Neurología. 2011;**26(1)**:20-25

NEUROLOGÍA

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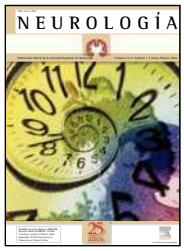

ORIGINAL ARTICLE

Normative and reliability study of fototest ☆

C. Carnero-Pardo[a,b,*], C. Sáez-Zea[a], L. Montiel-Navarro[c], I. Feria-Vilar[d], M. Gurpegui[e]

[a] *Servicio de Neurología Cognitivo-Conductual, Hospital Universitario Virgen de las Nieves, Granada, Spain*
[b] *FIDYAN Neurocenter, Granada, Spain*
[c] *Hospital Rafael Méndez, Lorca (Granada), Spain*
[d] *Servicio de Neurología, Complejo Hospitalario Universitario, Albacete, Spain*
[e] *Departamento de Psiquiatría e Instituto de Neurociencias, Universidad de Granada, Granada, Spain*

Received on June 20th, 2010; accepted on September 5th, 2010

KEYWORDS
Screening Test;
Test cognitive short;
Fototest;
Interobserver reliability;
Test-retest reliability;
Test of the photos;
Standardization

Abstract
Introduction: The Fototest is a brief cognitive test suitable for illiterate persons, and valid and accurate for detecting cognitive impairment or dementia. Our aim was to conclude the development of this instrument carrying out a normative and reliability study.
Method: The normative study was performed on a convenience sample of 223 healthy volunteers aged between 20 and 85 years. The test-retest reliability was assessed through a repeated-measures cross-sectional design on a sample of 50 subjects with no cognitive impairment; the inter-rater reliability was determined by the blind assessment of 10 test applications performed by 30 independent observers; in both instances, reliability was expressed as intra-class correlation coefficient. Internal consistency was analysed by Cronbach's alpha coefficient.
Results: The results on the Fototest are normally distributed and are not influenced by gender or educational level but they do vary with age. The test-retest reliability of the Fototest was 0.89 (95%CI: 0.81-0.93); the inter-rater reliability, 0.98 (95%CI: 0.96-0.99); and the internal consistency, 0.94.
Conclusions: The Fototest is free from educational influence and shows appropriate test-retest and inter-rater reliabilities, as well as a high internal consistency. Therefore, it is a suitable psychometric instrument to be used in the follow-up of patients with cognitive impairment or dementia, especially in contexts where evaluators are not the same on different occasions, or with patients of low educational level.

☆ This paper is dedicated to the memory of María del Sagrario Barquero Jiménez who collaborated throughout and in the development of the Fototest. Part of this work was presented as an oral communication at the 49th Annual Meeting of the Spanish Neurological Society.

* Corresponding author.
E-mail: carnero@neurocenter.es (C. Carnero-Pardo).

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PALABRAS CLAVE
Test de Cribado;
Tests cognitivos breves;
Fototest;
Fiabilidad interobservador;
Fiabilidad test-retest;
Test de las Fotos;
Normalización

Estudio normativo y de fiabilidad del fototest

Resumen
Introducción: El Fototest es un test cognitivo breve aplicable a analfabetos, válido y útil para la detección de deterioro cognitivo y demencia. Nuestro objetivo es completar el proceso de desarrollo del instrumento llevando a cabo un estudio normativo y de fiabilidad.
Métodos: El estudio normativo se realizó en una muestra de conveniencia de 223 sujetos voluntarios sanos entre 20 y 85 años. La fiabilidad test-retest (Ftr) se evaluó mediante un diseño transversal de medidas repetidas en una muestra de 50 sujetos sin deterioro cognitivo; la fiabilidad interobservador (Fio) se determinó mediante la evaluación a ciegas de 10 aplicaciones del test por 30 observadores independientes; en ambos casos se utilizó el coeficiente de correlación intraclase. La evaluación de la consistencia interna (CI) se llevó a cabo mediante el coeficiente alfa de Cronbach.
Resultados: Los resultados del Fototest se distribuyen normalmente y no están influenciados por el sexo ni el nivel educativo, pero sí por la edad. La Ftr del Fototest es 0,89 (IC 95% 0,81-0,93), la Fio es de 0,98 (IC 95% 0,96-0,99) y 0,94 la CI.
Conclusiones: El Fototest está libre de influencias educativas y tiene una adecuada fiabilidad, tanto Ftr como Fio, y una alta consistencia interna, por tanto, es un instrumento adecuado para ser usado en el seguimiento de pacientes con deterioro cognitivo y demencia sobre todo en entornos en que cambien los evaluadores, en especial en poblaciones con bajo nivel educativo.

Introduction

The Fototest (www.fototest.es) is a very short cognitive test that is easy to apply and evaluates several cognitive domains (memory, language and executive functions); it has the advantage over other instruments available in our setting that it can be applied to illiterate subjects[1]. Several studies have shown that it is a useful tool for the detection of cognitive impairment and dementia, with sensitivity and specificity results similar to or greater than those of other instruments widely used in our environment.[2,3]

Forming part of the process of validation and development of this instrument, we have carried out a normative study and a reliability study, assessing the internal consistency (IC), test-retest reliability (TRR) and inter-observer reliability (IOR).

Subjects and methods

Normative study

Convenience sample of 223 healthy volunteers aged between 20 and 85, free of any subjective complaints of memory loss, able to carry out basic and instrumental activities of daily life by themselves and without any history of abuse of alcohol or drugs, neurological disease (epilepsy, cranioencephalic trauma, cerebral vascular pathology or neurodegenerative processes), uncontrolled psychiatric or systemic disorders. For each subject, a note was taken of the following variables: age, gender, educational level and years at school.

Reliability study

The assessment of TRR was carried out using a transversal repeat measures design in which a single observer applied the Fototest on two occasions, separated by at least 30 days and a maximum of 3 months, to 50 subjects without cognitive impairment and whose cognitive status did not change between the two applications.

IOR was evaluated using a transversal design with multiple observers; to this end a digital video recording was made of the application of the Fototest to 10 subjects (2 without cognitive impairment, 3 with cognitive impairment without dementia and 5 with dementia); the selection of the subjects was effected on the basis of convenience, depending on availability and their agreement with being filmed; in all cases, a formal, explicit authorization was obtained in writing for the dissemination of the recording for research purposes. The recordings were collected on a DVD disc and a copy was sent to each of the observers taking part in the study so that they could assess each of these cases using the recording. A total of 30 observers participated, all of them practising or trainee neurologists or neuropsychologists. The assessment was done blind with respect to the socio-demographic and clinical data of the subjects assessed.

Statistical analysis

A descriptive study was carried out in the normative sample; the evaluation of the results' fit to a normal distribution was carried out using the Shapiro-Wilk statistic (SW); the possible influence of the socio-demographic variables on the results was evaluated using multiple linear regression analysis. The

Table 1 Socio-demographic characteristics of the sample in the normative study

	Total	<50 years	50-64 years	≥65 years	Sig.
Number of subjects	223 (100.0)	69 (30.9)	88 (39.5)	66 (29.6)	
Age (years)	54.3±15.8	35.0±9.9	56.5±4.3	71.6±4.3	
Gender (female)	148 (66.4)	41 (59.4)	66 (75.0)	41 (62.1)	n.s.
Educational level					
No studies	31 (14.4)	0 (0)	10 (11.8)	21 (33.9)	<0.001
Primary school	59 (27.3)	13 (18.8)	26 (30.6)	20 (32.3)	
> Primary school	126 (58.3)	56 (81.2)	49 (57.6)	21 (33.9)	
Years at school					
Never at school	25 (11.6)	0 (0.0)	7 (8.2)	18 (29.0)	<0.001
<10 years	61 (28.2)	13 (18.8)	24 (28.2)	24 (38.7)	
>10 years	130 (60.2)	56 (81.2)	54 (63.5)	20 (32.3)	
Illiteracy	12 (5.5)	0 (0.0)	4 (4.7)	8 (12.9)	<0.01

The results are expressed as the number of subjects (percentage) or mean±SD.

comparison of the results in the same sample was done using the t test for matched samples and with the t test for independent samples for comparison between different samples; the comparison between categorical variables was effected using the chi square test. TRR and IOR have been evaluated using the calculation of the intra-class correlation coefficient (ICC) with a two-factor random-effect model and internal consistency by Crombach's alpha coefficient (α). In all cases, the 95% confidence intervals (CI 95%) have been calculated for the different parameters and statistics.

Results

The normalization sample was 54.3±15.8 years of age (mean±SD) with a wide age range (20-85 years); for analysis purposes, it has been stratified into three age segments (<50, 50-64 and ≥65 years). Table 1 summarizes the socio-demographic characteristics. Females are more frequent throughout the sample (66.4%), without any significant difference between strata. Educational level changes with age, as it is clearly lower among the older segments and higher among the younger ones ($p<0.001$); illiteracy is only present in those over 50 years of age.

Table 2 summarizes the most characteristic descriptive statistics (range, mean, SD, P_{50}, P_{25}, P_{10} and P_5) of the Fototest results in the total sample and for the different strata, as well as the cut-off points corresponding to —1 SD, —1,5 SD and —2 SD. The Fototest results have a normal distribution in the total sample (39.4±6.4; SW=0.99, p=0.11) (fig. 1) and in the different strata; they are independent of gender, educational level and years of schooling, but reveal, on the other hand, a negative association with age (table 3 and fig. 2).

The mean age of the TRR study sample was 56.8+7.2, with a notable predominance of females (82.9%). Of the subjects in the sample, 77% had taken university-level or secondary-school courses and 91% had attended school on a regular basis for more than 10 years. The results of the second application

Table 2 Results of the Fototest in the normative sample

	Total	<50 years	50-64 years	≥65 years
N° of Subjects	223	69	88	66
Range	24-58	33-58	24-48	26-45
Mean±SD	39.4±6.4	45.0±5.5	38.7±4.8	34.4±4.4
—1 SD	33	39	34	30
—1.5 SD	31	37	31	28
—2 SD	27	34	29	26
P_{50}	39	45	39	34
P_{25}	35	41	35	31
P_{10}	31	37	33	29
P_5	30	34	30	27
SW (p)	0.99 (0.11)	0.98 (0.37)	0.98 (0.32)	0.97 (0.20)

SW (p): Shapiro-Wilk statistic (value of p).

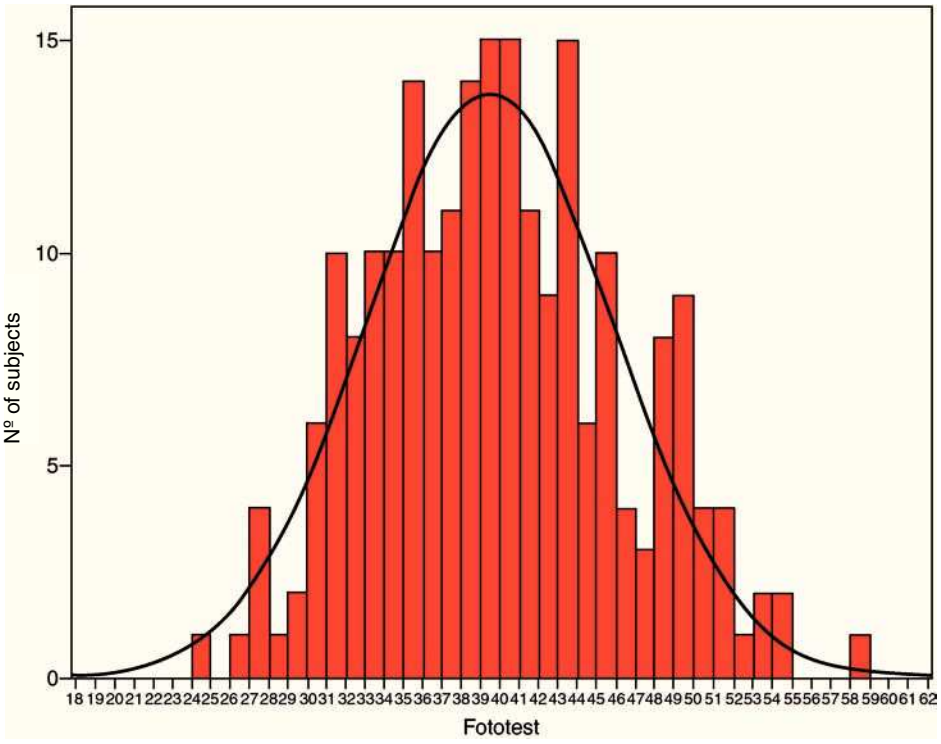

Figure 1 Distribution of the results of the Fototest.

Table 3 Multiple linear regression model of the Fototest results and socio-demographic variables

	β±ee	t	p
Constant	54.1±1.7	30.6	**<0.001**
Age (years)	−0.28±0.02	−13.10	**<0.001**
Gender (female)	0.80±0.65	1.23	0.22
*Educational level**			
No studies (Ref.)	—		
Primary school	0.04±1.95	0.02	0.98
> Primary school	0.13±1.63	0.08	
*Years at school**			
Never at school (Ref.)	—		
<10 years	0.83±2.05	−0.40	0.69
>10 years	1.08±1.67	0.65	0.52

(37.9±6.9) were slightly higher than those corresponding to the first (37.3±6.6), although these differences were not statistically significant (t=1.4; p=0.17). Figure 3 shows the cloud of points corresponding to the results of the Fototest in both applications; TRR is 0.89 (95%CI: 0.62-0.90) and the IC 0.94.

The IOR for the Fototest was 0.98 (95% CI: 0.96-0.99). Figure 4 shows a graphical representation of the scores given by the different observers for each case in order to facilitate the visual appreciation of the scant variability between observers. The greatest variability seen in case 9 probably corresponds to registration error.

Discussion

The results of the Fototest show a normal distribution and are not influenced by the gender or the educational level of the subjects, but they do reveal a negative association with age that translates into a lower score in the eldest subjects Our results also show that they have a high IC and high reliability for both TRR and IOR.

A negative association with age is a normal finding in a great many cognitive functions, except for certain tasks related to

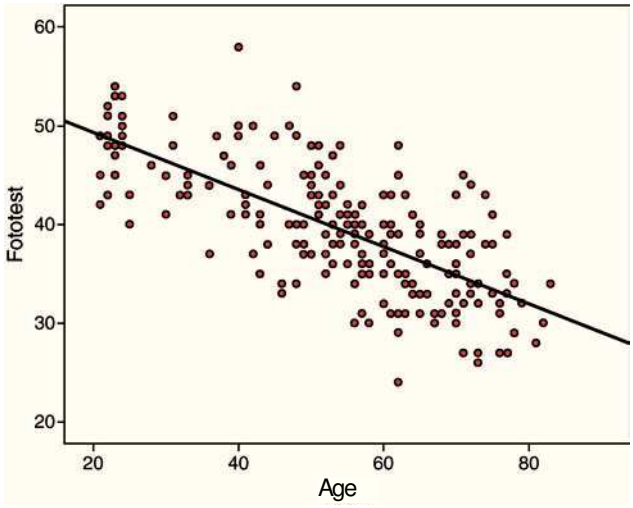

Figure 2 Dispersion graph of the results of the Fototest by age.

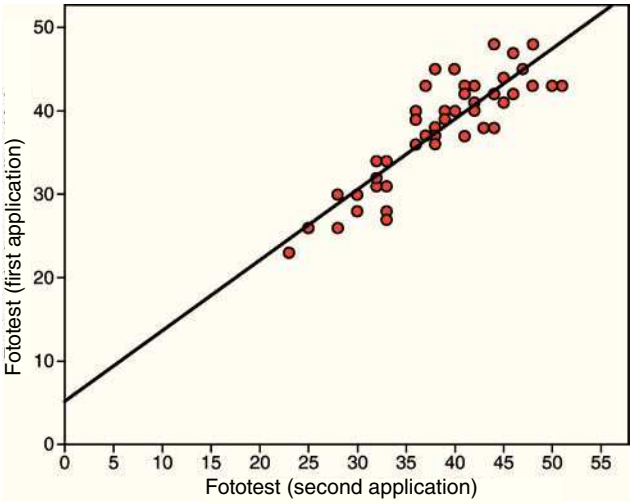

Figure 3 Dispersion graph of the test-retest scores in the Fototest.

verbal skills and vocabulary and this is justified in the cognitive changes associated with ageing,[4] fundamentally, by the slowing down of the processing speed, of particular influence in tasks involving fluency, an essential element of the Fototest. The independence of educational variables, on the other hand, is exceptional among cognitive tests and provides an undoubted advantage by making it unnecessary to apply adjustments or corrections to the results or their interpretation in the light of these variables, unlike other brief cognitive tools such as the MMSE,[5] SPMSQ[6] or MIS,[7] this fact makes Fototest an ideal instrument for use in populations with a low level of education or with a high level of illiteracy.

Fototest's TRR is high, 0.81(95% CI: 0.62-0.90), despite the inclusion of a verbal fluency task. These tasks generally have a high degree of variability and, in consequence moderate reliability, as they are strongly influenced, not

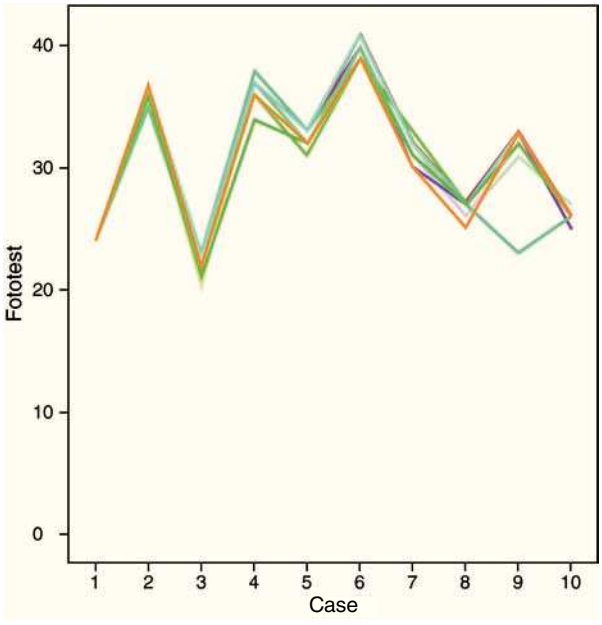

Figure 4 Fototest scores in the inter-observer study.

only by the subject's socio-demographic variables, but also by the circumstances in which the test is conducted, in terms of both the external conditions (temperature, distractions, etc.) and the situation of the subject under assessment (mood, motivation, level of attention, etc.).[8] The Fototest "names of people" fluency test has shown that, unlike other fluency tasks, it is not influenced by the subject's social and educational variables[9] and, although the different sub-scores of the test have not been independently analyzed in this study, our results also indicate that the "names of people" fluency test shows greater consistency and stability than other fluency tasks, which translates into a greater reliability of the instrument containing it. The Fototest's TRR is acceptable, similar to that shown by the MIS (0.81)[10] and a little lower than that shown by the Cognitive Mini-Exam (0.87),[11] Mini-Mental State (0.87),[5] EUROTEST (0.91)[12] or SPMSQ (0.92)[6] and MoCA (0.92)[13] in Spanish samples. However, it is necessary to be careful when drawing conclusions from these comparisons, as they are derived not only from different studies, but also with differing procedures and statistical methods; thus, in some studies the applications were not conducted by the same observer, in others, the separation between applications was only one day,[11] in still others the statistical method used varies (for example, the SPMSQ study[6] uses the diagnostic concordance kappa index) while in some cases the statistical method is inappropriate (Spearman's correlation coefficient in the MoCA study[13]). Having an adequate TRR indicates that, in the absence of relevant clinical events or long-term changes, the results remain stable and consistent over time; this therefore allows the Fototest, in addition to a screening and filtering tool, to be useful in the monitoring of subjects already diagnosed and in the assessment of their responses to therapeutic interventions.

Fototest's IOR is very high, ICC 0.98 (95%CI: 0.96 - 0.99), higher than that shown by the SPMSQ (0.73),[6] PCL (0.84),[14] MIS (0.85),[10] EUROTEST (0.91)[12] and MoCA (0.91)[13] and in line with those of the Mini-Mental State (0.96)[5] and RUDAS (0.99),[15] although it is necessary to insist on the inappropriateness of comparing the results of the different studies. In general, all these brief tests show a high degree of inter-observer reliability, probably because they are easy tools to apply with objective and unambiguous correcting. Having a high IOR makes it a very useful tool in those scenarios where the subject is monitored by different professionals instead of always by the same one, whether due to the unique features of the care unit or the patient's circumstances (moving house).

The study's strengths include the high number of subjects in the various samples and the wide range of ages represented. Its main limitation lies in the convenience of the samples, which therefore do not represent the population. This circumstance may not be significant in reliability studies in view of their nature and purpose, but the fact that the sample is not representative of the population as a whole is relevant in the case of the normative study. Normative studies based on the entire population or using representative samples are complex and costly, so there is a very limited number of instruments in our country backed up by normalization studies in samples of this kind (Mini-Mental State,[16] MEC[17]). The Leganés study has recently

allowed normative data to be obtained in several short cognitive tests such as Verbal Fluency, SPMSQ, the clock test and T7M;[18,19] the newer tools only have data available from convenience samples (T@M,[20] MIS[7]), as in our case, or do not have any normative data (MoCA,[13] ACE,[21] RUDAS[15]). Nonetheless, it would be a good idea to have our results corroborated in future with a population-based study or at least a representative sample of the population.

In conclusion, the Fototest combines its advantageous conditions of ease of application and demonstrated validity in prior studies[1-3] with the fact that its results have a normal distribution, are independent of the social and educational variables and are reliable; these characteristics make it an advantageous option with respect to the instruments available and in use, both for the detection of cognitive impairment and dementia and also for the monitoring of these subjects and the assessment of their response to treatment.

Conflict of interest

C. Carnero Pardo is the creator of Fototest; payment has been received for academic activities and consultancy from Janssen Cilag, Pfizer, Eisai, Esteve, Novartis, Lundbeck and Laboratorios Andrómaco.

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Acknowledgements

Our gratitude to E. Nogales García and M. J. Cabrera Martínez for their contribution in data collection, to the professionals who collaborated in the inter-observer reliability study and to the volunteers who agreed to take part.

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