Current Psychology (2024) 43:3266–3274
https://doi.org/10.1007/s12144-023-04534-z

Influence of cognitive reserve on neuropsychological performance in subjective cognitive decline and mild cognitive impairment older adults

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Accepted: 10 March 2023 / Published online: 29 March 2023

Abstract

The analysis of the relationships between cognitive reserve and different cognitive domains has become a matter of interest since it can help us detect deviations from the typical ageing process. The main objective of our study was to analyse a structural equation model representing cognitive reserve's relationships with three cognitive domains (episodic memory, working memory, and sentence comprehension) in older adults with subjective cognitive decline and mild cognitive impairment patients, in a cross-sectional study. A total of 266 Spanish-speaking older adults, from 65 to 80 years old, voluntarily participated in the study. The assessment protocol includes questionnaires as well as screening and domain-specific tests, providing relevant information for the classification of participants in the two groups previously mentioned ($n_1 = 150$ and $n_2 = 116$). The proposed model presented metric and configural invariance as well as stability across groups, since the indices reflecting goodness-of-fit reach acceptable values. Our hypotheses are partially confirmed since cognitive reserve strongly influences working memory and it does moderately in sentence comprehension in both groups, but it hardly influences episodic memory in the subjective cognitive decline group, while both are inversely associated in the patients' group. Working memory could be considered as a mechanism through which cognitive reserve exerts its protector role on other cognitive domains: on sentence comprehension in both groups, and on episodic memory in the subjective cognitive decline group. However, in mild cognitive impairments patients, cognitive reserve does no longer influence episodic memory via working memory in a significant manner.

Keywords Subjective cognitive decline · Mild cognitive impairment · Cognitive reserve · Episodic memory · Working memory · Sentence comprehension

Introduction

The concept of cognitive reserve (CR) refers to the adaptability of cognitive processes that help to explain the discrepancy between the degree of brain damage that an individual presents in a particular moment of her/his life and the clinical manifestations of her/his underlying brain pathology or age-related changes (Stern, 2009; Stern et al., 2020). There have been numerous studies that relate CR to the delay in the manifestation of the typical symptoms of Alzheimer's disease (AD) (Lojo-Seoane et al., 2012).

Among the studied proxies that contribute to the CR could be mentioned the years of formal education, the professional occupation throughout life, the leisure activities, or the individual's participation in cognitively stimulating and social activities (Cabeza et al., 2018). Higher CR has been related to more efficient neural networks or greater capacity, so individuals with higher CR will be more able to compensate for the disruption caused by brain pathology through more efficient and flexible cognitive functioning (Vance et al., 2010).

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There is also abundant evidence that people with higher CR, once the underlying pathology achieves a certain critical level (threshold), would show a faster decline compared to lower CR counterparts (Arenaza-Urquijo et al., 2015). The cognitive decline curve in older people with higher CR would present a less pronounced initial slope than other people with a lower level (and the same underlying pathology), but this slope tends to become steeper towards later stages of pathology accumulation.

During the last decade, there has been a growing interest to explore the relationship between CR and different domains in cognitive performance. Mitchell, Shaughnessy, Shirk, Yang and Atri (2012) used confirmatory factor analysis to test a four components model including memory/language, processing speed/executive functioning, attention, and CR proxies in cognitively intact older adults and in participants with amnestic MCI due to AD (aMCI-AD). Their model showed an excellent fit for the control group and adequate fit for the aMCI-AD group and supported the idea that CR was positively related to performance in memory/language, attention and processing speed/executive function. Additionally, other authors (Giogkaraki, Michaelides, & Constantinidou 2013) have found evidence from two structural equation models (SEM) supporting the moderating role of CR in reducing the direct negative effect of age on verbal episodic memory (EM) and executive function (EF). In the same vein, Lojo-Seoane, Facal, Guàrdia-Olmos, & Juncos-Rabadán (2014) developed an SEM to study the influence of CR on cognitive performance in a sample of adults older than 50 years with subjective memory complaints. Results revealed that CR had significant direct effects on EM, working memory (WM), and general cognitive performance, as well as indirect effects on EM via WM. They have confirmed the indirect effect of CR on other cognitive domains via WM over time observed in the previous studies in a new longitudinal study conducted over a sample of SCD participants (Lojo-Seoane et al., 2020).

Furthermore, it was also noted indirect effects of CR on other cognitive constructs at follow-up via WM. In a recent longitudinal study (Thow et al., 2018), the authors assessed EM, WM and language processing annually, over 4 years, in 359 cognitively intact older adults who attended university for a minimum of 12 months and were compared to 100 control participants. Using multiple group latent growth curve modelling they found improved language processing capacity in the group of older adults with further formal education, without an effect of university late-life education on EM, WM, or EF relative to the control group. In a study based on a sample of 158 cognitively intact older adults (Delgado-Losada et al., 2019), results have pointed out that CR had a higher direct significant association to cognitive status and, to a lesser extent, to EF. Participants' general cognitive status and EF had also a direct relationship. Besides, CR has an indirect positive relation to sentence comprehension (SC) via EFs' mediation.

Our study aims to analyse an SEM representing CR's relationships with three cognitive domains, EM, WM and SC, in older adults with SCD and MCI patients. Based on previous studies we have reviewed, we expect for SCD participants that CR will be strongly related to WM, and a lesser extent to EM and SC, and also that it indirectly influences EM and SC through WM. In the group of MCI patients, we hypothesized that CR would lose its capacity as a protective factor in different cognitive domains, especially in those participants with higher levels of CR. It is also expected that in this group CR would not influence EM and SC via WM in a significant manner.

The main novel contribution of this study focused on the effects of CR in different cognitive areas is the consideration of two domains that have been scarcely studied in previous works that use the same methodology, such as working memory and, especially, sentence comprehension, both in patients with mild cognitive impairment and with subjective cognitive complaints.

Method

Participants

A total of 266 Spanish-speaking older adults voluntarily participated in this study. All participants were recruited through announcements in residences and health centres in the Autonomous Community of Madrid (Spain). All participants gave their written informed consent to participate in the study, which had previously been approved by the Hospital Universitario San Carlos de Madrid local Ethics Committee (internal code: 18/422-E_BS).

Participants' age ranges from 65 to 80 years old. No one had a history of neurological or psychiatric disorders. From the total sample, 150 participants conformed the SCD group and 116 the group of MCI patients. Table 1 shows the demographic characteristics of the participants.

Design and materials

A cross-sectional study was used. The following instruments were applied for the diagnosis of the participants and for data collection.

Tests for diagnosis and inclusion criteria

A complete neuropsychological assessment provided relevant information for the classification of the total sample

Table 1 Percentage of cases in sociodemographic variables in both groups

		SCD	MCI
Gender	Male	26.7	39.7
	Female	73.3	60.3
Educational level	Illiterate	1.3	2.6
	Basic	5.3	6.0
	Primary	35.3	58.6
	High School	23.3	16.4
	University	34.7	16.4
Occupational attainment	Non-qualified manual workers	38.7	63.8
	Qualified non-manual workers	31.3	23.3
	Workers_ high educat. level	23.3	9.5
	Managers, doctors, etc.	6.7	3.4

in two separate groups: SCD participants and patients with MCI. This included the Mini-Mental State Exam (MMSE; Lobo et al. 1999), delayed paragraph recall in the Logical Memory subscale from the Wechsler Memory Scale III (WMS-III; Wechsler, 1997), the Memory Failures of Everyday (MFE) test (Montejo et al., 2011; Sunderland, Harris, & Gleave 1984), the Geriatric Depression Scale (GDS-15; Sheikh & Yesavage, 1986), the Trail Making Test parts A and B (TMT; Lezak et al., 2012), the Controlled Word Association Test (COWAT) FAS and semantic fluency (animals) (Benton et al., 1976), and the Functional Assessment Scale (FAQ; Olazarán et al., 2005). Participants were all interviewed by an experienced professional (psychiatrist or psychologist) and scored below 9 in GDS-15.

SCD participants, according to criteria proposed by Jessen et al. (2014), are those that have a self-perception of progressive deterioration in cognitive functioning in the absence of objective evidence of cognitive decline (MMSE ≥ 26 points; normal scores in WMS-III's delayed paragraph recall according to years of education). These participants: (a) presented self-perception of cognitive decline, mainly associated with memory loss; (b) had requested medical consultation because of their memory complaints; (c) felt that their subjective decline affected their daily activities; (d) set the onset of their subjective decline within the last 2 years, and (e) concerns associated with their subjective decline was confirmed by a reliable informant. To confirm the memory complaints, participants from this group had to score higher than 13 (mean 27.6) in MFE. None of these patients met the criteria for MCI and had no history of psychiatric or neurological disorders.

MCI diagnosis was determined according to the criteria proposed by Petersen (2016), that is: (1) cognitive complaints corroborated by an informant; (2) objective memory impairment documented by delayed paragraph recall in WMS-III's Logical Memory subtest. Additionally, some of the participants had low performance on measures of EF (> 1.5 standard deviations below the expected value in TMT parts A and B, as well as in FAS and semantic fluency (animals)); (3) Relatively preserved activities of daily living (FAQ < 6); (4) Not sufficiently impaired, cognitively and functionally, to meet criteria for dementia; (5) General cognitive functioning was determined by clinician´s judgement based on a structured interview with the patient and an informant. Finally, they presented an MMSE ≥ 24. According to their clinical and neuropsychological profile, all participants in this group were considered as amnestic only or multi-domain MCI. Table 1 provides percentages regarding sociodemographic variables (gender, educational level and occupational attainment) across groups.

Observable measures and tests for SEM analyses

- Cognitive reserve. Sociodemographic data were collected through an individual questionnaire that includes a specific question about the educational level to be answered by participants using a five point's scale (illiterate, basic reading and writing abilities, primary school, high school, university level). Occupational attainment score ranges from 1 to 4 (manual non-qualified work, qualified work, technical level, management level (including doctors, lawyers, professors, etc.).
- Working memory. Maintaining and manipulation in WM were assessed by the subtest of backward digits included in the third edition of the WMS-III, and also with a digit reordering task (MacDonald et al., 2001).
- Episodic memory. Immediate and delayed recall as well as the recognition index in the Word List of WMS-III were used to provide dependent measures related to a hypothetical EM latent variable.
- Sentence comprehension. The ECCO_Senior test (Exploración Cognitiva de la Comprensión de Oraciones para mayores; English translation: Cognitive Assessment of Sentence Comprehension for seniors; López-Higes et al., 2020) enables to assess the thematic role assignment ("*who did what to whom*") with a set of 36 sentence-picture pairs. Items can be either congruent or incongruent; incongruent items are syntactic or lexical foils. In syntactic foils, thematic roles are reversed in the picture concerning the sentence statements, whereas in lexical foils there is a certain change in the picture with respect to an action, a person, or an object mentioned in the sentence. For this study, we selected a subset of sentences from the test: non-canonical (sentences not fitted to the typical SVO order in Spanish) syntactic and lexical foils, since they reflect the different strategies employed (syntactic and/or lexically driven) in a simple verification task, and because they pose a higher burden over comprehension.

Table 2 provides descriptive statistics and differences between groups regarding age and relevant variables in the study. All post-hoc comparisons were significant ($p < .01$).

Procedure

An experienced professional conducted the neuropsychological assessment in all sessions. In the first session, participants were informed about the study and if they gave their informed consent, then they completed a socio-demographic questionnaire and the screening tests (e.g., MMSE, GDS-15, FAQ, MFE). All the remaining neuropsychological tests previously mentioned were applied, together with others not mentioned here, in two additional sessions of approximately 50 min each. Although there was a fixed block of tests for each session, their order of presentation was randomized across participants. All tests were applied and scored following instructions provided in their users' manuals. The interval between evaluation sessions ranged from one to five days in all cases.

Statistical analysis

First, we test using multiple regression if gender and/or age of the participants had some effect on the measures. As some of indicators were affected by gender and/or age, the residualization approach was used to control for confounder (gender and age). The residualization has clear advantages as provides one model with a clear statistical foundation. Residualizing the variables going into the SEM implies that the power of the confounders is eliminated, and the resulting model is based on the true relationship between the variables in the SEM (Kotzian, 2022).

To confirm if CR exerts its influence in EM and SC via WM, as suggested by other previous studies (Lojo-Seoane et al., 2014, 2020), we have conducted additional analyses focused on mediation effects joining all participants' data in a unique file and using the Sobel test (Preacher & Hayes, 2004).

We used AMOS 22.0 for Windows to try out the structural model proposed and choose the Generalized Least Squares (GLS) as the parameter estimation method. Our model includes two relevant indicators of CR, educational level and occupational attainment. It takes into account three other latent constructs, EM, WM and SC, each one associated with commonly observable indicators/measures. EM includes participants' immediate and delayed recall, as well as recognition scores, in the Word List subtest of WMS-III. Backward digits and digit reordering are the measures selected for WM. Regarding SC we choose non-canonical syntactic and lexical foils in the ECCO_Senior test.

All latent constructs were mutually interrelated, as in the study of Mitchell and colleagues (2012). First, we tested metric and configural invariance through Chi-Square statistic and multigroup confirmatory factorial analysis (CFA), respectively. Then we conducted a separate analysis for each group of participants. We examined a set of indices related to goodness-of-fit, namely: (1) the magnitude of Chi-square divided by its degrees of freedom (CMIN/DF, indicates a good fit when is minor to 3); (2) the Root Mean Square Error of Approximation (RMSEA shows a good fit when is minor to 0.05); (3) the Standardized Root Mean Residual (SRMR indicates a suitable fit when is minor to 0.08); (4) Goodness of Fit (GFI), and finally, (5) the Comparative Fix Index (CFI). The values of these last indices should be close to 0.90 or above to be considered a good fit (Tabachnick & Fidell, 2013). We used the Mardia coefficient considering multivariate normality when its critical ratio is equal to or minor than 1.96 (Bian, 2011). There were no missing cases in the sample, so it was not necessary to use any imputation method.

Table 2 Descriptive statistics and differences between groups (ANOVA) regarding age and relevant neuropsychological variables in the study. WL: Word List in WMS-III; NonC: non-canonical

	SCD		MCI			
	Mean	SD	Mean	SD	*F*	Sig.
Age	72.75	4.87	74.24	4.30	17.37	0.000
Mini-Mental	27.64	1.81	25.04	1.96	73.18	0.000
WL Immediate recall	25.77	5.95	19.53	4.38	109.44	0.000
WL Delayed recall	4.83	2.71	2.04	2.14	139.51	0.000
WL Recognition	21.21	2.60	19.12	3.11	77.49	0.000
Backward digits	4.90	1.87	3.95	1.62	42.02	0.000
Digit reordering	11.48	2.55	10.41	3.00	20.93	0.000
ECCO Syntactic foils NonC	4.26	1.20	3.62	1.16	27.15	0.000
ECCO Lexical foils NonC	3.93	1.33	2.93	1.40	75.32	0.000

Table 3 Regression of indicator variables on confounders variables. * $p < .05$; ** $p < .001$; Gender (0 = man; 1 = woman)

	Cognitive reserve		Episodic memory			Working memory		Sentence comprehension	
	Education	Occupation	Immediate recall	Delayed recall	Recognition	Backward digits	Digits reordering	Syntactic foils	Lexical foils
Age	−0.04	−0.13*	−0.27**	−0.21**	−0.11	−0.14*	−0.15*	−0.09	−0.26**
Gender	−0.20*	−0.35**	0.07	0.11	0.15*	−0.22**	−0.13*	−0.07	−0.01
R^2	0.04	0.13	0.08	0.06	0.04	0.06	0.03	0.01	0.06
Adj. R^2	0.04	0.13	0.08	0.06	0.03	0.05	0.03	0.01	0.06

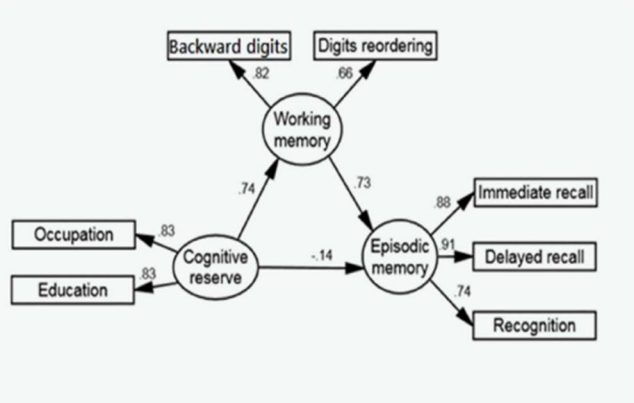

Fig. 1 Model showing the mediation effect of WM on the association between CR and EM.

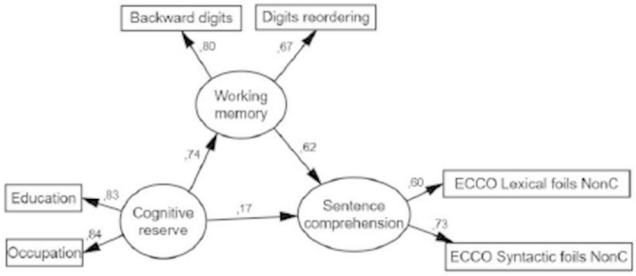

Fig. 2 Model showing the mediation effect of WM on the relationship between CR and SC.

Results

Effect of confounders

Effects of confounders (age and gender) on indicators were tested by multiple regression. Table 3 shows the standardized regression coefficients of indicator variables o confounders. As some of indicators were affected by gender and/or age, in subsequent analyses standardized residuals were used.

WM mediation effects for the total sample

Figure 1 represents the model used to test the mediation effect of WM on CR and EM association. Significant direct effects of CR on WM, as well as of WM on EM, were obtained ($p < .001$). The direct effect of CR on EM did not reach statistical significance ($p = .198$). The indirect effect of CR on EM mediated by WM was significant (Sobel test: $z = 5.05$, $p < .001$).

Regarding the mediation effect of WM on CR and SC relation, our results pointed out that there are significant direct effects of CR on WM, and of WM on SC ($p < .001$). The direct effect of CR on SC did not reach statistical significance ($p = .169$). However, the indirect effect of CR on SC mediated by WM was significant (Sobel test: $z = 4.07$, $p < .001$). Figure 2 showed the model used to test the mediation effect of WM on the relationship between CR and SC.

Invariance tests

Regarding measures invariance across groups the resulting Chi-square (with 8 degrees of freedom) was equal to 9.996, $p > .1$, thus the null hypothesis of metric invariance must be accepted. CFA confirmed that the structure was comparable across groups since CMIN/DF = 1.98, RMSEA = 0.03 (LO90 = 0.02, HI90 = 0.04), SRMR = 0.06, GFI = 0.97, and CFI = 0.98.

SEM for SCD older adults

Mardia coefficient was equal to 0.35, so multivariate normality was confirmed. Figure 3 shows the standardized solution for the proposed SEM model. This model presented adequate goodness-of-fit indices: CMIN/DF = 1.72, RMSEA = 0.05 (LO90 = 0.03, HI90 = 0.08); SRMR = 0.07; GFI = 0.94; CFI = 0.96.

In this model, occupational attainment was highly related to CR, followed by educational level, which in this group appeared as the second variable concerning its importance. Delayed recall showed the highest association with EM, followed (in this order) by immediate recall and recognition. WM was more associated with backward digits than with digits reordering performance. Participants' performance in non-canonical syntactic foils was a little more related to SC than non-canonical lexical foils, although correlations in both cases were of medium/moderate size.

The model also revealed that CR was mainly related to WM, then with SC (both with $p < .001$), and finally with EM (in this case the correlation was low and did not reach

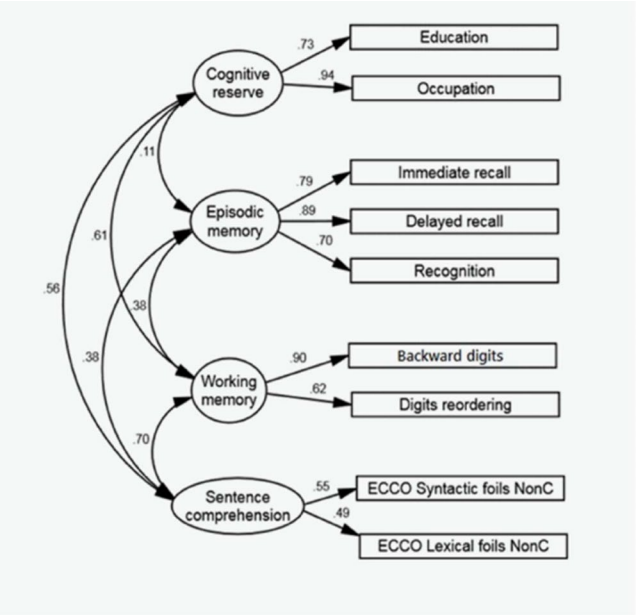

Fig. 3 Structural equation model for the SCD group

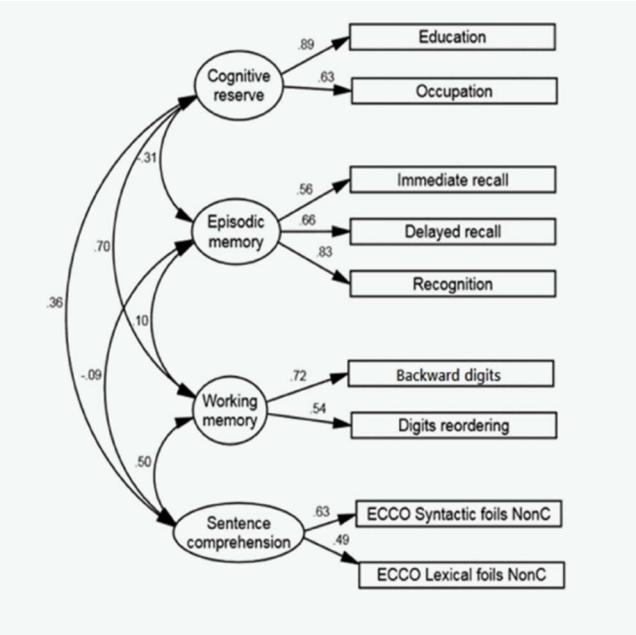

Fig. 4 Structural equation model for the MCI group

statistical significance; $p = .24$). CR has a high indirect influence on SC via WM, as well as an indirect medium-low effect on EM through WM too, both with $p < .001$.

SEM for MCI patients

Multivariate normality was confirmed for the model, given that Mardia coefficient was equal to 1.14. Figure 4 shows the standardized solution for the group of MCI patients. The proposed SEM model showed adequate goodness-of-fit indices: CMIN/DF = 1.63, RMSEA = 0.05 (LO90 = 0.02, HI90 = 0.08); SRMR = 0.07; GFI = 0.94; CFI = 0.93.

Educational level was highly related to CR, followed by occupational attainment. Recognition had the highest association with EM, followed (in this order) by delayed and immediate recall, respectively. WM was more associated with backward digits than with digits reordering performance. MCI patients' performance in non-canonical syntactic foils was more related to SC than non-canonical lexical foils.

As in previous analyses, CR was mainly related to WM (this is represented as the highest beta value considering relationships between latent variables; $p < .001$). Correlation between CR and SC only reached a significative moderate value ($p = .017$); CR was moderate and negatively related to EM ($p = .019$). CR has a mild and non-significant indirect effect on EM through WM ($p = .465$), but regarding SC the indirect influence through WM reaches significance ($p = .006$) and a moderate magnitude.

Discussion

As the mediation effects analyses pointed out, CR exerts an indirect effect on EM and SC via WM. Furthermore, we have obtained evidence about the model's metrics and configural invariance, which means that measures and structure are comparable across groups.

Considering CR indicators, the results in the MCI group pointed out that educational level explained a greater amount of CR's variance than occupational attainment, this pattern was inverted in the SCD group because occupational attainment had a higher weight than educational level. Regarding observable measures related to latent constructs (EM, WM, SC), we observed that Word List delayed recall was the most important EM's measure in the SCD group, whereas recognition had this role in the MCI group. Regarding WM, backward digits had a prominent role in the two groups. In relation to SC, syntactic foils explained a greater amount of SC total variance in both groups.

Regarding the CR direct impact on the three cognitive domains in the group of SCD participants, the results have shown that the construct CR exerts a strong protective role on WM and on SC and only a slight non-significant effect on EM. Our results are consistent with those obtained by Lojo-Seoane et al. (2014) with a sample of participants with subjective memory complaints regarding WM and EM, although in the case of EM the correlation was much higher than the one obtained in our study (0.38 vs. 0.11). Participants in the study conducted by Lojo-Seoane and colleagues were younger (over 50 years old) than our SCD participants. Probably the difference could also depend on

the inclusion criteria since in Lojo-Seoane's study participants had MMSE scores higher than 20 points whereas in ours the criterion was greater than or equal to 26 points. In their recent longitudinal study (Lojo-Seoane et al., 2020), they have analyzed data from a sample containing 42.5% middle-aged adults (less than 65 years old), 42.9% young-old adults (less than 75 years old), and 14.6% older adults (more than 75 years old), with subjective cognitive complaints. The results at the baseline confirmed a strong direct influence of CR on WM (0.718), thus in accordance with our result, but a low and negative impact on EM.

In the group of MCI patients, our results showed again that CR exerts a strong protective role regarding WM, which is only moderate with respect to SC, and additionally, the existence of an inverse relationship between CR and EM. The last result means that in MCI patients the higher the RC, the lower EM performance. According to CR's threshold model (Stern et al., 2020) in MCI participants the underlying pathology has passed a critical level in which patients with higher CR show a faster decline in EM than other patients with lower CR (Arenaza-Urquijo et al., 2015).

Results would indicate that CR acts as a protective factor regardless of the diagnostic profile when considering WM and SC, something that does not occur with EM. Relations between CR and SC has received much less attention in research, but in a previous study fulfilled by our group (Delgado-Losada et al., 2019), with a sample of cognitively intact older adults, sentence comprehension (measured through global ECCO_Senior indices) was not related to CR, a result that contrasts with the pattern observed in SC if other specific indices are considered.

The study of CR indirect effects on different cognitive domains via WM is a topic of particular interest since the last one has a critical role as a system that comprises encoding, maintenance, updating, temporal ordering, binding, attention, and inhibition (Baddeley, 2003). In our study, CR has a significant indirect medium-low influence on EM through WM for the SCD group and drop to a low no significant level in MCI patients. Lojo-Seoane and colleagues (2014) also observed in their participants with subjective cognitive complaints a lower significant indirect effect of CR on EM via WM than the one obtained in the present study. However, in their most recent work (Lojo-Seoane et al., 2020), the indirect influence of CR on EM via WM reached a much greater value (0.848). When we considered the indirect impact of CR on SC via WM, it reaches a high value in the SCD group and decreased slightly in the group of MCI patients. In a previous study fulfilled by our group (Delgado-Losada et al., 2019) with a sample of cognitively healthy older adults, CR was indirectly related to SC via EF with a similar weight. In summary, CR has an indirect effect on SC via WM in both groups, but it only exerts an indirect influence on EM via WM in the group of SCD participants, a result that is compatible with previous SEM models (Lojo-Seoane et al., 2014, 2020).

In conclusion, our hypotheses are partially confirmed: (1) CR strongly influences WM and it does moderately in SC in both groups, but it hardly influences EM in the SCD group, and they are inversely associated in the MCI group; (2) we could consider WM as a mechanism through which CR exerts its protector role on other cognitive domains: in this sense, the effects of CR on SC via WM are higher in both groups than those involving EM; in particular, CR has an indirect medium-low protective effect on EM through WM in the SCD group, but in MCI patients it does not longer influence EM via WM in a significant manner.

From a practical point of view, statistical models of cognitive performance that include CR can provide insights into the early detection of deviation from typical aging (Stern et al., 2020). This may further constitute a promising alternative to track changes in participants who receive cognitive training. Additionally, since CR helps to explain differences in cognition, functioning, or clinical status in AD prodromal groups (SCD, MCI), a methodological tool such as SEM provides a way to study potential mechanisms and relations implicated in this complex construct and constitutes a strength of the present study. In this sense, our study shows the direct and indirect effects of CR on specific cognitive domains such as working memory, episodic memory, and sentence comprehension in two key groups within the continuum from normal aging to dementia. The results obtained could have important implications regarding the prevention, diagnosis, and treatment of cognitive problems seen in patients with SCD and MCI.

The inclusion of additional proxies related to CR as well as additional observable measures related to latent variables are issues that could be considered in future works and constitutes a limitation of the present study. Our conclusions need to be confirmed in a longitudinal study, given the limitations of a cross-sectional design. Another possible drawback of our study is the sample size considered in each group and, as a logical consequence, the limited number of observed measures related to the latent constructs used.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12144-023-04534-z.

Funding Open Access funding provided thanks to the CRUE-CSIC agreement with Springer Nature. This study was supported by two grants from the Spanish government: PSI2015-68793-C3-3-R (Ministry of Economy, Industry and Competitiveness) and RTI2018-098762-B-C31 (Ministry of Science, Innovation and Universities). Open Access funding provided thanks to the CRUE-CSIC agreement with Springer Nature.

Availability of data and material Given restrictions from the ethical

review board and considering that sensitive personal data are handled, it is not possible to make the data freely available.

Declarations

Conflict of interest All authors declare that they have no conflict of interest.

Ethics approval Hospital Universitario San Carlos de Madrid local Ethics Committee (internal code: 18/422-E_BS).

Consent to participate Participants received written information on the study and signed an informed consent.

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