 6-8-month follow-up changed their living arrangements or were bereaved because of their family caregiver.

SF-DEM-J's reliability, validity, and responsiveness

Reliability

Table A1 summarizes participants' responses on the SF-DEM-J at baseline. Table 2 presents the results for the reliability and validity of SF-DEM-J.

PATIENTS	MEAN (SD)	FAMILY CAREGIVERS	MEAN (SD)
Female (%)	61 (59.2%)	Female (%)	69 (67.0%)
Age, years	78.5 (6.0)	Age, years	65.7 (12.8)
Length of education, years	12.6 (2.3)	Relationship to p	patient
MMSE score	24.4 (2.4)	Spouse	52 (50.5%)
CDR		Child	43 (41.7%)
0.5	65 (63.1%)	Sibling	3 (2.9%)
1	38 (36.9%)	Other	5 (4.9%)
Community affairs in CDR, 0: 0.5: 1: 2	21: 53: 27: 2		
Living situation, alone: together	29: 74		
Diagnosis			
MCI (%)	54 (52.4%)		
AD dementia (%)	34 (33.0%)		
DLB (%)	15 (14.6%)		
Composite NPI score			
Delusions	1.0 (2.3)		
Hallucinations	0.5 (1.8)		
Agitation	0.8 (1.6)		
Depression	0.8 (1.6)		
Anxiety	1.2 (2.4)		
Euphoria	0.1 (0.8)		
Apathy	2.9 (3.2)		
Disinhibition	0.3 (1.2)		
Irritability	1.1 (2.0)		
Aberrant motor behavior	0.3 (1.5)		
Nighttime behaviors	1.6 (2.6)		
Appetite/eating	1.4 (3.1)		
UCLA-LS	37.0 (9.6)		
AES	41.0 (11.1)		

Table 1. Clinical and demographic characteristics of patients and family caregivers

Data represent the mean (SD) or number (%) of participants.

MMSE, Mini-Mental State Examination; CDR, Clinical Dementia Rating; MCI, mild cognitive impairment; AD, Alzheimer's disease; DLB, dementia with Lewy bodies; NPI, Neuropsychiatric Inventory score; UCLA-LS, UCLA Loneliness Scale; AES, Apathy Evaluation Scale.

The Cronbach's α coefficients of the caregiver-rated version were acceptable only for the subscale score of Section 3 ($\alpha = 0.64$). The patient-rated version was low internal consistency compared to the caregiver-rated instrument. Interrater reliability was high for total scores on the patient- and caregiver-rated SF-DEM-J (ICC [95%CI] = 0.97 [0.95–0.98] and 0.97 [0.96–0.98], respectively). Interrater agreement for only item 16 was substantial ($\kappa = 0.74$) and that for other items was almost perfect ($\kappa > 0.80$) on the patient-rated instrument. Interrater agreement for all items had an almost perfect agreement ($\kappa > 0.80$) on the caregiver-rated instrument. We repeated the SF-DEM-J's assessment in 30 patients and caregivers after an average of 34.9 days (SD = 7.1; range = 25-49) for the testretest evaluation. Test-retest reliability exhibited a satisfactory level in the patient- and caregiver-rated versions (ICC [95%CI]= 0.68 [0.44-0.84] and 0.63 [0.35 - 0.81],respectively). Moderate to substantial agreement ($\kappa > 0.40$) was found for 8 of 17 items on the patient-rated instrument and 10 of 17 items on the caregiver-rated instrument.

VALIDITY

We found a moderate correlation between the overall patient- and caregiver-rated SF-DEM-J scores, suggesting convergent validity (ICC [95% CI] = 0.51 [0.28–0.67]; Table 2), whereas the patient- and caregiver-rated agreement was low for items 9–13 in Section 2 (Cohen's quadraticweighted $\kappa = 0.13$, 0.07, 0.11, -0.01, and 0.08, respectively) and items 14–16 in Section 3 (Cohen's quadratic-weighted $\kappa = -0.08$, 0.03, and 0.11, respectively).

The total score of the patient-rated version was significantly higher than of the caregiverrated version (mean [SD] score, 28.4 [4.3] vs. 26.5 [5.4], p = 0.002) (Table 3). The score of Section 3 of the patient-rated instrument was significantly higher than of the caregiver-rated instrument (mean [SD] score, 9.7 [2.3] vs. 8.3 [2.9], p = <0.001). The score of Section 1 of the patient-rated version was not significantly different from of the caregiver-rated version (mean [SD] score, 6.9[2.8] vs. 6.7 [2.4], p = 0.499). The score of Section 2 of the patient-rated instrument was not

Table 2. Results of evaluations for reliabilit	y and validity of the SF-DEM-J
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PSYCHOMETRIC PROPERTY	INTERNAL CONSISTENCY ITEM-SECTION CORRELATION SPEARMAN'S γ		INTERRATER RELIABILITY		TEST-RETEST RELIABILITY		CONVERGENT VALIDITY	
STATISTIC			COHEN'S K		COHEN'S K		cohen's k	
SF-DEM-J DOMAIN	PATIENT - RATED	CAREGIVER- RATED	PATIENT- RATED	CAREGIVER- RATED	PATIENT- RATED	CAREGIVER- RATED	_	
Section1								
1	0.28^{*}	0.24^{*}	0.98^{*}	0.87^{*}	0.80^{*}	0.43^{*}	0.59^{*}	
2	0.34*	0.45*	0.93*	0.92*	0.26	0.23*	0.26*	
3	0.39*	0.17	0.94*	0.86*	0.16	0.34*	0.30*	
4	0.64^{*}	0.58*	0.98*	0.95*	0.58*	0.42^{*}	0.47^{*}	
5	0.28*	0.29*	0.97*	0.96*	0.56*	0.55*	0.17^{*}	
6	0.65^{*}	0.55^{*}	0.89^{*}	0.97^{*}	0.47^{*}	0.54^*	0.49^{*}	
7	0.55^{*}	0.50^{*}	0.96*	0.99^{*}	0.60^{*}	0.75^{*}	0.41^{*}	
Section2								
8	0.47^{*}	0.56^{*}	0.98^*	0.95^{*}	0.52^{*}	0.71^{*}	0.32^{*}	
9	0.39^{*}	0.22^{*}	0.96^{*}	0.95*	0.47^{*}	0.45^{*}	0.13	
10	0.78^{*}	0.69^{*}	0.95^{*}	0.95*	0.21	0.54^*	0.07	
11	0.64^*	0.63*	0.96^{*}	0.94^{*}	0.13	0.52^{*}	0.11	
12	0.19	0.44^{*}	0.84^*	0.96*	0.16	0.37^{*}	-0.01	
13	0.19	0.48^{*}	0.81^{*}	0.86^{*}	0.18	0.13	0.08	
Section3								
14	0.72^*	0.76^{*}	0.97^{*}	0.95*	0.42^{*}	0.29^{*}	-0.08	
15	0.72^*	0.72^{*}	0.94^{*}	0.96^{*}	0.30^{*}	0.40^{*}	0.03	
16	0.48^{*}	0.65^{*}	0.74^*	0.96^{*}	0.25	0.42^{*}	0.11	
17	0.62^{*}	0.61^{*}	0.91^{*}	0.93*	0.30^{*}	0.29^{*}	0.20^{*}	
Statistic for section and total scores	Cro	onbach's α	Intraclass correla	ation coefficient				
Section1	0.43	0.26						
Section2	0.43	0.53						
Section3	0.55	0.64						
Total	0.36	0.52	0.97^*	0.97^{*}	0.68^{*}	0.63^{*}	0.51^{*}	
95%CI			0.95–0.98	0.96-0.98	0.44 – 0.84	0.35-0.81	0.28 - 0.67	

CI, confidence interval. To evaluate internal consistency, Cronbach's α was presented for the section and total scores, and Spearman's rank correlation coefficients were presented for the inter-item per the section score. For interrater reliability, test-retest reliability, and convergent validity for individual items, the data represent Cohen's quadratic-weighted κ . For interrater reliability, test-retest reliability, test-retest reliability, test-retest reliability, test-retest reliability, and convergent validity for individual items, the data represent Cohen's quadratic-weighted κ . For interrater reliability, test-retest reliability, test-retest reliability, test-retest reliability, and convergent validity for the total score, the data represent ICC (2, 1), (1, 1), and (2, 1), respectively. *Correlation is significant at the 0.05 level.

	PATIE	PATIENT-RATED VERSION ($N = 103$)				CAREGIVER-RATED VERSION ($N = 103$)			
SUMMARY		INDEPENDENT DEPENDENT				INDEPENDENT DEPENDENT			
SCORES	TOTAL	(N = 74)	(N = 29)	P^{\dagger}	TOTAL	(N = 74)	(<i>N</i> = 29)	\mathbf{P}^{\dagger}	P^{\ddagger}
Total	28.4 (4.3)	28.2 (4.3)	28.7 (4.2)	0.620	26.5 (5.4)	27.4 (5.0)	24.3 (5.7)	0.021*	0.002^{*}
Section 1	6.9 (2.8)	6.9 (2.6)	7.1 (3.1)	0.737	6.7 (2.4)	6.9 (2.4)	6.3 (2.3)	0.259	0.499
Section 2	11.8 (2.6)	11.8 (2.5)	11.9 (2.7)	0.871	11.5 (3.2)	11.9 (2.9)	10.4 (3.7)	0.033^{*}	0.541
Section 3	9.7 (2.3)	9.8 (2.3)	9.6 (2.2)	0.629	8.3 (2.9)	8.5 (2.6)	7.6 (3.4)	0.289	< 0.001*

Table 3. SF-DEM-J scores according to the level of independence on the "community affairs" domain in CDR

Data represent the mean (SD). Independent, 0 or 0.5 of the score of community affairs in Clinical Dementia Rating; dependent, 1 or more of the score of community affairs in Clinical Dementia Rating.

[†]Mann–Whitney *U* test between the independent and dependent groups.

[‡]Wilcoxon signed rank test between patient-rated and caregiver-rated scores in total participants.

 $^{*}p < 0.05.$

significantly different from of the caregiver-rated instrument (mean [SD] score, 11.8 [2.6] vs. 11.5 [3.2], p = 0.541).

According to the score obtained on "community affairs" in the CDR, 74 patients (mean [SD] age: 78.4 [6.1]) were judged to be independent in social activities, while 29 (mean [SD] age: 79.0 [5.8]) were judged to be dependent. The caregiver-rated SF-DEM-J scores were significantly higher in the "independent" group than in the "dependent" group in terms of the total score (mean [SD] score, 27.4 [5.0] vs. 24.3 [5.7], p = 0.021) and the score of Section 2 (mean [SD] score, 11.9 [2.9] vs. 10.4 [3.7], p = 0.033), while the patient-rated SF-DEM-J scores did not show significant differences between the "independent" and "dependent" groups (Table 3).

The principal component analysis for the caregiverrated SF-DEM-J extracted six components (Table 4). The first component – comprising items 16, 15, 14, and 17 – was consistent with Section 3 (sensitivity to others) of the SF-DEM-J. The second component – comprising items 11, 10, and 2 – was named "assertive communication." The third component – comprising items 1 and 9 – was named "casual communication"; the fourth component – comprising items 13, 12, and 8 – was named "conversational ability requiring cognitive function"; the fifth component – comprising items 5, 6, and 4 – was named "casual outing"; and the sixth component – comprising items 7 and 3 – was named "purposeful outing."

Responsiveness

We repeated the SF-DEM-J's assessment on 31 pairs of patients and caregivers after an average of 191.8 days (SD = 36.0; range = 140–259) to test responsiveness. The total score (mean [SD] = 25.6 [5.2] to 28.1 [5.0], p = 0.017), score for Section 2

(mean [SD] = 10.4 [3.5] to 12.1 [2.9], p = 0.005), and scores of three items of the SF-DEM-J (1, 8, and 13) significantly improved at follow-up. The total score rated by 20 caregivers increased after 6–8 months of follow-up and the mean caregiver-rated SF-DEM-J increased by 2.5 points [SD 4.9, range from 14 to -4]. No significant difference was found in patients' scores of community affairs in the CDR between baseline and follow-up (mean [SD] = 0.7 [0.4] vs. 0.7 [0.3], p = 0.58, respectively).

Relationships between social function and other psychometric instruments

Multiple regression analyses showed that the scores of SF-DEM-J were significantly associated with age, MMSE, irritability, and agitation in NPI-12, UCLA-LS, and AES (Table 5). According to weighted β , the scores of Section 1 and 2 in SF-DEM-J were strongly associated with loneliness and apathy, while the score of Section 3 was strongly associated with agitation and irritability.

Discussion

First, this study developed the Japanese version of the SF-DEM (SF-DEM-J) to evaluate social function – and demonstrated its reliability and validity – in people with MCI and mild dementia. Second, we examined longitudinal changes in patients' social function during the COVID-19 pandemic. Additionally, we explored psychometric and cognitive variables directly affecting the social function of people with MCI and mild dementia.

In the present study, the caregiver-rated SF-DEM-J showed reliable interrater and test-retest reliability, and convergent and content validity in this

	component 1	component 2	component 3	component 4	COMPONENT 5	component 6	
ITEM NUMBER OF SF-DEM-J	"SENSITIVITY TO OTHERS"	"ASSERTIVE COMMUNICATION"	"casual communication"	"CONVERSATIONAL ABILITY REQUIRING COGNITIVE FUNCTION"	"casual outing"	"PURPOSEFUL OUTING"	
16	0.91	0.23	-0.14	-0.18	0.12	0.04	
15	0.71	-0.25	-0.13	0.00	-0.06	0.04	
4	0.58	-0.28	0.13	0.11	0.03	0.12	
17	0.47	0.15	0.17	0.43	-0.01	-0.10	
11	0.04	0.88	0.13	-0.14	-0.05	0.05	
10	-0.06	0.70	0.12	-0.09	0.27	0.10	
2	-0.02	0.53	0.05	0.34	-0.01	-0.12	
	-0.02	0.08	0.85	0.04	-0.17	-0.05	
)	-0.11	0.19	0.81	0.00	-0.01	0.24	
.3	0.01	-0.11	0.17	0.78	-0.08	0.05	
2	-0.08	-0.09	-0.16	0.70	0.20	-0.02	
3	-0.13	0.21	-0.34	0.47	-0.02	0.16	
5	0.08	0.04	-0.2	-0.03	0.68	-0.03	
ó	-0.07	0.01	-0.13	0.05	0.65	0.16	
4	0.13	0.13	0.14	0.10	0.56	-0.15	
7	0.03	-0.21	0.28	0.01	0.20	0.80	
3	0.14	0.26	-0.19	0.04	-0.32	0.59	
Eigenvalues	2.72	2.12	1.78	1.27	1.13	1.10	
Explained variance (%)	16.02	12.44	10.49	7.44	6.65	6.47	
Cumulative variance (%)	16.02	28.46	38.95	46.39	53.04	59.51	

Table 4. Pattern matrix of principal component analysis for caregiver-rated SF-DEM-J

Principal component analysis with promax rotation was performed. The numbers in bold represent the highest loading of each variable on one factor. Item numbers 1–7 were included in Section 1 (spending time with others), 8–13 in Section 2 (communicating with others), and 14–17 in Section 3 (sensitivity to others) of the SF-DEM-J.

DEPENDENT VARIABLE	INDEPENDENT VARIABLE	в (95%сі)	SE	β	Т	Р
SF-DEM-J Total score	(Constant)	40.37 (23.12 to 57.62)	8.69		4.65	< 0.001
	Age	-0.13 (-0.28 to 0.02)	0.07	-0.15	-1.78	0.079
	Sex	0.70 (-1.18 to 2.59)	0.95	0.06	0.74	0.462
	MMSE	0.41 (0.04 to 0.78)	0.19	0.19	2.20	0.030^{*}
	NPI agitation	0.08 (-0.57 to 0.73)	0.33	0.02	0.25	0.806
	NPI irritability	-0.67 (-1.18 to -0.16)	0.26	-0.26	-2.6	0.011^*
	NPI appetite/eating	-0.11 (-0.41 to 0.19)	0.15	-0.06	-0.7	0.485
	UCLA-LS	-0.18 (-0.28 to -0.08)	0.05	-0.32	-3.66	< 0.001*
	AES	-0.15 (-0.24 to -0.07)	0.04	-0.32	-3.75	< 0.001*
Section1	(Constant)	7.8 (-1.11 to 16.69)	4.48		1.74	0.085
	Age	-0.01 (-0.09 to 0.06)	0.04	-0.03	-0.36	0.722
	Sex	0 (-0.97 to 0.98)	0.49	0.00	0.01	0.995
	MMSE	0.19 (0.00 to 0.38)	0.10	0.19	1.96	0.053
	NPI agitation	0.13 (-0.21 to 0.46)	0.17	0.09	0.75	0.457
	NPI irritability	-0.11 (-0.37 to 0.15)	0.13	-0.09	-0.84	0.404
	NPI appetite/eating	-0.02 (-0.18 to 0.13)	0.08	-0.03	-0.26	0.793
	UCLA-LS	-0.05 (-0.10 to 0.00)	0.03	-0.21	-2.02	0.046^{*}
	AES	-0.06 (-0.11 to -0.02)	0.02	-0.29	-2.95	0.004^{*}
Section2	(Constant)	17.09 (6.37 to 27.81)	5.40		3.17	0.002
	Age	-0.03 (-0.12 to 0.06)	0.05	-0.06	-0.65	0.515
	Sex	0.76 (-0.41 to 1.93)	0.59	0.12	1.28	0.202
	MMSE	0.14 (-0.09 to 0.37)	0.12	0.11	1.22	0.226
	NPI agitation	0.5 (0.09 to 0.90)	0.20	0.25	2.44	0.016^*
	NPI irritability	-0.04 (-0.36 to 0.28)	0.16	-0.03	-0.26	0.795
	NPI appetite/eating	-0.13 (-0.32 to 0.05)	0.09	-0.13	-1.41	0.161
	UCLA-LS	-0.11 (-0.17 to -0.04)	0.03	-0.32	-3.44	$< 0.001^{*}$
	AES	-0.08 (-0.13 to -0.03)	0.03	-0.28	-3.16	0.002^*
Section3	(Constant)	15.49 (6.17 to 24.82)	4.70		3.3	0.001
	Age	-0.09 (-0.17 to -0.01)	0.04	-0.18	-2.19	0.031^{*}
	Sex	-0.06 (-1.08 to 0.96)	0.51	-0.01	-0.12	0.908
	MMSE	0.08 (-0.12 to 0.28)	0.10	0.07	0.81	0.422
	NPI agitation	-0.54 (-0.90 to -0.19)	0.18	-0.31	-3.06	0.003^*
	NPI irritability	-0.52 (-0.79 to -0.24)	0.14	-0.36	-3.72	< 0.001*
	NPI appetite/eating	0.05 (-0.12 to 0.21)	0.08	0.05	0.58	0.566
	UCLA-LS	-0.02 (-0.08 to 0.03)	0.03	-0.08	-0.88	0.379
	AES	-0.01 (-0.06 to 0.03)	0.02	-0.04	-0.48	0.630

Table 5. Results of multiple regression analysis

MMSE, Mini-Mental State Examination; NPI, Neuropsychiatric Inventory; UCLA-LS, UCLA Loneliness Scale; AES, Apathy Evaluation Scale. *Correlation is significant at the 0.05 level. SE, standard error; CI, confidence interval.

sample of people with MCI and mild dementia, demonstrating that the SF-DEM-J may be a reliable and valid measure. In addition, we showed, for the first time, that the SF-DEM-J may have acceptable psychometric properties in people with MCI. However, the internal consistency was not acceptable except for the Section 3. The internal consistency of the caregiver-rated SF-DEM-J for the total score ($\alpha = 0.52$) was lower than the original study from the UK ($\alpha = 0.64$) and the validation study from Germany ($\alpha = 0.76$) (Grothe *et al.*, 2022; Sommerlad *et al.*, 2017). This result reflected the low internal consistency for Sections 1 and 2 of the SF-DEM-J. Given the contents of the assessment in Sections 1 and 2, these social functions may vary from culture to culture, perhaps indicating that what is consistent as social functioning in Europe may not be so in Japan. This is consistent with the results that in the principal component analysis of the present study; Section 3 was replicated as in the original SF-DEM, but Sections 1 and 2 were not extracted as such.

The patient-rated SF-DEM-J showed a sufficient but lower level of test-retest reliability and no evidence of content validity, and the internal consistency was low. The correlation between patient and caregiver ratings was moderate, but the worse psychometric performance of the scale may reflect lower accuracy on patient ratings of their own performance. People with dementia may lack insight and underestimate their changes in social function

and cognition (Vasterling et al., 1997; Williamson et al., 2010). As a result, patients with dementia tend to systematically rate their own quality of life as higher than their families do (Ready et al., 2004), thus precipitating difficulties in accurately reflecting their actual social function. This notion was supported by the results obtained when we compared the SF-DEM-J scores between people who were "independent" versus "dependent" in community affairs. The caregiver-rated scores were higher in the "independent" group, whereas the patient-rated scores did not differ between the groups. In this study, as well as in the UK and German studies, the patient-rated scores tended to be higher than caregiver-rated SF-DEM scores (Table 3) (Grothe et al., 2022; Sommerlad et al., 2017).

The principal component analysis for SF-DEM-J extracted six components that were generally consistent with those noted in the original SF-DEM. The first component of SF-DEM-J was the same as that found in Section 3 of the original SF-DEM. The original Section 1 was divided into two categories in this study - components 5 (casual outing) and 6 (purposeful outing) - depending on whether the outing's quality was casual, related to leisure, or had some social purpose. This classification is consistent with the concept of treating exercise and leisure and social activities and services as separate domains in social functions (Leung et al., 2004). The original Section 2 was divided into three parts depending on whether the communication was emotionally driven, required some cognitive function, or casual, as in the present study. In patients with dementia, the amount of activity, including that of communication, is heavily affected by apathy, which is defined as falling into three subtypes of disrupted - "emotional-affective," "cognitive," and "auto-activation" - processing (Levy and Dubois, 2006). Multiple regression analysis revealed an association between SF-DEM-J's Section 2 and the severity of apathy evaluated with AES. Therefore, the three components from Section 2 seem reasonable, considering the three apathy subtypes. When Section 2 is strongly related to apathy, the low convergent validity of patient-caregiver rated agreement of item 9-16 in Section 2 may be because of the influence of apathy, which is related to anosognosia in patients with AD (Starkstein et al., 1996). However, the result for SF-DEM-J was differed from the result of factor analysis for SF-DEM. One possible reason is that the method of spending time with others and communication - evaluated using original Sections 1 and 2-is significantly influenced by the social culture to which one belongs. The different results may be attributed to sociocultural differences between Japan and the UK. On the

contrary, Section 3 – concerning sensitivity to others – may be unaffected by sociocultural differences.

This study demonstrated that social functioning is related to cognitive impairment, apathy, irritability, and loneliness, which is consistent with previous findings (Arai et al., 2021; Arai et al., 2017; Kuiper et al., 2015; Manini et al., 2021). Although these associations' direction cannot be proven, cognitive impairment, apathy, and irritability plausibly increase the difficulty of functioning socially, whereas the resultant objective social impairment causes or worsens subjective feelings of loneliness. More specifically, our study reported that social functioning's different aspects were associated with different symptoms: spending time with others (Section 1) and communicating with others (Section 2) were related to apathy and loneliness, which supports social participation's importance in people with dementia, while sensitivity to others (Section 3) was related to age, agitation, and irritability, which suggests that this SF-DEM-J domain is closely linked to these associated BPSD. This further strengthens the validity of the SF-DEM-J's relevant sections.

The caregiver-rated SF-DEM-J's test-retest reliability was sufficient but relatively low (ICC [95% CI]= 0.63 [0.35–0.81]). During this study, states of emergency were declared twice in Japan – between April and May 2020 and January and March 2021 to prevent the spread of COVID-19. Furthermore, the Japanese government repeatedly urged citizens to stay at home (Office for COVID-19 and Other Emerging Infectious Disease Control, 2020; 2021). In Osaka Prefecture, where this study was conducted, the population exhibited a substantial temporary migration during the study period. For example, the average daily population in Osaka – compared to the usual population from March 1 to April 4, 2021 - was approximately 70% lower during the first state of emergency and more than 20% lower during the second state of emergency (Osaka Prefectural Headquarters Meeting on COVID-19, 2021). Consequently, numerous facilities for dementia care limited the number of users, and outreach activities decreased around the first emergency declaration (Niimi et al., 2021). The low test-retest reliability in this study would be affected by changes in the social activities of patients with MCI or mild dementia over a short period during the COVID-19 pandemic. Consistently, the caregiver-rated version's test-retest reliability was sufficiently strong (ICC = 0.94) in the original SF-DEM's validation study in 2017 (Sommerlad et al., 2017) but was relatively low (ICC = 0.58) in the German version of the SF-DEM (German SF-DEM), which also collected data during the pandemic (Grothe et al., 2022). Therefore, considering the social context regarding outcome measures' evaluations, such as the SF-DEM, is important.

The SF-DEM-J score significantly improved after 6-8 months (follow-up period) for scores of total (2.5 points), and Section 2 (1.7 points). Levene et al. reported the minimum clinically important differences of the SF-DEM were 2 and 1.7 points for total and Section 2 scores, respectively (Levene et al., 2022). We therefore considered that this change in score reflected the responsiveness of the scale. The scores were improved especially in two items namely, "Contacted friends or family by phone or computer" and "Initiated or participated in a conversation." An online survey administered on healthy older people aged 65–84 years living in a large city in Japan from January 2020 to January 2021 reported that social activities decreased after the COVID-19 pandemic compared to before the pandemic (Yamada et al., 2021). However, a comparison of online activities before and after the COVID-19 pandemic revealed that some social activities were replaced by online activities, including virtual meetings with their family and friends during the pandemic (Mouratidis and Papagiannakis, 2021). Considering these previous studies' results, the present results would reflect their efforts to maintain the social activities of patients with MCI and mild dementia by increasing contact using telephones and computers, while social distance was invariably required during the COVID-19 pandemic.

The present study's strength was the detailed evaluation of MCI and mild dementia in more than 100 patients and caregivers during a period when clinical research activities were limited owing to the COVID-19 pandemic. However, this study had some limitations. First, we interviewed participants using the SF-DEM-J when social interaction patterns were changing during the COVID-19 pandemic, which may have adversely affected the reliability and validity verification. Second, the small number of test-retest patients might have an impact on the low ICC for testretest reliability. The range of 95% confidence intervals for the ICC is large, and we should interpret this results with caution. Third, the number of patients followed up longitudinally was limited. Fourth, the target was limited to individuals with MCI and mild dementia owing to AD or DLB. Finally, we recruited only patients with reliable family caregivers.

In conclusion, we translated the SF-DEM into Japanese and demonstrated its reliability and validity in individuals with MCI and mild dementia. Using the SF-DEM-J, we revealed that the overall social function improved by using telecommunication, such as the telephone, even when voluntary restraint was required during the COVID-19 pandemic. Furthermore, we found that different aspects of social function were affected by different psychiatric states – such as apathy, agitation, irritability, and loneliness. These findings suggest that the early recognition and treatment of BPSD exacerbations are worth investigating as appropriate targets for promoting social function and interventions for social functioning should be a future research priority. Social function is likely influenced by sociocultural differences. Therefore, conducting research at a global level is vital in the future.

Conflicts of interest

The authors declare no conflicts of interest associated with this manuscript.

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Description of author(s)' roles

S.U. and H.K. conceived of and designed the study. S.U., H.K., M.S., A.S, G.L., and M.H. translated SF-DEM into the Japanese version according to the International Society of Pharmacoeconomics and Outcomes Research task force guidelines. S.U., T.W., T.S., K.K., Y.N., Y.S., M.Y., F.K., D.T., S.H., and N.H. conducted the research interviews. S.U., H.K., and M.S. interpreted data from qualitative interviews. S.U. and H.K. conducted statistical analyses. S.U. wrote the initial draft of the manuscript. H.K., M.S., K.Y., M.H., and M.I. contributed to analysis and interpretation of data and assisted in the preparation of the manuscript. All authors contributed substantially to drafting the article and read and approved the final article.

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Supplementary material

The supplementary material for this article can be found at https://doi.org/10.1017/S1041610224 000401.

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