Original Article

Preliminary evaluation of the Japanese version of the Cognitive Function Instrument in a memory clinic

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Abstract

Background: Early detection of dementia and mild cognitive impairment (MCI) is important for early and effective intervention. This study aimed to conduct a preliminary evaluation of the utility of the Japanese version of the Cognitive Function Instrument (CFI-J), which is a self-administered questionnaire that sensitively detects decline in activities of daily living due to minor cognitive decline.

Methods: Twenty outpatients (6 cognitively normal and 14 with MCI) at a single memory clinic participated; patients rated themselves in the self-CFI-J, and were rated by accompanying family members in the partner-CFI-J. On the same day, neuropsychological tests (i.e. the Alzheimer's Disease Assessment Scale-Cognitive Subscale, Logical Memory I & II of the Wechsler Memory Scale-Revised, Mini-Mental Examination, Clinical Dementia Rating, Frontal Assessment Battery, and the Geriatric Depression Scale-15) were also administered to patients, and a second CFI-J was administered approximately one month later.

Results: The intra-class correlation coefficient (95% confidence interval) of the CFI-J at the one-month interval was .442 [.008, .739] for the self-CFI-J and .811 [.566, .925] for the partner-CFI-J. The MCI group had a significantly higher partner-CFI-J score than the cognitively normal group. Both the self-CFI-J and partner-CFI-J scores were not correlated with any of the neuropsychological test scores.

Conclusion: The present study confirmed the test-retest reliability of the CFI-J. The partner-CFI-J adequately reflected the patients' stage of cognitive functioning. However, concurrent validity with neuropsychological tests was not confirmed, suggesting that use of the CFI-J as a self-administered questionnaire in patients with obvious memory impairment should be treated with caution.

Keywords : Activities of daily living, dementia, mild cognitive impairment, test-retest reliability, screening

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Introduction

Alzheimer's disease (AD), a typical degenerative disease that induces dementia, is often preceded by a preclinical phase in which there are changes in the brain (e.g. accumulation of beta-amyloid) but no clinical symptoms[1]. It is also often preceded by a prodromal phase (mild cognitive impairment [MCI]), in which there is objective cognitive decline but no decline in activities of daily living (ADL). Early identification of high-risk individuals in the preclinical or prodromal stages of dementia is very important. Previous studies have shown that interventions such as physical exercise and nutritional management can help revert older adults with MCI or minor cognitive decline back to normal cognitive function[2]. Furthermore, the target of drug discovery for disease-modifying drugs has shifted to the prodromal or preclinical stages due to the development of research on biological biomarkers such as beta-amyloid and tau levels in the cerebrospinal fluid[3]. It is very important to detect MCI or minor cognitive decline as early as possible and to prevent the progression to dementia (or delay the onset of dementia) through early therapeutic interventions, as this

will not only benefit the patients but will also reduce social burdens such as national health care costs[1].

Neuropsychological testing is a reasonable method for detecting cognitive decline. However, the Mini-Mental State Examination (MMSE), which is widely used as a screening test for cognitive function, does not have sufficient sensitivity or specificity to detect MCI, and is not very effective in detecting minor changes[4]. By contrast, complex cognitive function tests such as the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) and the Wechsler Memory Scale-Revised (WMS-R) can provide detailed assessments; however, these tests have limitations, such as the long time required to complete them and the need for a skilled examiner. In addition, all of the neuropsychological tests referred to above can only be performed when patients or family members complain of subjective cognitive decline and visit a specialist in a hospital. If it were possible to detect minor cognitive decline and risk of future cognitive decline more easily early on, that is, in community-based health check-ups, it would be possible to provide earlier therapeutic intervention.

In response to this issue, a research group from the Alzheimer's Disease Cooperative Study (ADCS) developed the Cognitive Function Instrument (CFI) as an assessment method to sensitively detect decline in ADL abilities due to cognitive decline, and reported its potential utility in February 2015[5]. The CFI can be used by self-administration, interviews, or telephonically and consists of 14 questions about daily life. In addition to the self-CFI, which is answered by the subjects themselves, the partner-CFI, which is answered by a person who is familiar with the subject's living situation, has been developed, and the total score of both versions of the CFI can be calculated. In a previous study[5], 468 elderly people who were considered cognitively normal at baseline were followed up for four years and assessed with the CFI at baseline and annually, in addition to being assessed using various neuropsychological tests. It was found that the subjects' CFI scores at baseline were significantly worse (higher) in the group that developed MCI or dementia during the follow-up period than in the group that did not, and that CFI scores in the group that developed MCI or dementia worsened (increased) over time. Thus, the CFI may be useful as an assessment method for detecting decline in ADL abilities that are due to cognitive decline from the stage before clinical diagnosis of MCI or dementia. The Norwegian[6] and Italian[7] versions of this test have already been developed, and their reliability and validity have been confirmed.

In this study, we developed a Japanese version of the CFI, which so far has not been translated, and conducted a preliminary evaluation of its utility by examining its test-retest reliability and validity in the memory clinic at Kobe University Hospital.

Methods

Subjects

Among those who visited the memory clinic at Kobe University Hospital during the study period from December 2016 to August 2020, subjects were selected based on specific selection and exclusion criteria. The selection criteria were as follows: (1) outpatients whose general cognitive function was judged by their physician, who was a dementia specialist, to be at the normal or MCI level; (2) patients who were scheduled to undergo a set of neuropsychological tests at the memory clinic (see below); (3) those who lived with or had a family attendant who had contact with the patient at least twice a week; and (4) those who verbally agreed to participate in the study. The exclusion criteria were as follows: (1) those judged to have obvious intra- or inter-day fluctuations in their cognitive function level; (2) those diagnosed as having schizophrenia, mood disorders, or other psychiatric disorders; and (3) those judged inappropriate for participation in the study for other reasons. After a series of routine examinations, patients with higher abilities were diagnosed as cognitively normal. Others were diagnosed with MCI according to the following criteria: (1) patients with a score missing on the MMSE, a clinical dementia rating (CDR) of 0.5 and an ADAS-Cog of less than 15; (2) considering the patient's educational history and pre-morbid abilities, a score of only serial 7 on the MMSE was not treated as a score loss; (3) a clear decrease in the score of II from the score of I in the Logical Memory of the WMS-R; and (4) no obvious depressive symptoms. The subjects were orally informed of the study by their physicians, and oral informed consent was obtained and recorded in their medical records. This study was approved by the ethics review committee of Kobe University Hospital.

A total of 21 dyads were collected, of which one dyad was excluded from the analysis because the patient was judged to be cognitively normal but significantly depressed, according to a medical record data check following data collection. Consequently, 20 dyads were analysed.

Cognitive Function Instrument-Japanese version (CFI-J)

First, we obtained permission from the original author of the Mail-In Cognitive Function Screening Instrument (MCFSI)[8], the original version of the CFI, to translate and use it in the Japanese version. The self-CFI and partner-CFI questions were translated into Japanese by two physicians specialising in dementia and one physician specialising in clinical research, both affiliated with Kobe University. In the original version of the self-CFI, question 10 was "Has your work performance (paid or volunteer) declined significantly comparedto one year ago?" However, in consideration of the difference in cultural and linguistic nuance,

this question was changed in the self CFI-J to "Has your work (paid or volunteer) or household chore performance declined significantly compared to one year ago?" The same change was applied to the partner's CFI-J assessment. As in the original version of the CFI, the 14 questions asking about changes in ADL in the past year were scored on a scale consisting of 1 (yes), 0.5 (maybe), and 0 (no), and the total score was calculated (range: 0–14). If a question did not apply (e.g. a person who did not hold a driver's license was asked about driving), the score for that item was set to zero after confirmation with the author of the original version of the CFI.

Both the first self-CFI-J and partner-CFI-J assessments were administered on the same day (time point 1: T1) as neuropsychological tests at the memory clinic (see below), and the second CFI-J assessment was sent to the subject's home by mail four weeks later (time point 2: T2) and returned by mail. In cases where the CFI-J was not returned at T2 for unknown reasons, only the data from T1 were used in the analysis. In addition, for one case in which the person who wrote the partner CFI-J at T2 was different from that at T1, only the data from T2 were treated as missing values.

Table 1. Characteristics of the CFI-J respondents

self-CFI-J respondents	
Mean age (SD)	76.6 (7.9)
Female sex, n (%)	11 (55.0)
Diagnosis, n (%)	
CN	6 (30.0)
MCI	14 (70.0)
partner-CFI-J respondents	
Mean age (SD)	64.7 (11.1)
Female sex, n (%)	15 (75.0)
Relation, n (%)	
Spouse	12 (60.0)
Child	7 (35.0)
Sibling	1 (5.0)

CFI-J, Cognitive Function Instrument-Japanese version; SD, standard deviation; CN, cognitively normal; MCI, mild cognitive impairment

Neuropsychological tests

The results from a set of neuropsychological tests performed as part of the usual practice in a memory clinic were collected from the medical records. The following assessments were performed: ADAS-Cog, Logical Memory (LM) I and II of the WMS-R, MMSE, clinical dementia rating (CDR), frontal assessment battery (FAB), and geriatric depression scale-15 (GDS). For reasons such as limited clinical time, some of the tests in the neuropsychological test set may have been omitted or performed on a different day. Tests for which data were not available on the same day as the CFI-J assessment (i.e. four datasets from the MMSE, six datasets from the CDR, and two datasets from the GDS) were treated as missing data.

Statistical analysis

The median and interquartile range (IQR) of the CFI-J and neuropsychological test scores were calculated for all subjects, and they were grouped according to their diagnosis; the groups were compared using the Mann-Whitney U test. The intra-class correlation coefficient using a two-way random effects model (ICC) and 95% confidence interval (CI) were used to evaluate the test-retest reliability of the CFI-J between T1 and T2. To assess concurrent validity, the association between CFI-J scores and each neuropsychological test score was evaluated using the partial rank correlation coefficient (Spearman's rho) with age and sex as adjusted variables. Statistical significance was set at $P < .05$. Statistical analyses were performed using SPSS version 27 (IBM Corp., Armonk, NY, USA).

Results

Characteristics

Table 1 shows the characteristics of the self-CFI-J and partner-CFI-J respondents. The mean (standard deviation [SD]) age of the self-CFI-J respondents was 76.6 (7.9) years; 11 (55%) subjects were female, six subjects were diagnosed as cognitively normal (CN), and 14 were diagnosed with MCI. The mean (SD) age of the partner CFI-J respondents was 64.7 (11.1) years, 15 (75%) were female, and the relationships of partner to participant included 12 (60.0%) spouses, seven (35.0%) children, and one (5.0%) sibling. The mean (SD) interval between the two CFI-J assessment dates was 32.0 (4.2) days.

CFI-J and neuropsychological tests

The CFI-J and neuropsychological test scores are shown in Table 2. The median (IQR) self CFI-J and partner CFI-J scores at T1 were 4.3 (3.5) and 4.5 (5.5), respectively, and those at T2 were 4.5 (2.0) and 5.3 (5.5), respectively. The median (IQR) neuropsychological test scores were 7.1 (6.7) for the ADAS-Cog, 11.5 (12.0) for the LM I, 4.5 (13.0) for the LM II, 27.0 (5.0) for the MMSE, 1.8 (1.9) for the CDR-Sum of Boxes (CDR-SB), 14.0 (5.0) for the FAB, and 4.0 (5.0) for the GDS. The CDR-global (CDR-G) score was 0.5. There was a significant difference between the CN and MCI

groups in the partner CFI-J assessment (P = .033 at T1; P = .010 at T2), but not in the self-assessment (P = .968 at T1; P = .579 at T2) (Figure 1). There were also significant differences in the neuropsychological test scores between the CN and MCI groups in the ADAS-Cog (P < .001), LM I (P = .012), LM II (P = .003), MMSE (P = .001), and CDR-SB (P = .044) tests, but not in the FAB (P = .179) and GDS (P = .143) tests.

Test-retest reliability and concurrent validity

Figure 2 shows the results of plotting the scores at T1 and T2 for the self- and partner-CFI-J assessments, respectively. The intra-class correlation coefficient [95% CI] for the two CFI-J scores, which were assessed approximately 4–5 weeks apart, was .442 [.008, .739] (P = .025) for the self- and .811 [.566, .925] (P < .001) for the partner-CFI-J assessments. Although the sample size for both groups is small, in the CN group, the correlation was significant only for the self-CFI-J [.892 (.416, .984)], and in the MCI group, the correlation was significant only for the partner-CFI-J [.782 (.425, 928)].

Both self-CFI-J and partner-CFI-J scores at T1 did not correlate with any of the neuropsychological tests.

Table 2. Results of the CFI-J and neuropsychological tests

Assessment	n	All	Diagnosis				*P* value
			n	CN	n	MCI	
CFI-J (T1)							
self	20	4.3 (3.5)	6	3.5 (5.1)	14	4.5 (3.6)	.968
partner	20	4.5 (5.5)	6	2.8 (3.3)	14	5.5 (6.0)	.033
CFI-J (T2)							
self	19	4.5 (2.0)	6	4.5 (3.6)	13	4.5 (2.0)	.579
partner	18	5.3 (5.5)	5	3.0 (1.0)	13	6.0 (6.5)	.010
ADAS-Cog	20	7.1 (6.7)	6	3.4 (3.5)	14	10.4 (5.8)	<.001
LM I	20	11.5 (12.0)	6	21.5 (18.0)	14	9.5 (8.0)	.012
LM II	20	4.5 (13.0)	6	16.5 (16.0)	14	0.5 (6.0)	.003
MMSE	16	27.0 (5.0)	4	All 30 (full)	12	26.5 (4.0)	.001
CDR-SB	14	1.8 (1.9)	2	All 0.5	12	2.0 (2.3)	.044
FAB	20	14.0 (5.0)	6	16.0 (4.0)	14	13.5 (4.0)	.179
GDS	18	4.0 (5.0)	5	8.0 (6.0)	13	3.0 (5.0)	.143

Data are presented as median (interquartile range). *P* value represents the results of the Mann-Whitney *U* test. T1, time point 1 (same day as neuropsychological testing); T2, time point 2 (approximately one month after T1); CN, cognitively normal; MCI, mild cognitive impairment; CFI-J, Cognitive Function Instrument-Japanese version; ADAS-Cog, Alzheimer's Disease Assessment Scale-Cognitive Subscale; LM I & II, Logical Memory I & II of the Wechsler Memory Scale-Revised; MMSE, Mini-Mental Examination; CDR-SB, Clinical Dementia Rating-Sum of Boxes; FAB, Frontal Assessment Battery; GDS, Geriatric Depression Scale-15.

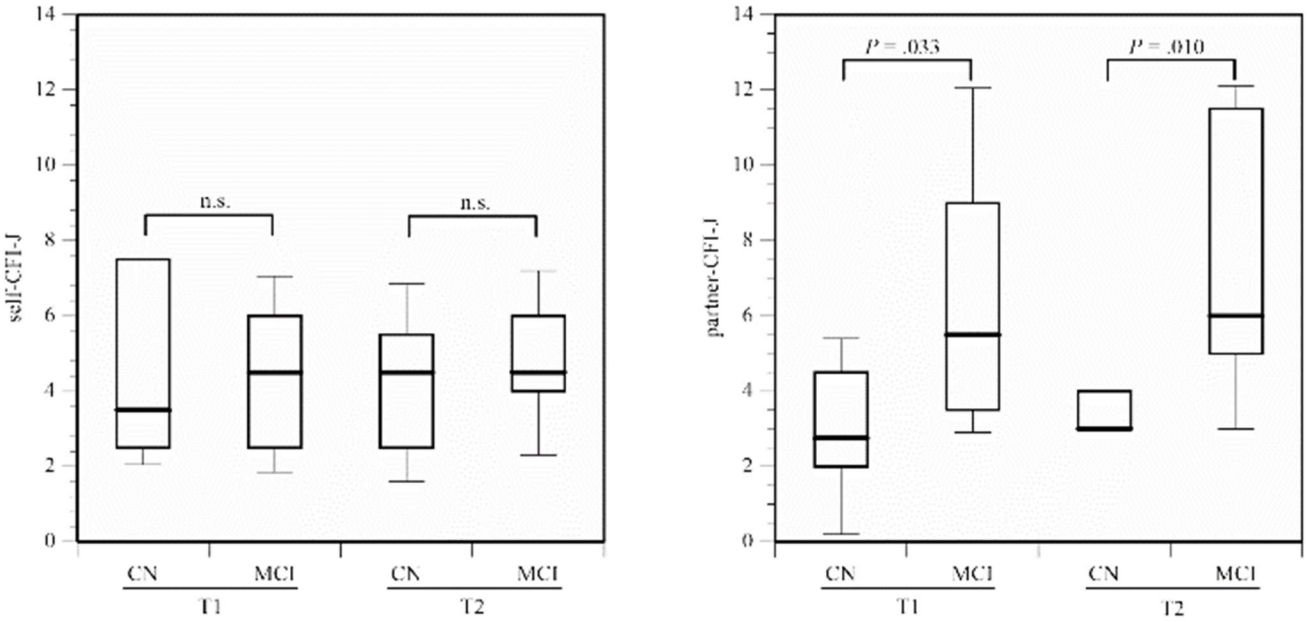

Figure 1. Box plots of group differences between the CN and MCI groups in the CFI-J scores at each time point.
The whisker boundary shows the 10th percentile (lower) and 90th percentile (upper). The Mann-Whitney U test was used for statistical analysis. T1, time point 1 (same day as neuropsychological testing); T2, time point 2 (approximately one month after T1); CN, cognitively normal; MCI, mild cognitive impairment; n.s., not significant.

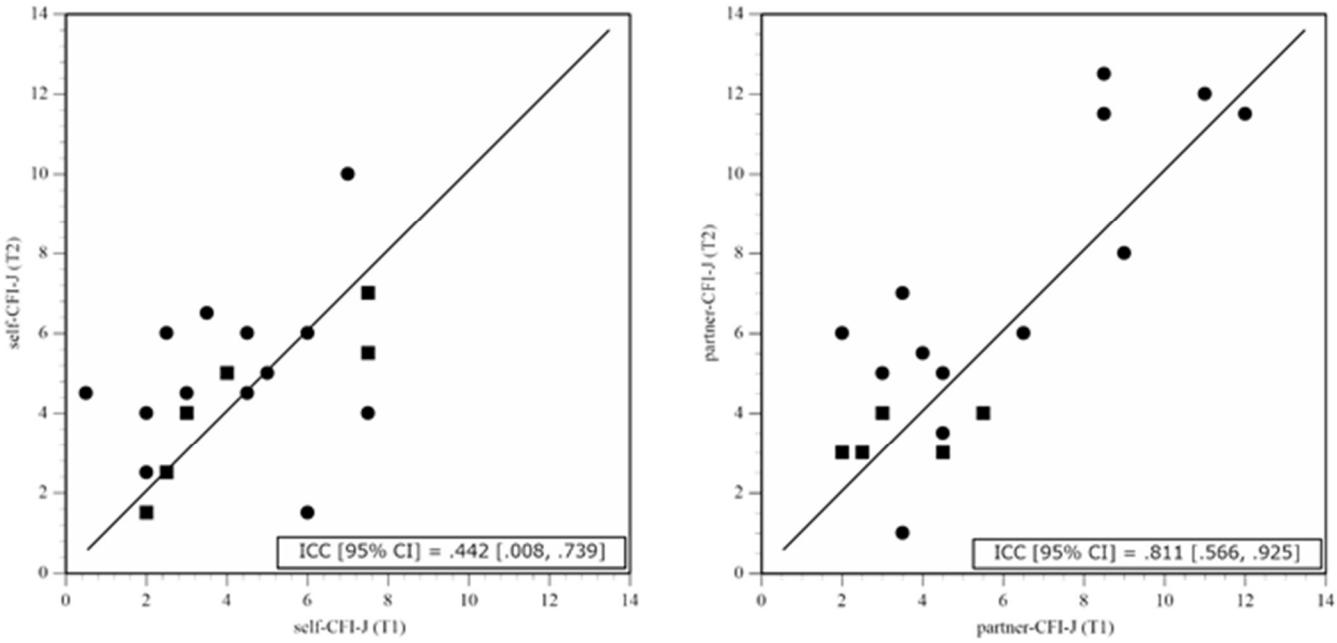

Figure 2. Intra-class correlation coefficients between T1 and T2 for the CFI-J.
The square plots represent the cognitively normal group, and the circles represent the mild cognitive impairment group. The reference lines of Y equal to X are shown in each figure. T1, time point 1 (same day as neuropsychological testing); T2, time point 2 (approximately one month after T1); ICC, intraclass correlation coefficient; CI, confidence interval.

Discussion

This study has provided certain findings on the properties of the CFI-J that have not been previously investigated. The test-retest reliability of the CFI-J was found for both self and partner assessments, and the partner-CFI-J score adequately represented the subject's status (CN or MCI). By contrast, concurrent validity with the neuropsychological tests used in the memory clinic was not found for either the self-CFI-J or partner-CFI-J assessments.

The ICC point estimate of .442 for the two self-CFI-J scores in the present study is considered to indicate moderate test-retest reliability, referring to the criteria given by Landis et al[9]. According to a previous study of the ADCS[10], the ICC [95% CI] of the self-CFI assessment at 3-month intervals was reported to be .75 [.69, .80] in 497 subjects with a CDR-G score of 0 and .72 [.59, .81] in 147 subjects with a CDR-G score of 0.5. Another previous study of the ADCS reported an ICC of .73 for the self-CFI assessment at 12-month intervals in 209 subjects, all of whom had a stable CDR-G of 0 and were APOE ε4 non-carriers, during four years of observation[5]. Compared to these data, the ICC of the self-CFI-J in this study was considered to be slightly lower. This may be related to the fact that the study was conducted only on outpatients in the memory clinic. According to a previous longitudinal study of community-dwelling elderly subjects with a CDR-G of 0 at baseline, CDR-G progressors (from 0 to 0.5, or higher) already showed an increasing trend in the self-CFI scores three months after baseline[5]. Generally, in Japan, the reason why a person with CN or MCI would visit an outpatient memory clinic is often due to the presence of a greater than normal decline (subjective or objective) in cognitive and ADL function and the need for specialised monitoring of these changes. Therefore, the self-CFI-J scores in this study were higher for more participants in the second experiment than in the first experiment (Figure 2), which may have resulted in a moderate ICC. The partner CFI-J assessment showed sufficient agreement ('almost perfect' according to the criteria by Landis et al.[9]), confirming the test-retest reliability at intervals of approximately one month. Additionally, the fact that this study was conducted in a clinical setting may explain why the ICC of the partner CFI-J was higher than that of the self-CFI-J. In addition to the patient's own factors of instability in cognitive functioning and psychological state, the characteristics of the family members who accompany the patient to the clinic may also play a role. The patient is usually accompanied to the memory clinic by someone who is familiar with the patient's usual living situation. The CFI question "Compared to one year ago..." may have resulted in a higher ICC, as the family members or attendants could have assessed it more objectively and reproducibly than the patients themselves.

The partner-CFI-J score was significantly higher in the MCI group than in the CN group and was considered to adequately reflect the decline in ADL ability due to minor cognitive decline. Previous studies have shown that CFI scores for both self and partner assessments were higher in the MCI group than in the CN group[6], and higher in the CDR-G 0.5 group than in the CDR-G 0 group[10]. For the partner-CFI-J, the results were similar to those of these previous studies and were considered to have some validity, but in respect of the self-CFI-J results, we were not able to confirm such inter-group differences. It has been suggested that the self-CFI and partner-CFI may differ in the accuracy with which they reflect the abilities of the subjects, depending on the target population. Specifically, it has been reported that in the CDR-G 0 group, the self-CFI and partner-CFI scores at baseline and the change in scores after two years were predictive of the change in the subject's cognitive function after two years, but in the CDR-G 0.5 group, only the change in the partner-CFI-J score was predictive[10]. In addition, in a previous study that examined whether dementia and MCI could be discriminated by receiver operating characteristic (ROC) analysis, the AUCs [95% CI] of the self-CFI and partner-CFI were .58 [.48, .67] and .79 [.70, 88], respectively, and it was reported that only the partner CFI showed significant discriminatory performance[6]. It is well known that MCI and AD are associated with impaired functioning of the dorsolateral prefrontal cortex (DLPFC), a central neural basis for working memory and executive function, and a recent study using macaque monkeys has shown that the DLPFC is specifically involved in the ability to reflectively monitor past experiences[11]. In this study, 14 out of 20 subjects were diagnosed with MCI, and 10 (71.4%) scored less than 4 points on the LM II. The results suggest that by using self-administered questionnaires in subjects with MCI who have obvious memory impairments, it may be difficult to detect a decline in ADL ability that is associated with minor cognitive decline.

There was no correlation between the CFI-J scores and neuropsychological test scores in this study, suggesting that the CFI-J should be used with caution as a cross-sectional screening tool for cognitive function in memory clinics. This result differs from previous studies[5,7], and unfortunately, the reasons for this difference are unclear. A previous study of the Japanese version of the Everyday Memory Checklist (EMC)[12,13], a self-administered questionnaire specific to memory impairment, in patients with mild AD, reported that the correlation with the LM II score was found only with EMCs rated by family caregivers and not with patient self-ratings. The results of the self-CFI-J may have been influenced

by the inclusion of subjects with obvious memory deficits, but it was difficult to fully discuss the results of the partner-CFI-J.

The present study had several limitations. The first is the effect of a small sample size. According to Bonnet[14], approximately 100 subjects are needed to estimate an ICC [95% CI] of approximately .7 [.6, .8]. The confidence intervals for the ICCs of the self-CFI-J in this study are very wide, and further subject aggregation is needed for a more accurate analysis. For correlation analysis with neuropsychological test scores, a number of subjects less than 200 would be required to estimate a Spearman's rank correlation coefficient of approximately .2 with a statistical power of 0.8, comparable to previous studies[7]. The lack of correlation between the CFI-J and neuropsychological tests could be the result of a statistical type II error. Second, as mentioned several times in this discussion section, the demographics of the study population are very limited; therefore, caution should be exercised when generalising the results of this study to people of other demographics. Finally, although this study focused only on the CFI-J at a single point in time, previous studies have used not only the score at a single point in time, but also the amount of change from baseline to months or years later as a measure.

In this study, partly because of the aforementioned limitations, we could not completely prove the retest reliability of the self-CFI-J, nor could we confirm the concurrent validity of the CFI-J. Nevertheless, because it can be conducted easily, the CFI-J is an appropriate measure for the early identification of high-risk individuals with dementia in community health check-ups and large-scale surveys, although, further studies are needed. Some of our members are currently conducting the CFI-J assessments in cognitively normal elderly people living in the community as part of another research project to observe changes in the CFI-J and cognitive function over time. It is envisaged that the CFI-J will be validated as an assessment method to detect minor cognitive decline in elderly people with normal cognitive function and extensively used following revisions and other developments.

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Disclosure statement

The authors have no potential conflicts of interest to disclose.

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