A modified version of the 2016 ACR fibromyalgia criteria cognitive items results in stronger correlations between subjective and objective measures of cognitive impairment

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ABSTRACT

Objective. *In a previous study, we showed that the subjective item assessing cognitive impairment (SSS-Cog) for fibromyalgia (FM) did not correlate with the objective cognitive measures. In the current study, we describe two modifications designed to enhance this correlation: extending the SSS-cog scale from 0-3 to 1-5, and administration of a new questionnaire that specifically targets the cognitive impairments associated with FM.*

Methods. *Sixty-two FM patients underwent a computerised cognitive assessment battery. FM symptoms were assessed on the Fibromyalgia Impact Questionnaire (FIQ); the Widespread Pain Index (WPI); the Symptom Severity Scale (SSS), the new SSS-Cog scale ranging from 1 to 5, the Beck Depression Inventory (BDI) and the new cognitive questionnaire developed by the authors.*

Results. *Significant correlations were found between the new SSS-Cog, the global cognitive score and all indices [Global Score r=-0.532, p=0.00; Indices: Memory r=-0.305, p=.01; Executive function r=-0.514, p=0.00; Attention r=-0.471, p=0.00; Processing Speed r=-0.468, p=0.00; Motor Skills r=-0.495, p=.00]. Significant correlations were found between the new questionnaire and the global cognitive score and all indices except the memory index [Global Score r=-0.522, p=0.00; Indices: Memory r=-0.163, p=0.212; Executive function r=-0.477, p=0.00; Attention r=-0.439, p=0.00; Processing Speed r=-0.496, p=0.00; Motor Skills r=-0.532, p=0.00].*

Conclusion. *Given the simplicity involved in extending the scale, we suggest incorporating this modification into the FM diagnostic criteria of the American College of Rheumatology (ACR).*

Introduction

Fibromyalgia syndrome (FM) is a chronic disorder characterised by widespread musculoskeletal pain, sleep disturbances, fatigue and prominent symptoms of cognitive impairment (1). The most frequent comorbidities include depression, anxiety and other mood disorders such as bipolar disorder, which can lead to decreased quality of life (2, 29, 31). FM is an example of a centralised pain condition characterised by aberrant pain processing within the central nervous system (3). The pathophysiology of FM is related to abnormalities in central pain processing, which results in central pain sensitisation and abnormalities in the HPA axis. It is thought that the relationship between pain conditions and mood disorders may be due to the fact that shared neurotransmitters are involved in both pain perception and mood regulation, which also affects sleep regulation and cognitive functions (29). This neurochemical rationale can partially account for the wide range of symptoms seen in FM patients. Neurochemical mechanisms involving the serotonergic and noradrenergic pathways may be the common factor linking pain and depression (29). A recent extensive overview has documented the associations between changes in pain and depression (30).

Although the pathogenesis of FM remains poorly understood, a recent review suggested that the immune system could be closely related to FM pathogenesis, since auto-immune triggers of trauma and infections are some of the most frequent events preceding its onset (28).

To date, diagnosis and clinical assessment rely almost entirely on patients' descriptions of their symptoms (including cognitive complaints). Differ-

ent sets of criteria have been suggested over the years for the diagnosis and classification of FM. In 2010, new diagnostic criteria were introduced, based on the Widespread Pain Index (WPI), a self-report questionnaire reflecting the degree of pain dispersion, and the Symptom Severity Scale (SSS), which assesses accompanying symptoms (1). These criteria were designed to evaluate other symptoms connected to FM such as fatigue, decreased cognitive abilities and unrefreshing sleep.

The addition of the SSS to the current FM diagnosis makes the cognitive impairment reported by FM patients an integral diagnostic feature of FM. Known as "fibrofog", it is associated with severe functional and occupational disabilities and is reported by almost 80% of all FM patients (8). Several domains of cognitive impairment in FM patients have been identified in previous studies. These include memory, executive function, working memory and attention (especially when presented with competing stimuli or distractors) (2, 9). These multifaceted deficits negatively impact patients' social and occupational quality of life (12, 13). Fibrofog is a major cause of social isolation, decline in daily activities, and loss of career (12, 13).

In clinical practice, the assessment of cognitive impairments related to FM relies almost exclusively on self-reported symptoms. However, previous studies exploring the correlations between subjective and objective measures of cognitive impairment in FM patients have been inconclusive and contradictory (10). For example, Gelonch *et al*. reported correlations between subjective reports of cognitive decline and objective measures of working memory and response inhibition. On the other hand, in our previous study, the subjective measure of cognitive decline was unrelated to objective measures in a range of cognitive domains including memory, executive functions and attention (4).

Using the original scale that ranged from 0-3 (where higher scores indicate greater severity of impairment) we found no significant correlation between the SSS-Cog and objective measures of cognitive functioning as assessed on a standardised computerised cognitive assessment battery (4). Interestingly, however, there was a positive correlation between the SSS-Cog scale and the Fibromyalgia Impact Questionnaire (FIQ), a measure designed to assess daily functioning rather than cognitive function. In other words, the subjective appraisal of cognitive impairment was strongly and significantly related to patients' functional ability but not to cognitive function. This prompted us to suggest revisiting the definition of the SSS-Cog and to develop more accurate items to measure cognitive impairment in FM patients for both diagnostic and epidemiological purposes.

The purpose of the current study was to examine the value of simple modifications to the current SSS-Cog to improve its accuracy as a valid index of cognitive impairment. Our first goal was to extend the original SSS-Cog from 0-3 to 1-5 and to examine the associations between the extended scale and objective cognitive assessment instruments. This modification derives from research showing that by extending the scale of a questionnaire, the variance increases as well as the correlation coefficient (15).

The second goal was to develop specific questions targeting FM patients' cognitive difficulties to replace the single generic question now in the SSS-Cog, which asks respondents to "indicate your level of symptom severity of cognitive symptoms (concentration and memory, on a scale of 0-3)". Six specific questions were developed by the authors (see Method), based on clinical experience and empirical data.

Methods

Participants

The data were obtained from a specialised FM clinic operating in a tertiary rheumatology clinic in Tel Aviv, Israel. Participants were included if they were over age 18 and had a diagnosis of FM meeting the 2010/2011 ACR diagnostic criteria. These criteria require a Widespread Pain Index (WPI) score of over 7 along with a Symptom Severity Scale (SSS) score above 5, or a WPI between 4 and 6 with an SSS above 9. Exclusion criteria included pregnancy, patients suffering from "secondary" FM, *i.e*. who had been diagnosed with another disease-causing chronic pain, lack of fluency in Hebrew, inability to use a computer or inability to understand the instructions. One hundred and six medical records of FM patients were screened. The data were collected from March 2018 to September 2019. One hundred and two patients met the inclusion criteria and were asked to participate in the study. Four subjects were ineligible (due to inability to use a computer, pregnancy or diagnosed with another disease-causing pain). Thirty-five declined for personal reasons, 2 were discharged before the testing sessions had begun and 3 did not complete the questionnaires. Of the original sample contacted, 62 FM patients were recruited; namely, 55 women (88.7%) and 7 men (11.3%) with an average age of 46.17. The patient demographics are presented in Table I. This study was approved by the institutional ethics review board and all participants gave their written informed consent.

Research instruments

– NeuroTrax™

NeuroTrax™ , a computerised cognitive assessment battery, was used to evaluate cognitive function. This battery has been validated for the assessment of mild cognitive impairment and difficulties in attention and concentration, both for clinical as well as research purposes (16, 17). It is composed of standard neuropsychological tests adapted for computerised delivery, where the participant responds using the computer mouse or keyboard numbers. The test results are automatically uploaded to a central server on which the raw outcome parameter data are corrected for age and education. These corrections are based on data from a pool of normal individuals with no neurological, cognitive or psychiatric impairments. The corrected scores are adjusted to a standardised IQ scale (mean = 100, SD=15) and index scores are computed for the average performance of individuals with similar cognitive performance. The entire test

Table I. General demographics and group outcomes on the self-report questionnaires.

Variable	M (SD) n= 62	Range
Age (years)	46.17 (12.5)	21-78
Education (years)	13 (1.2)	8-18
Female (%)	88.7% (n=55)	
Male (%)	11.3% (n=7)	
WPI (0-19)	12.46 (5.13)	1-19
SSS (0-12)	9.2 (2)	2-12
FIQ (0-100)	69.61 (16.97)	16.29-98.96
BDI-II (0-63)	23.03 (10.48)	0-48
GAD-7 (0-21)	12.72 (5.3)	0-21

*WPI: widespread pain index; SSS: symptom severity scale; FIQ: fibromyalgia impact questionnaire; BDI-II: Beck depression inventory; GAD-7: generalised anxiety disorder 7-item scale.

is 45-60 min long and has been validated in English, Hebrew, Russian, and Spanish (http://www.neurotrax.com). The following domains were used in the current study: memory, speed of information processing, executive function, attention and motor skills. The following tasks were included:

a. Verbal and non-verbal memory (memory).
b. Go-no-go response inhibition (attention + executive function).
c. Stroop interference (attention + executive function).
d. Staged information processing speed (attention + speed of processing).
e. Finger tapping, catch game (motor skills).

The outcome parameters included mean accuracy across trials, mean response time across trials and its standard deviation, and a composite score, computed as the mean accuracy divided by the mean response time.

– Fibromyalgia Impact Questionnaire (FIQ)

The FIQ is a self-report instrument composed of 19 items relating to function, general affect and symptoms. The first question lists 10 activities related to daily living; where the ability to engage in each activity is reported on a 4-point Likert scale. The FIQ also contains seven 100mm visual analog scales (VAS), designed to measure fatigue, sleep quality, stiffness, pain, work interference, anxiety and depression. The FIQ has high internal validity, with a Cronbach's alpha of 0.95 and a test-retest consistency which ranges from 0.56 for the pain score to 0.95 for the function score (18). A validated Hebrew translation of the FIQ was utilised (19).

– Widespread Pain Index (WPI)

The WPI is a score calculated by documenting the number of sites where the patient has felt pain over the last week, out of a total of 19 specific-predesignated sites. The score ranges from 0 to 19.

– Symptom Severity Scale (SSS)

The SSS is an evaluation measuring symptom of fatigue (on a scale of 0-3), unrefreshing sleep (0-3) and cognitive symptoms (on a single SSS-Cog question rated on a scale of 0-3). The scale also includes points given for the presence of the following symptoms: headache, lower abdominal pain, and depression over the last six months (1 point for each symptom). The total SSS score ranges from 0 to 12.

– The new SSS-Cog Scale

The new SSS-Cog extends the scale of the original SSS-Cog. Participants are asked to rate their cognitive symptoms related to concentration and memory on a single scale ranging from 1-5, rather than the original 1-3, where higher scores indicate greater severity.

– Beck Depression Inventory (BDI)-II

This self-report instrument is made up of 21 items that assess the severity of depressive symptoms in the cognitive, behavioural, affective and emotional domains. The total BDI-II score ranges from 0 to 63. A score between 10 and 19 indicates mild depression, 20 and 25 moderate depression and a result above 25 indicates severe depression (20). The BDI-II has high internal consistency, with a Cronbach's alpha of 0.94 (21).

– Test of Memory Malingering (TOMM)

The TOMM is a forced-choice performance validity test composed of 50 pictures of everyday objects. The TOMM consists of two learning trials and a retention trial. A score of 45 or less has been shown to have a sensitivity of 100% in identifying feigned cognitive dysfunction (22).

– Montreal Cognitive Assessment (MoCA)

The Montreal Cognitive Assessment (MoCA) is a brief measure of global cognitive function. The MoCA is a 30-point screening tool that requires approximately 10 minutes to administer and evaluates aspects of attention, orientation, language, verbal memory, as well as visuospatial and executive function (24).

– Generalised Anxiety Disorder 7-item scale (GAD-7)

The GAD-7 is a self-report questionnaire for screening and assessing the severity of generalised anxiety disorder. GAD-7 has seven items, which measure severity of various indicators of GAD. The total score is the sum of the responses for all seven items. The scale uses a normative system of scoring with a final question qualitatively describing the severity of the patient's anxiety over the past 2 weeks (25).

– The New Fibro-Fog Questionnaire

Six questions referring to cognitive decline were developed by the first author (OE), a senior neuropsychologist, based on her clinical and academic experience. The other authors revised, and suggested modifications of the items based on their clinical practice with patients suffering from FM. The questions deal with frequent cognitive complaints among FM patients such as decreased word retrieval, high distractibility, difficulties in complex functions, and others (Supplementary Table).

Procedure

FM patients were recruited during clinical follow -ups at the fibromyalgia

clinic and were asked to participate in a study of cognitive functioning. After providing their informed consent and demographic information, the patients completed the questionnaires and then were given a 10 min break. After the break, the TOMM was administered, followed by the computerised cognitive assessment battery. The assessment took about 90 min. in total. All the tests were anonymous.

Data analysis and statistics

A Spearman correlation coefficient was used to assess whether the new SSS-Cog scale for cognitive symptoms (1-5) correlated with performance on the computerised cognition battery and the MoCA test. Other Spearman coefficient correlation tests were conducted to assess the associations between the new SSS-Cog and the other questionnaires administered in the study (WPI, FIQ, BDI-II). SPSS 25.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for analysis.

Results

General demographics and the clinical characteristics of the FM patients who participated in the study are listed in Table I that reports the means, standard deviations and range of measures.

Patients scored moderately high on the WPI with a mean score of 12.46 (SD=5.13) and the Symptom Severity Scale (SSS) with a mean score 9.2 (SD=2). The FIQ showed the impact of disease to be moderate in the patients, with a mean score of 69.61 (SD=16.97). The BDI-II showed moderate levels of depression, with a mean score 23.03 (SD=10.48). Table II presents the scores on the objective and subjective cognitive assessments.

Validation of the New SSS-Cog Scale

As hypothesised, the new SSS-Cog scale ranging from 1-5 was significantly correlated with the global cognitive score (GCS; r=-0.532, p=0.000) and with all indices on the computerised cognitive assessment battery [Memory Index (r=-0.305, p=0.018); Executive Function Index (r=-0.514, p=0.000); Attention Index (r=-0.471, p=0.000); Information Processing Speed Index (r=-0.468, p=0.000); Motor Skills (r=-0.495, p=0.000)] (Table III).

The original SSS-Cog scale (rated on an ordinal scale from 0-3), was correlated with the global cognitive score (GCS; r=-0.456, p=0.000) and with the Executive Function Index (r=-0.443, p=0.000); Attention Index (r=-0.459, p=0.000); Information Processing Speed Index (r=-0.404, p=0.002) and Motor Skills (r=-0.346, p=0.009)]. No correlation was found between the original SSS-Cog scale and the Memory Index score (r=-0.188, p=0.150).

Table II. Descriptive statistics for the subjective (SSS-Cog) and objective (computerised testing) assessment.

Variable (range)	M (SD) n= 62	Range
Subjective:		
New SSS-Cog (1-5)	3.1 (0.8)	1-5
Original SSS-Cog (0-3)	2.0 (0.7)	0-3
Objective: Computerised Sub-tests, MoCA, TOMM		
Global cognitive score (M=100, SD=15)	86.0 (13.0)	59.10-109.80
Memory (M=100, SD=15)	89.3 (18.0)	25.0-110.30
Executive function (M=100, SD=15)	88.4 (12.5)	58.50-120.40
Attention (M=100, SD=15)	84.4 (16.7)	34.80-114.60
Information processing speed (M=100, SD=15)	81.8 (17.9)	48.30-113.10
Motor skills (M=100, SD=15)	87.0 (18.4)	40.10-110.30
MoCA (0-30)	24.4 (3.1)	18-30
TOMM (0-50)	47.7 (3.0)	45-50

*SSS-Cog: cognitive symptoms score; SSS-Cog new: extended scale version of the SSS Cog; MoCa: Montreal cognitive assessment; TOMM: test of memory malingering.

Table III. Correlations between the objective (computerised cognitive battery, MoCA) and subjective (original SSS-Cog, new SSS-Cog) cognitive measures.

Variable	Subjective: New SSS- Cog		Subjective: Original SSS- Cog		n
	Spearman correlation	p-value (2-tailed)	Spearman correlation	p-value (2-tailed)	
Global cognitive score	-0.532**	0.00	-0.456**	0.00	60
Memory	-0.305*	0.018	-0.188	0.150	60
Executive function	-0.514**	0.00	-0.443**	0.00	58
Attention	-0.471**	0.00	-0.459**	0.00	60
Information processing speed	-0.468**	0.00	-0.404**	0.002	57
Motor skills	-0.495**	0.00	-0.346**	0.009	56
MoCA	-0.356**	0.005	-0.220	0.086	62

*p<0.05, **p<0.01.

Table IV. Correlations between the new questionnaire and scores on the computerised testing battery and the MoCA.

Variable	Subjective: The New Questionnaire		n
	Spearman correlation	p-value (2 tailed)	
Global cognitive score	-0.522**	0.000	60
Memory	-0.163	0.212	60
Executive function	-0.477**	0.00	58
Attention	-0.439**	0.000	60
Information processing speed	-0.496**	0.000	57
Motor skills	-0.532**	0.000	56
MoCA	-0.356*	0.005	62

*p< 0.05, **p<0.01.

Table V. Comparison between the previous and current study; sample characteristics.

Variable	Current study		Previous study (Elkana *et al*., 2019)			
	M	SD	M	SD	T-test	*p*-value
Age	46.17	12.5	42.2	13.5	1.574	0.118
Education	13.9	2.2	14.2	2.9	0.544	0.588
BDI	23.03	10.48	18.70	10.0	-2.217*	0.029
WPI	12.46	5.13	12.16	4.33	-0.338	0.736
Global cognitive score	86.0	13.0	94.586	13.0	3.422**	0.001
Memory	89.3	18.0	91.502	17.2	0.636	0.526
Executive function	88.4	12.5	97.33	15.1	3.348**	0.001
Attention	84.4	16.7	92.238	15.6	2.490*	0.014
Information processing speed	81.8	17.9	91.952	17.0	2.975**	0.004
Motor skills	87.0	18.4	92.166	22.0	1.300	0.196

*$p<0.05$, **$p<0.01$
*BDI: Beck depression inventory; WPI: widespread pain index.

The New SSS-Cog Scale versus the SSS-Cog scale results

In Elkana *et al*. (4), we found that 6% of the participants (3 out of 50) responded 0 on the SSS-Cog. Scale question (M= 2.04, SD= 0.9), which is comparable to the participants in the current study (M=3.1, SD=0.8) who responded 1 (2 out of 62; 3.22%), since both of these numbers were the low anchor on the scale (0-3 and 1-5 respectively). However, as compared to the previous study where 36% of the participants marked 3, the high anchor, only 4.8% selected the high anchor of 5 on the new SSS-Cog extended scale.

Correlations between the New Questionnaire and the Computerised Testing

The six questions written by the authors to examine cognitive decline were significantly correlated with all scores except the Memory Index (r=-0.163, p=0.212) (Table IV).

Correlation between the SSS-Cog, the New SS-Cog and the MoCA

There was a significant correlation between the new SSS-Cog and the MoCA test, a brief measure of cognitive function (r=-0.356, p=0.005), but no correlation between the original SSS-Cog and the MoCA (r=-0.220, p=0.086).

Discussion

The current study was designed to enhance the utility and reliability of the cognitive item on the SSS, a major component of the FM diagnostic criteria, and test whether the correlation between this item and objective measures of cognitive impairment in FM could be strengthened. For this purpose, we used an extended 1-5 scale (instead of the original SSS-Cog of 0-3) as well as a set of directed question items and compared the results to objective measures of cognitive performance on a computerised cognitive battery.

The results showed significant correlations between the new SSS-Cog and the global cognitive score, including all five indices on the computerised cognitive battery. The SSS-Cog is a self-report scale designed to subjectively evaluate cognitive impairment and deficits in FM patients, where a higher score indicates a more severe perceived cognitive deficit. The computerised standardised cognitive test provides a comprehensive standardised objective evaluation of cognitive function (16), with higher scores indicating lower cognitive deficit.

In our previous study, no correlations were found between the original 0-3 SSS-Cog scale and the computerised cognitive battery (4), thus raising doubts as to the validity of the SSS-Cog for assessing cognitive impairment in FM patients. To remedy this discrepancy, we tested two solutions. The first was to extend the original scale and the second was to formulate more specific questions that target the specific cognitive impairment of FM patients. The findings showed moderate to high negative correlations between the objective (Computerised testing and MoCA) and the subjective (new SSS-cog) measures of cognitive decline. Hence, the scale extension, together with the elimination of the 0 value suggests that the new SSS-Cog scale may be a useful self-report tool that can be utilised in the clinical diagnosis of cognitive impairment in FM patients.

Surprisingly, and contrary to our previous results, in the current study we found negative correlations between the original SSS-cog scale (0-3) and all the cognitive indices on the computerised cognitive battery, except for the memory index (Table III). These results may be due to differences in sample characteristics (although the same inclusion and exclusion criteria were applied; see Table V for a comparison of the sample characteristics in the two studies). As can be seen, the two studies differed in level of depression as well as in some cognitive domains (Table V). It is well documented that FM affects a heterogeneous population in terms of age, cognition, psychological distress (*e.g.* depression) etc. (12, 28-30), as also confirmed by the discrepancy in cognitive performance between the previous study (n=50) and the current one (n=62). Further research should recruit larger FM samples to examine the correlations between the original SSS-Cog scale and the new scale with objective cognitive measurements that take sociodemographic characteristics such as education, gender, as well as depression level and pain level into consideration.

To summarise, in the current study the new SSS-Cog scale better characterised FM cognitive impairment only for the memory domain as compared to the original SSS-Cog Scale. The responses to the six specific questions formulated to better identify FM patients' cognitive difficulties (decreased word retrieval, high distraction, difficulty in complex functions, etc.; see Supplementary table) were highly correlated with the global score and with all cognitive indices except for the memory index. This is not surprising since the questionnaire was initially designed to capture the "fibrofog" complaints of FM patients. Therefore, the nature of the questions refers to attentional and executive functions rather than mem-

ory per se and overall, the new questionnaire did not correlate well with the objective measures. Future work could retest this questionnaire and also extend the scale anchors from 0-3 to1- 5.

Limitations

A number of limitations in this current study should be addressed. The participants were recruited in a voluntary manner and were informed in advance that they would be administered computerised neurocognitive tests, thus perhaps eliminating certain patients with self-perceived cognitive impairment. The relatively small sample is another limitation to consider. Furthermore, the study focused on a sample of FM patients, without recruiting a control group. Nevertheless, the computerised cognitive assessment battery is based on a wide database of normal responders, thus making it possible to compare the participants' results with normal values (adjusted for age and education) without the use of a control group.

Conclusion

Modifying the cognitive item of the 2016 ACR fibromyalgia criteria, either by extending the response scale or by introducing more specific patient-experience oriented questions, could lead to a more accurate representation of objective cognitive impairment in FM patients. Specifically, the new SSS-Cog scale was shown to better describe FM cognitive impairment mainly for the memory domain as compared to the original SSS-Cog Scale. In view of the simplicity of the extended scale SSS-Cog modification, we suggest incorporating this item into the FM diagnostic criteria.

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