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Original Article

Development and validity of an evaluation of higher cortical dysfunction in the daily life of patients with stroke and traumatic brain injury

Hiroyuki Miyasaka, OTR, PhD,[1,2] Wataru Narita, MD, PhD,[2,3] Yuuki Nakagawa, OTR,[2] Rieko Kanamori, SLHT,[2] Maki Ohshita, SLHT,[2] Satsuki Kawakami, OTR,[2] Koji Shimomura, CSW,[2] Izumi Kondo, MD, PhD,[1,4] Shigeru Sonoda, MD, PhD[1,2,5]

[1]Fujita Memorial Nanakuri Institute, Fujita Health University, Tsu, Mie, Japan
[2]Fujita Health University Nanakuri Memorial Hospital, Tsu, Mie, Japan
[3]Department of Behavioral Neurology and Cognitive Neuroscience, Tohoku University Graduate School of Medicine, Sendai, Miyagi, Japan
[4]National Center for Geriatrics and Gerontology, Obu, Aichi, Japan
[5]Department of Rehabilitation Medicine II, School of Medicine, Fujita Health University, Toyoake, Aichi, Japan

ABSTRACT

Miyasaka H, Narita W, Nakagawa Y, Kanamori R, Ohshita M, Kawakami S, Shimomura K, Kondo I, Sonoda S. Development and validity of an evaluation of higher cortical dysfunction in the daily life of patients with stroke and traumatic brain injury. Jpn J Compr Rehabil Sci 2016; 7: 61−72.

Purpose: To develop a valid Cognition-oriented Performance Evaluation (COPE) questionnaire for the evaluation of higher brain function in any environment using the nominal group technique (NGT).

Method: The NGT participants included nine expert staff members of our hospital. The NGT process was performed twice and involved: 1) enumerating questions regarding the presence or absence of higher cortical dysfunction symptoms, 2) judging each item on a four-point scale and posing additional questions, 3) determining the level of agreement across participants using the NGT, and 4) modifying, removing, and adding questions based on the agreement and comments of the NGT participants. In addition, a correlation analysis between COPE areas and the social cognition items of the Functional Independence Measure (FIM) was performed in 20 patients with higher cortical dysfunction.

Results and discussion: An initial 126 questions were crafted prior to the NGT. During the first NGT, 12 items failed to achieve adequate agreement, and during the second NGT, three items failed. Furthermore, we coordinated the expressed opinions after the second NGT. The final version contained 96 items. Correlation analysis demonstrated significant correlation between the COPE and FIM in related items such as memory and problem-solving. Thus, the validity of the COPE was verified using a qualitative research technique (consensus method) and by correlation with another scale.

Key words: cerebrovascular disease, higher cortical dysfunction, ADL (activities of daily living), evaluation, validity

Introduction

Cerebral damage from stroke and traumatic brain injury induces higher cortical dysfunction including inattention, memory impairment, executive dysfunction, and social behavior disorders [1,2]. Several neuropsychological tests have been developed to evaluate higher cortical dysfunction in patients [3−6]. The Neurobehavioural Rating Scale (NRS), Neurobehavioral Functioning Inventory (NFI), Patient Competency Rating Scale (PCRS), and the cognitive-behavior scale for traumatic brain injury (TBI-31) have been used for the evaluation of neurobehavioral abnormalities [7−10]. These questionnaire evaluations include items regarding physical symptoms, cognitive function, daily living activities, and personal relationships, assessing the degree of disability using Likert scales with 4−6 points. The validity and reliability of these questionnaires have been confirmed and they have been used in clinical situations.

However, it has been reported that the recognition of higher cortical dysfunction and clinical findings

Correspondence: Hiroyuki Miyasaka, OTR, PhD
Fujita Memorial Nanakuri Institute, Fujita Health University, 423 Oodori, Tsu, Mie 514−1296, Japan.
E-mail: hmiyasak@fujita-hu.ac.jp
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differs between patients and others. For example, Hart et al. [11] reported that recognition of a problem in communication, aggression, and memory was different between patients with traumatic brain injury and others. Moreover, Seel et al. [12] reported that there was a difference in the recognition of a problem in communication between the patient and the family. Furthermore, Port et al. [13] reported that there was a difference between the patients themselves and the rater only in executive function among six areas such as cognition, memory, or emotion. The difference between these research results may be related to the severity of disturbance in the patient's consciousness as well as the contents of the evaluation scales. Moreover, regarding higher cortical dysfunction, it is possible for a symptom to be different in specific conditions or environments (e.g., hospital, home, or workplace). However, existing questionnaires do not consider different situations and environments for every response. Thus, it is difficult to observe changes in symptoms using one evaluation tool throughout both the acute and chronic phase of the disease or injury.

Therefore, we developed the Cognition-Oriented Performance Evaluation (COPE) questionnaire to evaluate higher cortical dysfunction in every environment using the nominal group technique (NGT), which is a consensus method. Furthermore, we examined the construct validity to confirm the clinical significance of the COPE using a correlation analysis with social cognition items of Functional Independence Measure (FIM).

Methods

1. The nominal group technique

We used the NGT to develop the COPE and examine its content validity. The consensus method, a qualitative study method, has been used to examine and obtain consensus for inconclusive issues for which there is insufficient scientific evidence or conflicting arguments exist [14]. NGT is a representative consensus method and has often been used in the field of health science [15,16].

2. NGT participants

The NGT participants consisted of nine experts working at a clinic for higher cortical dysfunction in a comprehensive rehabilitation ward of our hospital (three medical doctors (MD), three occupational therapists (OT), two speech-language-hearing therapists (ST), and one certified social worker (CSW)). The MDs had 28, 26, and 4 years of clinical experience, respectively. In addition, two of the MDs had a board license for rehabilitation medicine. The OTs had 13, 7, and 6 years of clinical experience. The two STs both had 6 years of clinical experience and the MSW had 4 years. The CSW had worked for 5 years as a higher cortical dysfunction support coordinator in a previous job. In addition, one of the MDs served as a facilitator for the NGT and was in charge of feedback regarding results and conducting the meetings.

3. Questionnaire development and discussion using the NGT

Initially, the facilitator requested that NGT participants enumerate potential questions for the COPE. The concept of making a question for the COPE was taught to the participants with the requirements that: 1) the question was usable in every environment of the home and for those hospitalized due to higher cortical dysfunction, 2) the question was easy to understand, and 3) the question could be answered with a "Yes" or "No." Thereafter, the facilitator requested the participants to score and organize the questions. The content of the question was scored using four points (4: should be adopted, 3: may be adopted, 2: cannot say, 1: should not be adopted). Moreover, questions and comments for each item were recorded. The participants then discussed the agreement or non-agreement of each item using the NGT. This study used an agreement criterion of a median of 2.1 points or more, which was set in advance [17].

Based on the results of the first NGT, some items were deleted or modified, creating a second version of the questionnaire. A second NGT was performed, and the questionnaire was further adjusted based on the results of the second NGT, creating the final version of the questionnaire. In addition, the final version was scored and examined for agreement and disagreement.

4. Construct validity

After confirming the content validity using the NGT, we verified the construct validity using the following hypotheses to clarify the clinical significance of the COPE. We hypothesized that the COPE memory, empathy and cooperation, attention, emotion, motivation, and executive areas would show high correlation with the corresponding memory, social interaction, and problem-solving areas of the FIM, while other COPE areas that were not included in the FIM would have low correlation. Therefore, we evaluated the correlation between three areas (memory, problem-solving, and social transaction) of the FIM social cognition scale and the COPE in 20 inpatients or outpatients with higher cortical dysfunction from Fujita Health University Nanakuri Memorial Hospital, the Mie Prefectural Welfare Center for Persons with Physical Disabilities, or Matsusaka Central General Hospital. Patient characteristics are shown in Table 1.

The total score for each COPE area was calculated and the Spearman's rank correlation coefficient with each FIM area was evaluated. A p-value less than 0.05 was considered statistically significant.

Table 1. Patient characteristics.

Number of patients	20
Age (mean ± SD) [year]	43.2 ± 15.3
Sex (male / female)	13 / 7
Etiology	
Stroke	8
TBI	9
Other	3
Status	
Inpatients	16
Outpatients	4
Days after onset (mean ± SD)	511.1 ± 641.7
FIM cognitive item	26.9 ± 3.8

SD, Standard deviation; TBI, Traumatic Brain Injury; FIM, Functional Independence Measure.

Results

A total of 126 potential questions were initially crafted and presented to the participants prior to the first NGT (Table 2). Table 3 shows the results of NGT of this study.

1. Result of the first questionnaire and NGT

Twelve items did not reach agreement criteria in the first questionnaire. Disagreement occurred most frequently in the area of memory (6/32 items). While most items reached the agreement criteria, eighty-nine items contained comments regarding the need for modification of the contents of the question. Example comments are as follows: "the contents of an overlapping question need to be integrated," "should be evaluated in another area," and "should be more

Table 2. Initial questions for each area enumerated before the NGT.

Area	Question
Memory	I don't know the date and day in a tense situation (medical examination, phone, etc.).
	I don't know the date and day in daily conversation.
	I notice that the date or the day is wrong by checking a calendar.
	I cannot recall that I was told to memorize something in a tense situation.
	I have asked someone to repeat the content of everyday conversation.
	I forget what to do after going to the toilet.
	I forget what I should be doing from a conversation while working.
	I have an appropriate daily routine.
	I need to check the schedule book for daily tasks.
	I need to have someone teach me daily tasks.
	I remember and execute plans for tomorrow.
	I can recall something scheduled 1 week later.
	I can recall something scheduled 1 month later.
	I forget the schedule of something that occurs once a week.
	I forget the schedule of something that occurs once a month.
	I remember without looking at the notes for your schedule.
	I manage the plan by using a notebook.
	I remember your birthday or anniversary.
	I am conscious of the necessity of training to improve memory function.
	I am not troubled by forgetfulness.
	I get lost in the home, hospital room, or at work.
	I get lost around the home or workplace.
	I cannot remember a new location.
	I get lost when going out.
	I can come back somehow and get lost.
	I cannot remember a person's face after meeting the first time.
	I cannot remember a person's name after the meeting the first time.
	I cannot remember the relationship between us the first time we met in person.
	I forget a written memo of requirements.
	I remember that I have got a memo, but I don't remember the contents.
	I cannot recall the memory of going out and traveling.
Attention	I am sometimes said to be restless.
	I often do something else before folding the clothes that I take off.
	I cannot fold 10 towels.
	I cannot listen to conversations in daily living until the end.
	I cannot listen to explanations of medical examinations and in the workplace until the end.
	I cannot clean up around the bed and room.
	I sometimes stop in the middle of doing something.
	I get frustrated during work.

Table 2. Continued.

Area	Question
	I space out during work.
	I soon want to take a rest.
	I talk on a different topic during conversations, one after the other.
	I cannot summarize the contents of a conversation.
	I am distracted from eating.
	I take care of other people while working.
	I collide with people or obstacles when talking while walking.
	I collide with people or obstacles when lost in thought while walking.
	I cannot take notes while listening to conversations.
	I cannot continue to work while talking.
	I forget how many when I receive two or more instructions.
	I am conscious of the necessity of training to improve attentiveness.
	I cannot follow the conversation when the topic is changed.
	There are times I do not understand what a person says.
	I am not good at talking with others.
	I cannot keep up with the topic when speaking with a lot of people.
	I have become slow at thinking.
	I have become slow at calculating.
	Small failures or errors have increased.
	I am not aware of calling out when I am concentrating on other things.
	I am often curious about other things.
	I don’t like changing to the next work item.
Emotion	My mood changes easily.
	I am frustrated too easily.
	I sometimes shout.
	I easily get frustrated.
	I am sometimes violent when angry.
	I am conscious of the necessity of training to control emotion.
	I become pessimistic too easily.
	I become depressed too easily.
	I sometimes become depressed in one day.
	I become childish.
	I sometimes suddenly cry.
	I sometimes suddenly laugh.
	I can suppress emotion.
Empathy and coordination	I speak what I want to say without thinking about the situation.
	I laugh in a serious situation.
	I cannot adjust to the schedule of the ward and work.
	I cannot keep a promise of the ward and work.
	I cannot greet acquaintances.
	I cannot greet others.
	I feel a need for training to live in a group smoothly.
	I hardly change my mind once it’s made up.
	I am not good at guessing a person’s thoughts.
	I speak as soon as I think of something.
	I am often warned by others.
Execution	I cannot take action after a sudden change in my schedule.
	I cannot behave as intended at the outset when there is a sudden change in the schedule.
	I can respond flexibly even if something differs from usual.
	I cannot take action since the things I am worried about stay in my mind all day long.
	I am conscious of the necessity of training in the ability to achieve goals.
	I cannot decide the priority of things.
	I can plan behavior.
	I cannot consider things in order.
	I repeat the same mistakes.
	Someone says it is dangerous when I think it is no problem.
Motivation	I rest in bed or a chair all day.

Table 2. Continued.

Area	Question
	I am reluctant to behave.
	I can behave when needed by others.
	I can act appropriately if someone prepares an adequate tool and guides me to a specific place.
	I continue when encouraged by somebody.
	I can do anything by using a schedule table.
	I take action by myself.
	I cannot put up with favorites.
	I eat food in spite of likes and dislikes.
	I quickly use up money.
	I buy things impulsively.
	I am conscious of the necessity of training to increase motivation and spontaneity.
	I am slow to react.
	I get sleepy and yawn quickly.
	I don't have any ideas.
	I am difficult to judge.
	I depend on others for trivial things.
Others	I need assistance in self-care.
	I often have an excuse.
	I become anxious without confirming many times.
	I can consult with others when in trouble.

specific (time or situation)." Examples or definitions of low agreement or commented upon were clarified. For example, "hours worked" was defined in the "forget when discussed during work with somebody" item within the memory area, and a concrete example and situation were added to the "cannot behave with consideration for surroundings" item in the sympathy and cooperation area. In addition, requested modifications included clarifying the specific examples and definitions in order to make it easier to answer the question. Based on the first NGT, some questions were removed, content was modified, similar questions were integrated, and definitions were created. The second version of the questionnaire was reduced to 103 items.

2. Result of the second questionnaire and NGT

Three items (out of 103) did not reach agreement criteria in the second version of the questionnaire. Two items in the memory area did not reach the criteria; however, "defining a specific example," was agreed upon resulting in the addition of a question. Moreover, after having discussed the questions in the memory area, we added: "May you leave a thing?," "When you leave the room, can you turn off the power supply for the television?," and "Can you confirm fire and locking when at home?."

The emotive area included items that could all be observed in a clinic. However, we integrated an item because there was an opinion that this area was "too subdivided." Moreover, a question regarding frequency was added to the emotive questions on "cry" and "anger" because frequency differed by condition.

We judged the internal validity to be adequately verified during the second NGT and concluded the NGT process. The final number of questions was 96 with 24 items on memory, 19 items on attention, 6 items on motivation, 14 items on emotion, 16 items on empathy coordination, 12 items on execution, and 5 items considered 'other.' Table 4 shows the final version of the COPE.

3. Results of construct validity

Table 5 shows the correlation coefficients between the COPE and FIM social cognition areas. The coefficient of correlation of FIM memory item and the COPE memory was 0.57, attention was 0.47, and execution was 0.47. The coefficient of correlation of FIM problem-solving item and the COPE attention was 0.66, sympathy and cooperation was 0.66, execution was 0.73, and 'other' was 0.65. The coefficient of correlation of FIM social transaction item and the COPE emotion was 0.48, sympathy and cooperation was 0.66, and execution 0.64. Items expected to be related showed high correlation; however, there was no significant correlation between FIM social cognition areas and the COPE motivation area.

Discussion

We performed a qualitative research study to consider the content validity of the COPE using the NGT. Examination of the content validity of evaluation scales using the consensus method has been frequently reported [16,18–20]. Patients with higher cortical dysfunction require support from a variety of medical professionals in order to return to work. Therefore, we believe that consideration of the content validity using the NGT involving participants from each medical

Table 3. NGT results.

First time

	Number of items	Median			
		0–1.0	1.1–2.0	2.1–3.0	3.1–4.0
Memory	32	0	6	9	17
Attention	31	0	3	12	16
Emotion	14	0	0	3	11
Empathy and coordination	13	0	2	2	9
Execution	11	0	0	2	9
Motivation	18	0	0	12	6
Others	7	0	1	6	0

Second time

	Number of items	Median			
		0–1.0	1.1–2.0	2.1–3.0	3.1–4.0
Memory	22	0	2	12	8
Attention	23	0	0	19	4
Emotion	11	0	1	10	0
Empathy and coordination	15	0	0	12	3
Execution	11	0	0	11	0
Motivation	9	0	0	7	2
Others	12	0	0	8	4

Final version

	Number of items
Memory	24
Attention	19
Emotion	14
Empathy and coordination	16
Execution	12
Motivation	6
Others	5

profession is beneficial because the repeated discussion allows the aggregation and agreement of different opinions. Fink et al. [21] introduced various other methods regarding the agreement level and definition, and stated that it was at least necessary to clarify the agreement level before beginning the investigation. Pope et al. [17] reported that it was common to obtain consensus using the median and interquartile range. The NGT method of the current study is considered valid because the criterion was agreed upon before discussing the questionnaire and feedback was provided to the participants. Furthermore, the construct validity of the COPE in patients with higher cortical dysfunction was demonstrated by correlation with related areas on the FIM.

The number of items was largest for attention and memory. Memory impairment has been reported to be the most important factor in predicting the return to work for patients with traumatic brain injury [22–24]. In addition, more than 50% of patients with chronic stroke have memory and attention disorders [25]. Thus, within higher cortical dysfunctions experienced by patients with brain disorders, memory function is considered to be of high importance. The memory area of the COPE included items on orientation, daily routine, short-term memory, long-term memory, prospective memory, and method of compensation in order to evaluate a variety of symptoms. Given our goal that the questions be applicable to both mild and severe symptoms and could be used in both the workplace and hospital, a large number of questions was necessary. Moreover, attention has been reported to be related to memory and executive function as the basis of many higher cortical dysfunctions [26, 27]. The number of items in the attention area of the COPE was increased in order to evaluate sustained and divided attention as well as processing capacity. Examples include “Can you concentrate at work?,” “Are you aware of a trivial failure or error?,” and “Can you keep up with the topic when speaking with a lot of people?.” Some items in the memory area did not reach agreement during the NGT process. As mentioned above, the results of this study reflect the higher importance of memory function and it was considered to be discussed sufficiently by using the NGT.

The COPE used a scoring method consisting of the selection of “Yes” or “No” rather than a multi-step scale such as a Likert scale. One reason for this is that the intervals of a multi-stage scale have been reported to be unequal [28]. In addition, variations in the answer for different environments or evaluators may cause problems during judgment of a therapeutic effect. Thus, the final COPE contained 96 items. Although fewer items is preferable as this simplifies the evaluation, it may lead to the omission of an important change or effect in a clinical situation. Another advantage of the COPE includes the ability to evaluate environmental differences and differences in the degree of difficulty for specific items within an area because one area can be divided into several sub-areas. A Rasch analysis would provide information regarding the difficulty of the items.

The FIM social cognition areas were used as an external criterion for the construct validity for the COPE. Nakajima et al. [29] showed that FIM social cognition items and personal social responsibility (self-intentionality, sense of responsibility, and sociality) of the Adaptive Behavior Scale (ABS) for stroke patients are correlated. The ABS evaluates adaptability in the everyday life of patients with cognitive impairment as a screening test. Therefore, it is appropriate to use FIM social cognition items as an external criterion for the validity of the COPE. In the current study, COPE items related to memory, attention, emotion, empathy and coordination, and execution were correlated with FIM

Table 4. Questions and concrete examples of the final COPE.

Area	Number	Question	Concrete examples / notes	Respondent: Family, etc.		Respondent: His / Herself	
Memory	1	Do you know the date and day of the week?	The correct date and day in a conversation	Yes	No	Yes	No
	2	Do you get lost in familiar places? (at your home, office or hospital)?	"Familiar place" is a place where you have lived for at least a one week.	Yes	No	Yes	No
	3	Do you get lost in unfamiliar places?	"Unfamiliar place" is different from "familiar place" in question 2. If your answer of the question 2 is [No], this question must be checked as [No].	Yes	No	Yes	No
	4	Can you come back somehow if you get lost?		Yes	No	Yes	No
	5	Do you repeat what you said a few minutes ago?		No	Yes	No	Yes
	6	Do you remember what you talk about with people?	[No]: Talking about the same thing, don't remember what was confirmed in terms of the content of a recent conversation	Yes	No	Yes	No
	7	Can you describe any recent event?	[Yes]: Explainable. For example, recent news, own events, hospital test results	Yes	No	Yes	No
	8	Can you describe going out recently?		Yes	No	Yes	No
	9	Do you remember what you took notes of and the contents of a document?	Notes: phone message content, shopping list. Contents of document: a message written by someone, hospital guide, flyers, circulars, etc.	Yes	No	Yes	No
	10	Can you handle a call or pass on telephone messages?	It is possible to use a method of compensation, such as memos, etc.	Yes	No	Yes	No
	11	Do you remember what you were going to do if it was spoken to when you were doing something?	[No]: Forget when spoke to others, for example, to pick up things on shelves, get a snack, go to the rehabilitation room, call someone	Yes	No	Yes	No
	12	Do you follow a routine (for example, eating, washing your face, brushing your teeth, fixing your hair)?	Check [No] if you cannot but it is possible to remember.	Yes	No	Yes	No
	Can you remember a plan and perform it? [Yes]…Ask the following questions. [No]…Check "No" No. 13−15.						
	13	Do you remember the plan for the next day?		Yes	No	Yes	No
	14	Do you remember the plan for the next week?		Yes	No	Yes	No
	15	Do you remember an irregular schedule, for example, meeting people or staying out?	An irregular schedule: the dates and days of the week are scheduled irregularly	Yes	No	Yes	No
	16	Do you remember the face of a new person?		Yes	No	Yes	No
	17	Do you remember the name of a new person?		Yes	No	Yes	No
	18	Can you remember the relation with a person you met for the first time?		Yes	No	Yes	No
	19	Do you forget what you are going to bring and where you have put something?	Check "Yes" if one or more are applicable.	No	Yes	No	Yes
	20	Do you remember to close the gas tap and lock the door?	In the case of a hospital, the examiner asks if you can switch off the TV and lights when leaving the room.	Yes	No	Yes	No
	[21−24] Please answer the following questions if you checked a double underline in items 1 to 20 [Yes]/[No].				—		—
	21	Do you suffer from forgetting things?		Yes	No	Yes	No
	22	Are you conscious of the necessity of training to improve your memory function?		Yes	No	Yes	No
	23	Do you have any alternative means to compensate memory decline?	[Yes]: Using a notebook or mobile phone or deciding where to put things	Yes	No	Yes	No
	24	Please describe the details.	A specific method: notes, schedule book, deciding where to put things Multiple answers allowed.				
Attention	25	Do you wait for a while?	[No]: You cannot wait even when you have been told to wait and come back. You cannot wait with someone in a noisy environment. You do not wait for instructions for a medical examination or for the bus.	Yes	No	Yes	No
	26	Do you have difficulty keeping attention during meals?		No	Yes	No	Yes
	27	Can you concentrate on work?		Yes	No	Yes	No
	28	Can you finish simple work?	Specific examples of simple tasks: In the case of a hospital: simple calculation, organizing your room, etc. In the case of the home: Filling in documents (such as your address), washing the dishes, etc. In the case of the workplace: copying, shredding, organizing documents and mail, etc.	Yes	No	Yes	No

Table 4. Continued.

Area	Number	Question	Concrete examples / notes	Respondent: Family, etc.		Respondent: His / Herself	
	29	Can you finish work which takes time in the home and food preparation?		Yes	No	Yes	No
	30	Can you concentrate on what people say to you about their impressions of TV programs or news programs?	Short story: work instructions (conveying things, etc.), describing a schedule, casual talk, etc.	Yes	No	Yes	No
	31	Can you listen to the long story of a meeting, class or interview?	Long story: explanation of goods and services, etc.	Yes	No	Yes	No
	32	Do you not talk to others and digress when you were going to do something?	[Yes]: You do not talk to others and digress from achieving the aims.	Yes	No	Yes	No
	33	Do you change the topic during a conversation?		No	Yes	No	Yes
	34	If you are worried about something, can you do it?	[No]: You cannot concentrate on the meeting if you receive mail during the meeting. You cannot concentrate on training when visitors come.	Yes	No	Yes	No
	35	Can you continue to work while carrying on a conversation?		Yes	No	Yes	No
	36	Can you avoid pedestrians and obstacles while continuing a conversation?		Yes	No	Yes	No
	37	Can you take notes while listening to conversations?		Yes	No	Yes	No
	38	Are you aware of trivial failures or errors?		Yes	No	Yes	No
	39	Are you aware of calling out when you are concentrating on other things?		Yes	No	Yes	No
	40	Can you understand what you want to say to the other party in a one-to-one conversation?		Yes	No	Yes	No
	41	Can you keep up with the topic when speaking with a lot of people, for example, friends, conferences, meetings, etc.?		Yes	No	Yes	No
	42	Can you understand the contents of a TV drama/series and movies?		Yes	No	Yes	No
	[43] Please answer the following questions if you checked a double underline in items 25 to 42 [Yes]/[No].				—		—
	43	Are you conscious of the necessity of training to improve your attentiveness?		Yes	No	Yes	No
Emotion	44	Can you express emotions, for example, crying, laughing?	[No]: Do not laugh when having fun, do not cry when sad, no change in emotion, etc.	Yes	No	Yes	No
	45	Does your mood change easily?		No	Yes	No	Yes
	46	Do you think you have become childish?		No	Yes	No	Yes
	47	Do you have family or others who are seriously worried about your illness?		No	Yes	No	Yes
	48	Do you get angry and cry when you are stopped from what you want to do?	[Yes]: Even if your hopes do not come true, you can follow rules.	No	Yes	No	Yes
	49	Are you unable to change to the next work item due to panic when you have failed?		No	Yes	No	Yes
	Do you make family uncomfortable due to your mood when you get emotional? [Yes]…Ask the following questions. [No]…Check "No" No. 50, 51.						
	50	Do you do it more than once a month?	[Yes]: Cannot talk, continues laughing, yells out, suddenly cries or continues to cry, depressed, etc. Check [Yes] if any of the above are true.	No	Yes	No	Yes
	51	Do you do it more than once a week?	Same as above	No	Yes	No	Yes
	Do you make who uncomfortable due to your mood when you get emotional? [Yes]…Ask the following questions. [No]…Check "No" No. 52, 53.						
	52	Do you do it more than once a month?	Same as above	No	Yes	No	Yes
	53	Do you do it more than once a week?	Same as above	No	Yes	No	Yes
	Do you make acquaintances uncomfortable due to your mood when you get emotional at the workplace or school? [Yes]…Ask the following questions. [No]…Check "No" No. 54, 55.						
	54	Do you do it more than once a month?	Same as above	No	Yes	No	Yes
	55	Do you do it more than once a week?	Same as above	No	Yes	No	Yes
	Do you making strangers uncomfortable due to your mood when you get emotional? [Yes]…Ask the following questions. [No]…Check "No" No. 56, 57.						
	56	Do you do it more than once a month?	Same as above	No	Yes	No	Yes
	57	Do you do it more than once a week?	Same as above	No	Yes	No	Yes
Empathy and coordination	58	Can you make appropriate greetings?	[No]: Cannot be self-introduced to people at the first meeting, cannot greet acquaintances, cannot greet at the appropriate volume of voice to match the atmosphere of the place (too loud or quiet)	Yes	No	Yes	No

Table 4. Continued.

Area	Number	Question	Concrete examples / notes	Respondent: Family, etc.		Respondent: His / Herself	
	59	Can you have an appropriate conversation corresponding to the situation?	[No]: Laugh when in a sad atmosphere, say something when meeting a person for the first time about their illness or disability, etc.	Yes	No	Yes	No
	60	Can you think of the feelings of the other party?		Yes	No	Yes	No
	61	Do you have to be taken care of more than necessary?		No	Yes	No	Yes
	62	Can you understand jokes and flattering words?	[No]: Out of politeness, the next meeting is promised with a "see you again", angry when taking a joke seriously, etc.	Yes	No	Yes	No
	63	Can you talk about considering the convenience of the other party?	[Yes]: A request to speak later, leaving the place out of consideration when busy	Yes	No	Yes	No
	64	Have you been blamed about not knowing how to interact with other people?	[Yes]: Receives attention regarding speech and behavior from family, friends, the workplace and hospital staff	No	Yes	No	Yes
	65	Can you accept that it has been pointed out to other people?		Yes	No	Yes	No
	66	Do you often make an excuse?		No	Yes	No	Yes
	67	Can you follow the schedule of the hospital, workplace and school?		Yes	No	Yes	No
	68	Do you observe the rules for the hospital, workplace, school and region?	[No]: Cannot follow rules regarding smoking areas, workplace, traffic, industrial waste; escapes from the hospital and facilities	Yes	No	Yes	No
	69	Can you talk while looking at the eyes of the other party?		Yes	No	Yes	No
	Please tell us about your socializing.						
	70	How close are you with your family?	[Yes]: No trouble in interpersonal relations. However, disinhibition conditions are not included.	Yes	No	Yes	No
	71	How close are you with your friends?	Same as above	Yes	No	Yes	No
	72	How close are you with others?	Same as above	Yes	No	Yes	No
	[73] Please answer the following questions if you checked a double underline in items 58 to 72 [Yes]/[No].						
	73	Are you conscious of the necessity of training to allow for a smooth life in the ward and society?		Yes	No	Yes	No
Execution	74	Can you perform systematic behavior?		Yes	No	Yes	No
	75	Can you plan realistic goals?		Yes	No	Yes	No
	76	Do you think of things in an orderly sequence?		Yes	No	Yes	No
	77	Can you briefly speak what you want to say?		Yes	No	Yes	No
	78	Do you repeat the same mistakes?		No	Yes	No	Yes
	79	Can you consult with someone when in trouble?	[No]: Cannot ask people around you when you do not know the road or location. Cannot ask the store clerk when you cannot find products you are looking for. Cannot ask others when you do not know how to use machinery and tools.	Yes	No	Yes	No
	80	Can you behave calmly even if you do not know?		Yes	No	Yes	No
	81	Can you respond flexibly even if the situation differs from usual?		Yes	No	Yes	No
	82	Can you choose one out of several choices and ways of thinking?	[No]: Cannot decide what to eat from a menu. Cannot choose among various proposed ideas.	Yes	No	Yes	No
	83	Can you decide the priority of things?		Yes	No	Yes	No
	84	Can you finish doing something now when you have another appointment?	[No]: Do not hurry when you need to hurry to prepare to depart and are eating. Arrive earlier than the promised time.	Yes	No	Yes	No
	[85] Please answer the following questions if you checked a double underline in items 74 to 84 [Yes]/[No].						
	85	Are you conscious of the necessity of training to efficiently behave?		Yes	No	Yes	No
Motivation	86	Do you rest in bed or on the couch all day?		No	Yes	No	Yes
	87	Can you do as you should even if it is not instructed by others?	Examples of things to do: grooming, rehabilitation tasks, study, etc.	Yes	No	Yes	No
	88	Can you put up with going without favorite items, for example, alcohol, cigarettes and sweet foods?	[No]: Drinking too much, eating too many snacks	Yes	No	Yes	No

Table 4. Continued.

Area	Number	Question	Concrete examples / notes	Respondent			
				Family, etc.		His / Herself	
Others	89	Can you use a plan for allowance money or salary?		Yes	No	Yes	No
	90	Can you put up without what you want?	Do not heed the needs of the situation, clothes, ornaments, favorite items, etc.	Yes	No	Yes	No
	91	Do you sexually harass others?	[Yes]: Grope at the opposite sex	No	Yes	No	Yes
	92	Do you often check the locking of a door, potential fire and belongings?	Check "Yes" if any of the following applies.	No	Yes	No	Yes
	93	Are your body and clothes clean?	[No]: Dirty clothes, urine odor, do not brush your teeth more than once a day, do not bathe more than once a week	Yes	No	Yes	No
	94	Can you dress to suit the season and situation?	[No]: Wearing long sleeves (or overdressed) in the summer, wearing short-sleeves in the winter, dressed informally in a formal place	Yes	No	Yes	No
	95	Do you manage medicines by yourself?		Yes	No	Yes	No
	96	Do you take a rest or visit a hospital when not in a good condition?		Yes	No	Yes	No

Note: The order of "Yes" and "No" is reversed at gray shaded columns.

Table 5. Construct validity of the COPE.

COPE areas	FIM social cognition	ρ	p Value
Memory	Memory	0.57	0.008**
	Problem-solving	0.39	0.086
	Social interaction	0.31	0.185
Attention	Memory	0.47	0.037*
	Problem-solving	0.66	0.001**
	Social interaction	0.43	0.060
Emotion	Memory	0.02	0.947
	Problem-solving	0.34	0.142
	Social interaction	0.48	0.031*
Empathy and coordination	Memory	0.38	0.100
	Problem-solving	0.66	0.002**
	Social interaction	0.66	0.002**
Execution	Memory	0.47	0.037*
	Problem-solving	0.73	<0.001**
	Social interaction	0.64	0.002**
Motivation	Memory	0.10	0.676
	Problem-solving	0.19	0.422
	Social interaction	0.16	0.496
Others	Memory	0.35	0.125
	Problem-solving	0.65	0.002**
	Social interaction	0.42	0.062

COPE, Cognition-Oriented Performance Evaluation; FIM, Functional Independence Measure; ρ, Spearman rank correlation coefficients, ** $p<0.01$, * $p<0.05$.

social cognition items, suggesting that the COPE could evaluate daily social cognition problems in patients with higher cortical dysfunction. In particular, the COPE can be used to evaluate memory problems regarding daily routine in patients with higher cortical dysfunction, including adequateness of speech or response to the situation and purposeful behavior. In contrast, correlations between the COPE and FIM within the areas of emotion and motivation were low, possibly because these areas are not well captured in the FIM. Although emotion correlated with FIM social interaction, emotional areas of the COPE evaluated different interpersonal situations; thus, the COPE can evaluate emotion in interpersonal situations that cannot be evaluated using the FIM social interaction. Regarding motivation, apathy has been reported to be correlated with memory and executive function following traumatic brain injury [30]. The COPE

includes a question evaluating the control of desire (e.g., suppressing the desire to have an article of taste or purchase something) in addition to other questions regarding behavioral motivation. This might have been the cause of the low correlation with the corresponding FIM social cognition area. As mentioned above, a mixture of high and low correlations between the COPE and FIM as hypothesized provides evidence of the validity and clinical significance of the COPE.

In conclusion, the validity of the COPE was established using the NGT method, which involved modifying the content through discussion among participants who were experts in higher cortical dysfunction, and was confirmed by correlation with another instrument, complementing the shortcomings associated with the consensus method for qualitative studies. Further validation of the COPE using a large sample of patients as well as a reduction in the number of items using a Rasch analysis (item response theory) is planned for the future.

Study limitations

First, although we achieved a high level of agreement from the NGT participants and verified the construct validity of the COPE, the COPE is based on the opinions of the participants of the current study. In the future, we plan to increase the content validity of the COPE by using the Delphi method, which involves gathering the opinions of external experts, and by performing a Rasch analysis.

Second, the examination of the construct validity involved relatively few patients. To avoid information bias by a participant engaged in development of the COPE, we asked staff members who were not engaged in development of the COPE to administer the COPE to establish construct validity. Thus, usage of the COPE was limited during this process. In the future, we plan to collaborate with many hospitals in order to increase the number of patients.

Finally, symptoms of higher cortical dysfunction may differ not only across personal relationships or environments, but also across time from the onset or existence of the disturbance in consciousness. The current study covers only the sub-acute to the chronic phase; thus, it is necessary to extend the examination to patients in the acute phase.

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