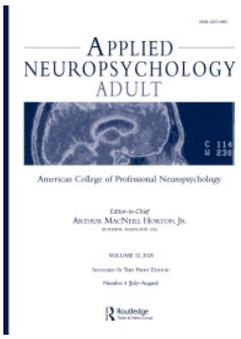

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Construct validity of the CoCo-P: Associations between cognitive complaints during participation and cognitive and emotional consequences

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ABSTRACT

Cognitive complaints are common following acquired brain injury (ABI) and can hinder social participation. To address this, the CoCo-P was developed as a tool to identify cognitive restrictions experienced in various everyday contexts, such as work and leisure. This study aimed to evaluate the construct validity of the CoCo-P by assessing its associations with two widely used clinical questionnaires, the USER-P and CLCE-24, as reference measures. Forty-five ABI survivors completed these questionnaires, along with assessments of mood (HADS), self-efficacy (GSES), health-related quality of life (EQ6D), and cognitive functioning (MoCA). Results indicated strong positive associations between the CoCo-P and both USER-P and CLCE-24. Additionally, self-efficacy was strongly negatively associated with reported restrictions, while no significant associations were observed with estimated mood disorders or cognitive functions. These findings demonstrate the construct validity of the CoCo-P, supporting its potential as a valid tool for assessing cognitive restrictions experienced in daily life by individuals with ABI.

KEYWORDS

Acquired brain injury; cognition; participation; restrictions; validity

Introduction

Cognitive impairment after acquired brain injury (ABI) can be subtle and often only come to light when patients return home from the hospital or rehabilitation center and start to ***participate*** in society (i.e. the engagement of a person in daily life activities, in a social context (Viscogliosi et al., 2011). ABI survivors can then be referred for cognitive rehabilitation when they report cognitive complaints and/or when cognitive impairment is detected with a screening instrument. As a first step, a clinical interview is usually conducted as an inventory of cognitive complaints from the ABI survivor. Frequently also a relative (or significant other) is interviewed about important aspects of the history, lifestyle, and symptoms of the patient. Cognitive complaints refer to the subjective difficulties that ABI survivors experience in daily life (Van Rijsbergen et al., 2014) distinguishing them from cognitive impairment, which are typically evaluated through objective assessment.

However, there remains limited standardization in the assessment of cognitive complaints, which may result in the risk of complaints being overlooked or changes in complaint severity going undetected. Although several questionnaires are available to assess cognitive complaints (e.g., Checklist for Emotional and Cognitive Consequences) (Van Heugten et al., 2007; Rasquin et al., 2006), their items are not directly linked to specific daily life activities. On the contrary, several instruments particularly focus on daily life activities in a social context yet the focus is not on cognition, such as the Frenchay Activities Index (Holbrook & Skilbeck, 1983; Schuling et al., 1993), Instrumental Activities of Daily Living Lawton and Brody (1969), Assessment of Life Habits (Fougeyrollas et al., 1998), the Utrecht Scale for Evaluation of Rehabilitation – Participation (USER-P) (Post et al., 2012). In the latter instruments, the reported restrictions may also be caused by motor, emotional and/or behavioral problems.

To address this gap, we developed the Cognitive Complaints-Participation (CoCo-P), an inventory designed to systematically assess cognitive complaints in individuals with ABI across various ***daily activities*** and cognitive domains (Spreij et al., 2021). At the time of development, the construct validity of the CoCo-P was not examined, which is the primary focus of the present study. Specifically, we investigated whether the inventory accurately measures the intended theoretical constructs (i.e., cognitive restrictions impacting participation) by assessing its associations with other patient-reported measures: the Utrecht Scale for Evaluation and Rehabilitation (Participation) (USER-P; Post et al., 2012) and the Checklist for Cognitive and Emotional Consequences following stroke (CLCE-24; Van Heugten et al., 2007; Rasquin et al., 2006). Moreover, to make sure the CoCo-P is not associated with scales measuring dissimilar cognitive constructs, convergent validity was also examined. Therefore, a secondary objective was to explore the

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relationships between the level of reported restrictions and most frequently used clinical outcomes for cognitive rehabilitation in The Netherlands. These consisted of estimations of cognitive functioning, symptoms of anxiety and depression, self-efficacy, and quality of life.

Methods

Data for this study were derived from a larger project: the InDiCa-study (**In**novatieve **Di**agnostiek voor **C**ognitie in **A**lledaagse participatie; Innovative Assessment of Cognition during Daily Participation), which focused on the innovative assessment of cognition during daily participation. The InDiCa-study aimed to examine the added value of a digital neuropsychological assessment (dNPA) within a Virtual Reality (VR) simulation, with a primary focus on cognitive complaints during societal participation. Cognitive complaints were assessed using the CoCo-P, USER-P, and CLCE-24. One of the objectives of the InDiCa study was to investigate the associations among these three measures to determine the construct validity of the CoCo-P.

Participants and recruitment

Participants were recruited via the patient associations (e.g., Hersenletsel.nl), social media networks, and different (academic) hospitals and rehabilitation centers. Inclusion criteria for participation in the InDiCa study were: (1) clinically diagnosed with stroke or brain tumor as indicated by clinical computed tomography (CT) or magnetic resonance imaging (MRI) scan, or clinically diagnosed with traumatic brain injury (TBI) as indicated by a neurologist; (2) aged 18 and above (no upper age limit); (3) fluent in Dutch; (4) no neuropsychological assessment in the past 3 months; (5) experienced cognitive restrictions; (6) living at home; and (7) written informed consent. The experiments were performed in accordance with the Declaration of Helsinki. The research protocols were approved by the Medical Ethics Committee of University Medical Center Utrecht (METC protocol number 19-112/C).

Demographic and clinical characteristics

We collected data on sex, age, and level of education. Level of education was assessed by using a Dutch classification system (Verhage, 1965) that consists of seven ranks, with 1 being the lowest (less than primary school) and 7 being the highest (academic degree). These levels were converted into three categories for analysis: low (Verhage 1–4), average (Verhage 5), and high (Verhage 6–7). In addition, we extracted the following clinical characteristics from the medical files: ABI type, time post ABI onset, and hemisphere of lesion.

Procedure

Interested individuals with ABI received an information letter detailing the InDiCa-study. Subsequently, an appointment was scheduled to address any questions and provide additional information. For the InDiCa-study, an appointment was specifically arranged to respond to questions or offer further details. If patients still wished to participate afterward, a follow-up appointment was scheduled. The questionnaires (i.e., CoCo-P, USER-P, CLCE-24, HADS, EQ6D, and GSES) were sent to patients in advance to complete at home in approximately 45 minutes total. The questionnaires were then brought to the appointment, which included the MoCA, dNPA, and a VR simulation. Total scores (and relevant sub-scores) from all questionnaires and the MoCA were used in the analyses. Relevant clinical data were obtained from the electronic patient records by the treating clinicians. All patients received a compensation of 10 Euros for participation.

Questionnaires and outcome measures

CoCo-P

The CoCo-P is a patient-reported measure to assess cognitive complaints during daily life activities (for a full description please see Spreij et al., 2021). The CoCo-P contains 38 items focusing on memory (i.e., retrospective memory, prospective memory), attention (i.e., arousal, orienting, monitoring, sustained) or executive function (i.e., planning, self-evaluating, initiative, mental flexibility) divided over 10 daily life activities (i.e., work/education, leisure activities, travel, driving, finances, use of medication, family life, contact with family, friends and community, cooking, grocery shopping). The response options reflect different grades of independence and effort (0 [independently without effort], 1 [independently with effort], 2 [with help], 3 [not possible], 4 [not applicable]).

Scoring

We computed a complaint score per cognitive domain with the following formula: complaints score = mean score/3 *100. Only items that were applicable for the participant were included. Higher scores indicated a higher degree of reported complaints. For the current study a total CoCo-P score was calculated.

Other clinical questionnaires and outcome measures

The USER-P (Post et al., 2012) is a questionnaire measuring participation in general. The USER-P consists of 32 items in total, with 3 scales: frequency of participation, self-reported restrictions, and satisfaction with current participation. Only the second scale was used in this study, as this measures self-reported restrictions for participation in general. The other subscales might be too dissimilar to the CoCo-P to establish convergent construct validity. Scores range from 0 to 100, with higher scores indicating more experienced restrictions. The USER-Participation scales showed satisfactory internal consistency ($\alpha = 0.70–0.91$) with Spearman correlations ranging from 0.36 to 0.52. Concurrent validity was demonstrated by strong correlations with the The Frenchay

Activities Index (FAI) (Frequency scale: 0.59), ICF Measure of Participation and Activities Screener (IMPACT-SP) (Restrictions scale: 0.75), and Participation Scale (Satisfaction scale: −0.73). Discriminant validity was evidenced by significant score differences among participants with varying levels of independence and health conditions (Post et al., 2012).

Self-reported cognitive complaints were measured with the CLCE-24 (Van Heugten et al., 2007; Rasquin et al., 2006). Both cognitive and emotional consequences after acquired brain injury are measured, with scores ranging from 0 to 13 for the cognitive aspects (e.g., having trouble concentrating by being easily distracted; having trouble planning or organizing activities), and 0-9 for the emotional aspects (e.g., feeling anxious; easily agitated). There are two items where patients can indicate complaints that have not been addressed (1 point per complaint). The total score is maximally 24. The CLCE-24 is a valid cognitive screening tool for use by healthcare professionals in the chronic phase post-stroke. In a study with 69 patients (37 men; mean age 66 years), both patients and assessors reported positive experiences with the CLCE-24. Cognitive and/or emotional problems were identified in 80% of patients (73% cognitive; 51% emotional). Patients with CLCE-24 complaints also showed issues on the Mini Mental State Examination (MMSE) and Cambridge State Examination (CAMCOG) ($p < 0.05$). The CLCE-24 predicted MMSE and CAMCOG scores at 12 months post-stroke (R^2=0.13 and 0.16, respectively). Internal consistency was good ($\alpha = 0.81$) (Van Heugten et al., 2007).

Cognitive functions were estimated with the total scores on the MoCA (Nasreddine et al., 2005). Total scores could range in between 0 and 30, with scores above 26 being indicative for normal cognitive functions.

Symptoms of anxiety and depression were reported by filling out the HADS (Zigmond & Snaith, 1983). Total scores could range between 0 and 42 (21 per subscale). Scores in between 8 and 11 (subscale) are interpreted as potential anxiety or depressive disorder, whereas score above 11 are interpreted as an assumed anxiety or depressive disorder. The current study focused on the underlying construct of the HADS did not make use of the diagnostic properties.

The General Self-Efficacy Scale (GSES; Schwarzer & Jerusalem, 1995) was used for measuring the general self-efficacy during challenging situations. The scores range from 10 to 40, with higher scores indicating more self-efficacy. Reliability was assessed through internal consistency using Cronbach's Alpha. A comparison of the GSES in 23 countries showed generally good to excellent reliability, ranging from CR-$\alpha = 0.76$ to 0.90. In German samples, Cronbach's Alpha ranged from 0.80 to 0.90. In a German evaluation sample, item-total correlations ranged from 0.42 to 0.54, while the normalization sample reported correlations between 0.63 and 0.72 (Schwarzer & Jerusalem, 2010).

Last, the Six-Dimensional EuroQol instrument (EQ6D; Williams, 1990) is a standardized instrument for quality of life, scoring at six levels of health (mobility, self-care, daily activities, pain/discomfort, anxiety/depression, and cognition). On a 5-point scale, patients indicate their degree of impairment per level, with a 1 indicating 'no impairment' and 5 indicating 'unable to perform'. The EQ-6D was validated against a self-reported measure of health, the 36-Item Short Form Health survey (SF-36; Ware & Sherbourne, 1992), with favorable results (Hoeymans et al., 2005). Analyses were conducted on 9,685 respondents aged 18 years and older. Most respondents reported no health problems, while 33% reported pain or discomfort. Women and elderly participants reported more issues, except for depression/anxiety, which was unrelated to age. Educational level was closely linked to problems in all dimensions. The cognitive dimension of the EQ-6D, used for the first time in a general population, showed promising psychometric results. The average scores per level of the EQ6D were used to *describe* the current cohort of patients.

Analysis

Descriptive statistics were applied to summarize the demographic and clinical characteristics of the cohort, including percentages, means, and measures of variability. Construct validity of the CoCo-P was assessed through Pearson correlation analysis by correlating the inventory with USER-P, CLCE-24, HADS, GSES, and MoCA. The criteria for the strength of Pearson correlations were as follows: 0.1 = None to Moderate; 0.3 = Medium; 0.5 = Strong (Cohen, 1992). In addition, a linear regression analysis (R^2) was used to determine the degree of variance explained by the CoCo-P in the USER-P, CLCE-24, HADS, GSES, and MoCA. The effects were determined based on Cohen's criteria (2013), which encompassed 0.01 = small; 0.09 medium; 0.25 large.

Results

Demographic and clinical characteristics

Of the 48 ABI survivors that were invited to participate in this study, 3 declined to participate eventually, leaving 45 participants that were included for analysis (see Table 1 for demographic and clinical characteristics); one participant did not complete the HADS. The EQ6D, which estimates health related quality of life, indicated that patients on average did not experience problems with mobility or self-care. On average, they experienced a little bit of pain and/or discomfort and anxiety and/or depression. With respect to daily activities and cognition, the group indicated to have moderate impairments.

Cognitive restrictions during participation: associations between the CoCo-P and other patient-reported measures

The intended theoretical construct of interest appeared to be valid, as the total scores of the CoCo-P were strongly positively correlated with the USER-P ($r(43) = .53$, $p < .001$), with a significant amount of the variance explained ($R^2 = .278$; $F(1, 43) = 16.58$; $p = .001$). There was also a strong positive correlation with the cognitive part of the CLCE-24 ($r(43) = .72$, $p < .001$), and a significant amount of the variance explained ($R^2 = .514$; $F(1, 43) = 45.49$; $p = < .001$). A moderate positive correlation was found with the emotional

Table 1. Overview of demographic and clinical characteristics.

Male (%)	35.6
Age in years (median, range)	53 (20-73)
Handedness (%)	
Left	4.4
Right	93.3
Ambidextrous	2.2
Level of education (%)	
Low	2.2
Moderate	24.4
High	73.3
Type of ABI (%)	
Stroke	53.3
TBI	37.8
Brain tumor resection	8.9
Lesion side (%)	
No lesion visible	8.9
Left	31.1
Right	20.0
Both	15.6
Unknown	24.4
Time ABI onset (median, range)	40 months (4-509)
USER-P subscale (0-100; average (SD))	31.00 (19.54)
CLCE-24	
Cognition (0-13; average (SD))	6.13 (2.92)
Emotion (0-9; average (SD))	4.4 (2.20)
MoCA total (0-30; average (SD))	25.68 (2.61)
HADS total (0-42; average (SD))	24.51 (5.11)
HADS Anxiety (0-21; average (SD))	14.77 (5.40)
HADS Depression (0-21; average (SD))	9.94 (3.59)
GSES (10-40; average (SD))	30.81 (5.41)
EQ6D (average (SD))	
Mobility	1.44 (0.72)
Self-care	1.04 (0.21)
Daily activities	2.60 (1.05)
Pain/discomfort	2.42 (1.12)
Anxiety/depression	1.98 (0.97)
Cognition	2.76 (1.13)

consequences of the CLCE-24 ($r(43) = .42$, $p = .004$), additionally showing a moderate portion of explained variance ($R^2 = .175$; F (1, 43) = 9.15; p = .004). Moreover, there were no associations between the amount of reported cognitive restrictions (i.e., CoCo-P) and estimated cognitive functions (i.e. MoCA ($r(42) = -.09$, $p = .55$) nor reported overall symptoms of depression and anxiety (HADS Total[1] ($r(42) = -.25$, $p = .10$). Finally, there was a strong negative correlation between reported cognitive restrictions and the optimistic self-beliefs construct from the GSES ($r(43) = .51$, $p < .001$), with a significant portion of the variance explained ($r^2 = .263$; F (1, 43) = 15.38 p = <.001). This indicates that more positive self-beliefs of patients were related to less experienced cognitive restrictions, and a higher score on the CoCo-P would predict a lower score on the GSES (Figure 1).

Discussion

The primary objective of the present study was to examine the theoretical construct of the CoCo-P, which pertains to cognitive restrictions during daily participation, by evaluating its relationship with two clinically recommended patient-reported outcome measures of participation: the USER-P and the CLCE-24. The findings suggest that the CoCo-P construct is valid, as strong associations were observed with the USER-P and the cognitive components of the CLCE-24, respectively. These associations highlight both the overlap between cognitive difficulties in daily life and participation, as well as the unique contribution of the CoCo-P. Specifically, the CoCo-P does not measure the same construct as either of the clinical questionnaires used in current clinical practice. The varying strength of the associations reflects the distinct emphases of the USER-P and the CLCE-24. The CLCE-24 primarily addresses cognitive and emotional issues following ABI, while it does not focus on the specific contexts of daily life. The CoCo-P may offer greater insight into the particular daily life situations in which individuals experience cognitive restrictions, compared to the CLCE-24. Conversely, the USER-P concentrates on the restrictions experienced during participation but does not distinguish between the underlying causes, whether motor, cognitive, emotional, personal, or environmental, as delineated by the International Classification of Functioning, Disability, and Health (ICF) model. For those specifically interested in cognitive aspects of participation-related restrictions, the CoCo-P may be a more suitable option than the other two questionnaires.

The secondary objective of this study was to examine the relationships between reported levels of cognitive restrictions and key clinical outcomes, as specified in Dutch clinical guidelines (e.g., Van Heugten et al., 2017). When patients are referred to specialists due to cognitive complaints during participation, a standard set of questionnaires is typically administered for general screening. These usually include the MoCA, the HADS (or an alternative mood assessment), and the GSES (or another measure of self-efficacy and/or coping style). An important finding was lack of association between the CoCo-P and the MoCA. This may be due to a difference between assessing cognitive functions at a functional level through standard NPA, which is our gold standard, and evaluating the impact of cognitive deficits on activities of daily living (ADL) and participation. Another explanation could be the dissimilarity of both tools in terms of construction, and not the underlying cognitive construct.

The results also indicated a strong negative association between reported cognitive restrictions (as measured by the CoCo-P) and self-reported optimistic self-beliefs, suggesting that patients with more positive self-beliefs experienced fewer cognitive restrictions. Existing literature provides substantial evidence for the influence of personal factors (ICF-model), such as coping style and self-efficacy, on reported complaints and experienced restrictions, particularly in the domain of cognition (Nijsse et al., 2021b; De Graaf et al., 2022; Van Rijsbergen et al., 2019; De Graaf et al., 2018).

These findings offer indirect support for the notion that the CoCo-P assesses a construct similar to that measured by other questionnaires, such as the CLCE-24 (Van Rijsbergen et al., 2019; Nijsse et al., 2017). Moreover, no associations

[1]Please note that there was a moderate negative association with reported anxiety symptoms in isolation (HADS Anxiety ($r(42) = -.35$, $p = .02$; $R^2 = .122$; F (1, 43) = 5.83 p = .02)) and no association with reported depressive symptoms in isolation (HADS Depression ($r(42) = -.03$, $p = .83$; ($r^2 = .007$; F (1, 43) = .31 p = .583)).

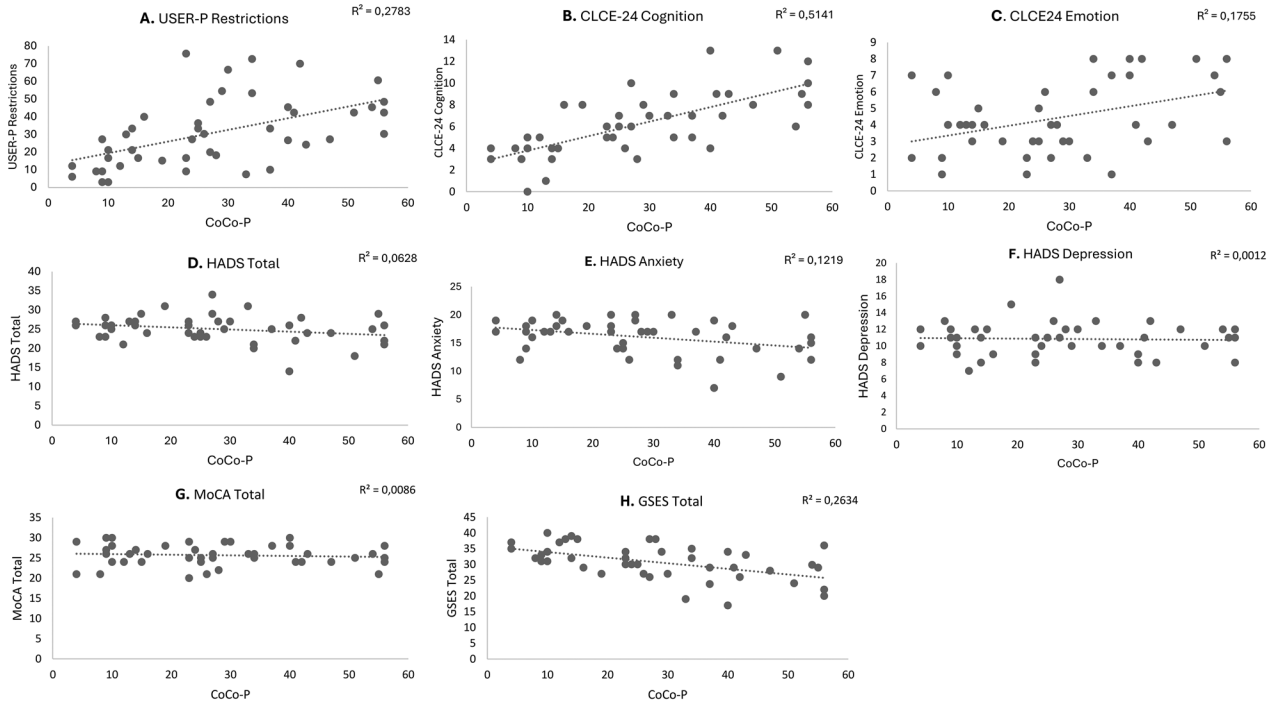

Figure 1. Overview of associations between reported cognitive restrictions in daily life situations (i.e. CoCo-P; x-axis) and other patient-reported measures: (USER-P; CLCE-24; HADSy-axis).
Note: A = Participation in general; B = Self-reported cognitive complaints, C = Self-reported emotional complaints; D, E, F = Symptoms of anxiety and depression; G = Estimations of cognitive functioning; H = Self-efficacy

were found between reported cognitive restrictions and indication of depressive symptoms or estimated cognitive functions, only a weak negative association with anxiety. Therefore, the CoCo-P may offer clinical value when integrated into cognitive screening or more extensive neuropsychological assessment, providing information on cognitive functions, cognitive complaints in daily life contexts, and personal factors such as self-efficacy and/or coping style.

Strengths and limitations

The participants in this study were recruited from a wide range of sources, including social media, patient organizations, academic hospitals, and rehabilitation centers, which helped ensure a diverse and representative sample. The health-related quality of life data (e.g., mobility, self-care) indicated that the sample was representative for individuals with ABI in the late sub-acute to chronic phases of recovery. All participants were relatively active in social and societal participation and did not report difficulties with basic ADL, such as mobility or self-care. However, they did report mild pain, discomfort, and emotional issues, along with moderate restrictions in instrumental ADLs and cognitive functioning. Reported mood complaints and cognitive limitations (as assessed by the HADS and CLCE-24 cognitive consequences) were somewhat higher in this sample compared to other populations, such as that reported Nijsse et al. (2021).

Even though the sample size may be considered modest, we feel that the data quality was adequate to draw robust conclusions about the construct validity of the CoCo-P total scores. However, for determining normal ranges or cut off scores, a larger sample is required. There was sufficient variability in the level of reported participation restrictions, as measured by the CoCo-P, USER-P, and CLCE-24, and the sample was representative of the targeted population. Yet the sample size limited the ability to assess the validity of the cognitive domain scores (Spreij et al., 2021), or explore associations across specific daily living situations. Additionally, despite broad recruitment efforts, the sample predominantly consisted of stroke and TBI patients, with fewer patients with brain tumor resection. Thus, the construct validity of the CoCo-P has been verified primarily for these groups, and further research is needed to determine whether these findings can be generalized to other ABI populations.

Future research and clinical implications

With the construct validity of the intended theoretical construct now established, we took the first steps in paving the way for the CoCo-P to be more readily implemented in clinical practice. It can serve as a valuable tool for patient anamnesis and the tailoring of treatment plans. Given that the questionnaire comprises 38 items, its completion may take approximately 20–30 minutes, making it somewhat lengthy. It is recommended that patients complete the CoCo-P at home (with help of an informal caregiver when needed) prior to their clinical appointment and bring the completed questionnaire with them. Due to its length, administering the CoCo-P as part of a clinical interview,similar to the CLCE-24, is not advised. Alternatively, administering the questionnaire in multiple stages could offer a more patient-friendly approach.

Future research should focus on the test-retest reliability of the scale next to validating the cognitive domain scores

and exploring the associations between cognitive restrictions and specific daily living situations. In conclusion, since the CoCo-P's construct validity has been confirmed, it is recommended to add the tool into clinical protocols. However, caution is advised when interpreting the cognitive sub-scores. In addition, it is recommended to explore longitudinal studies to assess the sensitivity of the CoCo-P to changes over time. Such studies would provide valuable insights into the tool's ability to detect variations in cognitive participation and predict the progression of cognitive restrictions. Lastly, a negative perception of self-efficacy is correlated with higher CoCo-P scores, which may theoretically lead to increased restrictions in daily activities. Therefore, it is advisable to investigate this aspect when the CoCo-P score is elevated.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

The participants of this study did not give written consent for their data to be shared publicly, so due to the sensitive nature of the research supporting data is not available.

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