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Ethical Approval from Jessa Hospital (B243201836858) and Hasselt University (18.61/reva18.02)

The development and measurement properties of the Dutch version of the Fear-Avoidance Components Scale (FACS-D) in persons with chronic musculoskeletal pain

Objective: The Fear-Avoidance Components Scale (FACS) is a recently developed patientreported instrument assessing different constructs related to the fear-avoidance model of pain. The aim was to translate the original English FACS into Dutch (FACS-D) and assess its measurement properties in persons with chronic musculoskeletal pain.

Methods: The original English FACS (20 item-scale, range: 0-100) was translated in Dutch through standard forward-backward translation methodology. The FACS-D's measurement properties were evaluated in 224 persons with chronic musculoskeletal pain. Internal consistency, test-retest reliability and measurement error were assessed with the Cronbach's alpha coefficient (α), intraclass correlation coefficient (ICC), and standard error of measurement (SEM). Construct validity was assessed through inter-item correlation analyses, exploratory factor analysis, association with other fear-avoidance-related constructs, and hypothesis testing.

Results: Internal consistency, test-retest reliability and hypotheses testing were good (α =0.92; ICC=0.92, CI 0.80-0.96; 7/8 hypotheses confirmed). Similar to the original FACS and other translated versions, a two-factor model best fit the data. However, item distribution differed from other versions. One factor represented "pain-related cognitions and emotions" and a second factor represented "avoidance behaviour". In contrast to the original FACS, low inter-item correlations for item 12 were found. The FACS-D was more strongly associated with fear-avoidance-related constructs of pain severity, perceived disability, feelings of injustice, and depressive/anxiety symptoms than other fear-avoidance-related scales studied here.

Conclusion: The FACS-D demonstrated good reliability and construct validity, suggesting that it may be a useful measure for Dutch-speaking healthcare providers. Two clinically relevant factors, with a different item distribution than the original FACS, were identified: one covering items on pain-related cognitions and emotions, and one covering items on avoidance behaviour. The stronger association between FACS-D and fear-avoidance related constructs suggests that the FACS-D may be more effective in evaluating the cognitive, emotional and behavioural constructs of pain-related fear-avoidance.

Ethical approval number: B243201836858

Keywords: psychometric; pain-related fear; kinesiophobia; avoidance; fear of movement.

INTRODUCTION

Musculoskeletal pain is the leading cause of disability worldwide.[1] Dysfunctional painrelated cognitive, emotional and behavioural factors are known contributors to pain severity, disability, and physical performance in musculoskeletal pain conditions, and can lead to poor treatment outcomes.[2-11] The identification of factors underlying the transition from acute to chronic pain and disability is essential to optimize treatment.[12]

After a tissue injury or a painful experience, and in line with natural healing processes, a normal recovery trajectory involves a gradual increase in movement and use of one's affected body parts, and motivation to re-engage in valued activities, until pre-morbid levels of function have been achieved.[13] Although it is appropriate to reduce activity and avoid painful activities during the acute stage of injury, persisting activity avoidance will likely lead to negative consequences. According to the fear-avoidance model of pain, [13-15] a subgroup of injured patients gets stuck in unhelpful beliefs concerning pain. Interpreting pain as threatening and worrying about pain can initiate maladaptive coping behaviours, hypervigilance of pain symptoms, and avoidance of activities of daily living, which can result in physical deconditioning, functional impairments, and sustained pain-related disability.[13-15] High levels of fear-avoidance have been found to predict the transition from subacute to chronic low back pain, and low levels of fear-avoidance have been found to predict recovery after chronic disabling low back pain. [10, 11] Furthermore, it is known that a subset of persons in pain adopt a victim role (e.g. persons after a work injury can blame their employer for the injury or blame the workers compensation insurance company for not providing sufficient treatment) which further promotes activity avoidance and disability.[16]

Pain-related cognitions, emotions, and avoidance behaviours are typically assessed with patient-reported instruments, including the Fear-Avoidance Beliefs Questionnaire (FABQ),[17] Pain and Anxiety Symptoms Scale (PASS),[18] and Tampa Scale for Kinesiophobia (TSK).[19] However, these instruments have been criticized for limited construct validity, lack of item specificity (e.g. not differentiating between fear of movement and avoidance behaviour; not specifying reasons for avoidance), and for missing important components of the current fearavoidance model of pain.[20, 21] To note, none of the above-mentioned scales assesses different domains of pain-related avoidance behaviour, like avoidance based on fear of (re)injury, fear of increased pain, fear of functional loss or actual increased pain (without fear).[22] The Fear-Avoidance Components Scale (FACS) was developed in 2015 within a framework of the current fear-avoidance model in an attempt to overcome the limitations of previous fear-avoidance-related scales and to more effectively assess all important cognitive, emotional and behavioural constructs of pain-related fear-avoidance.[23, 24] It includes adapted items from the FABQ, [17] PASS, [18] TSK, [19] the Pain Catastrophizing Scale (PCS), [25] and the Injustice Experience Questionnaire (IEQ).[16] It also includes new items on unrepresented concepts that were not found in these previously published scales, including types of activities that one avoids and the reasons for avoidance. The original English FACS, and other translated versions have demonstrated appropriate measurement properties.[23, 24, 26-28] The FACS is responsive to treatment (i.e. FACS scores improved in chronic musculoskeletal pain patients after completing an interdisciplinary functional restoration treatment program), [24] and FACS outcomes are predictive for work-return outcomes. [24]

Because the FACS offers a comprehensive measure of fear-avoidance-related components in one scale, and assesses the 'what' and 'why' of avoidance behavior in more detail than former

scales, the FACS has potential benefit for Dutch speaking researchers, healthcare providers and persons with musculoskeletal pain. We aimed to translate the FACS into Dutch (FACS-D), and investigate its measurement properties in patients with chronic musculoskeletal pain, with specific attention towards additional insights of the FACS-D in comparison to the original English FACS.

<u>METHODS</u>

Medical ethics

The study was approved by the ethical review committees of Jessa Hospital (B243201836858) and Hasselt University (18.61/reva18.02).

Translation and cross-cultural adaptation

The original English FACS items can be found in AppendixS1 and, together with other translated versions of the FACS, it can also be found at https://www.pridedallas.com/questionnaires/.

The cross-cultural adaptation process was performed in accordance to the guidelines of Beaton et al. (2000).[29] This process consisted of five stages, i.e. 1. initial translation, 2. synthesis, 3. back translation, 4. review and consensus and 5. field test of the prefinal version (face validity). Details are described in AppendixS2 (Part A).

Measurement properties

Participants

Eligibility criteria for participation in this cross-sectional study were: a) musculoskeletal pain for at least 3 months, defined as low back, neck, shoulder, hip or knee pain as primary pain complaint; b) between 18 and 80 years of age; c) no current or past surgical treatment for the current pain complaint; d) Dutch language as mother tongue; e) no previous (<6 months) or currently ongoing psychotherapy or physiotherapy for the pain complaint. Exclusion criteria were: a) pain from a non-musculoskeletal origin (e.g. tumour), b) suffering from a neurological disease (e.g. stroke or multiple sclerosis) or c) cognitive impairments. Eligible participants were recruited via social media and from different settings, including the multidisciplinary pain centre, the orthopaedic department, and the Physical and Rehabilitation Medicine department of Ziekenhuis Oost-Limburg and Jessa Hospital, and local physiotherapist practices. Recruitment started in December 2018 and ended in December 2020. Eligibility criteria were assessed by a member of the research team based on the medical file and/or information provided by each participant. The study's purpose was explained in detail by a member of the research team and after agreeing to participate, each participant signed an informed consent form.

Procedure

In addition to the FACS-D, all participants completed a battery of sociodemographic information and patient-reported questionnaires which assessed pain intensity and various constructs (e.g. perceived disability, fear avoidance beliefs, pain catastrophizing, general anxiety and depression and perceived injustice).

For reliability assessment, 35 participants were asked to complete the FACS-D a second time approximately one-week later.

Patient-reported clinical data

Sociodemographic information

Participants were asked to indicate their age, sex, height, weight, work status, and duration of the primary pain complaint.

Fear-avoidance components scale – Dutch version (FACS-D)

Fear-avoidance was assessed by the FACS-D, which is a 20-item questionnaire. Each item is scored on a 6-point Likert scale, resulting in scores ranging from zero ("completely disagree") to five ("completely agree"). There is a maximum total score of 100, with higher scores indicating more fear-avoidance. Five severity levels have been proposed: subclinical (0-20), mild (21-40), moderate (41-60), severe (61-80), and extreme (81-100).[23]

Numeric Pain Rating Scale (NPRS)

The average pain intensity over last week was assessed by the Numeric Pain Rating Scale (NPRS), an 11-point scale ranging from zero ("no pain") to ten ("worst possible pain").[30] The NPRS has appropriate measurement properties in patients with musculoskeletal pain.[31, 32]

Fear-Avoidance Beliefs Questionnaire (FABQ)

Fear-avoidance beliefs were assessed by the FABQ-physical activity subscale.[33] Each item is scored on a 7-point Likert scale with a score ranging from zero ("completely disagree") to six ("completely agree"). Higher scores indicate higher levels of fear avoidance beliefs, with a maximum total score of 24 for the FABQ-physical activity subscale. Measurement properties of the FABQ are sufficient in patients with chronic musculoskeletal pain.[17, 34, 35]

Tampa Scale for Kinesiophobia (TSK)

Pain-related fear of movement and (re)injury was assessed with the 17-item version of the TSK.[19] Each item is scored on a 4-point Likert Scale, ranging from one ("strongly disagree") to four ("strongly agree"). The total score ranges between 17 and 68, with higher values reflecting greater fear of movement. Measurement properties of the TSK are sufficient in patients with chronic musculoskeletal pain.[34-38]

Pain Catastrophizing Scale (PCS)

Negative thoughts and feelings when experiencing pain were assessed with the PCS, consisting of 13-items.[25] Each item is scored from zero ("not at all") to four ("all the time"). Its total score ranges between 0 and 52, with a higher total score indicating higher levels of pain catastrophizing. Acceptable validity and reliability results of the PCS in musculoskeletal patients are reported.[39, 40]

Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item questionnaire evaluating symptoms of anxiety and depression without involving physical complaints.[41] One subscale covers symptoms of anxiety (HADS-A), the other symptoms of depression (HADS-D). Each item is scored from zero ("not applicable") to three ("certainly applicable"). The maximum score on each subscale is 21, with higher values indicating more anxiety/depression symptoms. Both the anxiety and depression subscales have good psychometric properties in musculoskeletal pain populations.[42]

Injustice Experience Questionnaire (IEQ)

Perceived injustice was measured with the Injustice Experience Questionnaire (IEQ).[16] The IEQ consists of 12 items, each item is scored from zero ("not at all") to four (all the time"). The total score ranges between 0 and 48 and higher total scores reflect higher levels of perceived injustice. The validity of the IEQ is sufficient in patients with musculoskeletal pain.[16]

Perceived disability questionnaires

Perceived disability was assessed with specific disability questionnaires per pain location. The Oswestry Disability Index (ODI),[43] Neck Disability Index (NDI),[44] Disabilities of the Arm, Shoulder and Hand questionnaire (DASH),[45, 46] Hip dysfunction and Osteoarthritis Outcome Score (HOOS)[47, 48] and Knee dysfunction and Osteoarthritis Outcome Score (KOOS)[47, 48] and Knee dysfunction and Osteoarthritis Outcome Score (KOOS)[49] were used to assess perceived disability in persons with low back, neck, shoulder, hip and knee pain, respectively. All of these scales range from 0 to 100. For the ODI, NDI and DASH, a higher score indicates more disability. For the HOOS and KOOS, a higher score indicates lower disability. The psychometric properties of these scales are acceptable for their respective problem (i.e. low back pain, neck pain, shoulder pain, hip pain, knee pain). [43-46, 49]

Statistical analysis

Statistical Package for Social Sciences (SPSS) version 27 (IBM corporation, 2020) was used.[50] The level of significance was set at P<0.05. Analyses were performed according to the recommendations of De Vet et al. (2011) and Ellis (2013).[51, 52]

To assess internal consistency, Cronbach's alpha (α) and lambda 2 (λ_2) were calculated.[53] Internal consistency was considered sufficient when structural validity was sufficient and Cronbach's alpha was ≥ 0.70 and ≤ 0.95 for each subscale.[54, 55] The absolute agreement intraclass-correlation coefficient (ICC) was calculated to assess test-retest reliability. An ICC ≥ 0.70 was needed for test-retest reliability to be considered sufficient.[54, 55] To evaluate measurement error, the standard error of measurement (SEM) and smallest detectable change (SDC) were calculated using the following formulas: SEM =

$$\sqrt{(\sigma_{\text{measurements}}^2 + \sigma_{\text{residual}}^2)}$$
 and $SDC = SEM \ x \ 1.96 \ x \ \sqrt{2}$.[51]

Structural validity was first assessed by calculating the inter-item correlation matrix, followed by an exploratory factor analysis. Principal axis factoring was used as a method of factor extraction and Varimax was selected as a method of factor rotation. The following criteria were used to determine the number of factors to be extracted: Eigenvalues >1.0; Catell's scree plot inflection point; and cumulative explained variance >50%. Parallel analysis was carried out as well,[56] which is considered to be a more accurate method for determining the appropriate number of factors to retain.[57] Factors with an Eigenvalue larger than the corresponding Eigenvalue from a randomly generated correlation matrix were retained.

Hypothesis testing was performed with regard to the assessment of construct validity. A priori hypotheses were formulated and tested with Pearson's or Spearman's correlation coefficients[54, 55]. Correlation coefficients of 0-0.3 were considered very weak, 0.3-0.5 weak, 0.5–0.7 moderate, 0.7–0.9 high, 0.9–1.0 very high.[58] Construct validity was considered sufficient if at least six of the following hypotheses (75%) were confirmed[54, 55]:

- Hypotheses 1-4: Since adapted items of the FABQ, TSK, PCS and IEQ were used in the FACS' development process, we expected these patient-reported instruments to have at least moderate correlations with the FACS-D (r≥0.5).
- Hypothesis 5: Because weak to moderate positive correlations have been reported between pain-related beliefs and disability,[59, 60] we expected the perceived disability instruments to have at least a weak correlation with the FACS-D (r≥0.3).
- Hypothesis 6: Because a weak correlation has been reported between pain intensity and fear-avoidance beliefs,[61] at least a weak correlation was expected between the NPRS and the FACS-D (r≥0.3).

 Hypotheses 7-8: Because a weak correlation has been reported between fearavoidance beliefs and depressive symptoms,[17] at least a weak correlation was expected between the anxiety and depression subscale of the HADS and the FACS-D (r≥0.3).

Additionally, because the FACS-D purports to capture more fear-avoidance-related dimensions than current fear-avoidance-related scales, we investigated whether the FACS-D had higher correlations than the TSK, FABQ-PA, and PCS with measures of perceived disability, pain intensity, HADS-A, HADS-D and IEQ.

<u>RESULTS</u>

Participants

Two hundred twenty-four individuals with chronic musculoskeletal pain participated in this study. The mean age (SD) of the total participant sample was 48.6 (SD=16.0) years, and the mean pain duration was 26.3 (SD=40.3) months. Details on the participants' characteristics per pain location can be found in Table 1.

Table 1. Participants' characteristics						
		Low back pain (n=56)	Neck pain (n=24)	Hip pain (n=47)	Knee pain (n=17)	Shoulder pain (n=80)
Age (y), mean (SD)		42.7 (16.6)	43.0 (14.6)	51.5 (17.0)	52.1 (18.1)	51.9 (13.3)
Sex (female), n (%)		31 (55%)	20 (83%)	35 (75%)	11 (65%)	51 (64%)
Works	status, n (%)					
-	Working	23 (43%)	16 (67%)	22 (47%)	7 (41%)	33 (41%)
-	Sick-leave	12 (22%)	3 (13%)	6 (13%)	1 (6%)	18 (23%)
-	Retirement	6 (11%)	2 (8%)	12 (26%)	5 (29%)	20 (25%)
-	Student	9 (17%)	2 (8%)	6 (13%)	3 (18%)	3 (4%)
-	Unemployed	4 (8%)	1 (4%)	1 (2%)	1 (6%)	6 (8%)
Pain duration (m), mean (SD); range		42.0 (65.9);	18.1 (17.7);	23.6 (21.3);	36.1 (46.0);	17.6 (20.5);
		3-355	3-72	3-96	5-167	3-87

Legend. n=number of participants, y=years, SD=standard deviation, m=months

Translation and cross-cultural adaptation

The outline of the translation and cross-cultural adaptation process can be found in AppendixS2 (Part B). The final FACS-D is presented in AppendixS3.

Patient-Reported Outcome Measures

Outcomes on the patient-reported instruments are reported in Table 2. FACS-D scores ranged from zero to 87/100, with a mean score of 22.00, 34.00 and 51.75 at the 25th, 50th and 75th

percentiles, respectively. The distribution of the FACS-D scores in the total sample is presented in Fig. 1 Subjects were organized into FACS severity subgroups based on recommended score ranges. [23, 24] The distribution of the participants into FACS severity subgroups (number and percentage of participants) was as follows: 49 subclinical (22%), 84 mild (38%), 58 moderate (25%), 31 severe (14%) and 2 extreme (1%).[23, 24]

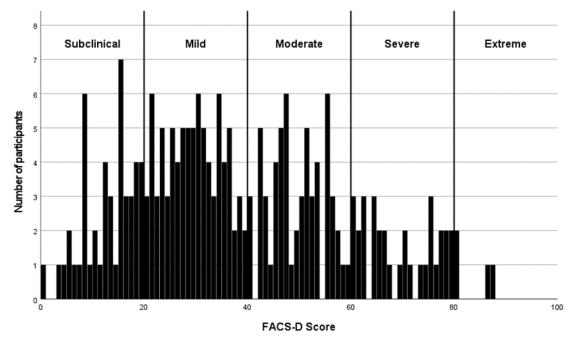


Fig. 1 Distribution of total scores of the Dutch version of the Fear Avoidance Component

Scale (FACS-D).

	Total sample (n=224)	Low back pain (n=56)	Neck pain (n=24)	Hip pain (n=47)	Knee pain (n=17)	Shoulder pain (n=80)
FACS-D (0-100)	37.5 (20.0); 0-87	37.4 (20.3); 5-75	29.9 (16.5); 0-65	45.2 (23.0); 8-87	34.0 (22.3); 9-80	36.0 (17.2); 3-7
NPRS (0-10)	5.0 (2.3)	4.9 (2.1)	4.5 (1.6)	5.7 (2.5)	4.8 (2.3)	5.0 (2.4)
ODI (0-100)	/	22.0 (13.9); 2-50	/	/	/	/
NDI (0-100)	/	/	22.7 (11.1); 8-56	/	/	/
HOOS (0-100)	/	/	/	48.6 (22.0); 13-91	/	/
KOOS (0-100)	/	/	/	/	59.9 (18.9); 20-91	/
DASH (0-100)	/	/	/	/	/	36.7 (17.7); 8-8
FABQ-PA (0-24)	13.2 (5.4); 0-24	12.3 (5.5); 1-24	10.2 (5.4); 0-20	13.3 (5.4); 4-22	13.3 (6.5); 4-24	14.7 (4.7); 0-24
TSK-17 (17-68)	36.2 (8.1); 17-56	36.6 (8.0); 18-52	31.6 (6.6); 21-46	38.7 (8.2); 23-56	37.4 (9.8); 24-54	35.5 (7.6); 17-5
PCS (0-52)	15.6 (10.9); 0-49	18.9 (10.5); 1-49	11.29 (9.3); 0-34	18.7 (12.5); 0-48	17.6 (14.2); 0-45	12.5 (8.4); 0-38
HADS-A (0-21)	5.7 (4.2); 0-19	6.6 (4.4); 0-15	6.3 (3.6); 2-14	5.7 (5.2); 0-19	4.6 (3.4); 0-11	5.2 (3.6); 0-14
HADS-D (0-21)	4.0 (3.8): 0-19	4.8 (4.2); 0-15	3.8 (3.4); 0-10	4.5 (4.4); 0-19	2.7 (3.1); 0-9	3.7 (3.2); 0-13
HADS (0-42)	9.7 (7.4); 0-35	11.3 (7.8); 0-27	10.1 (6.2); 3-24	10.1 (9.2); 1-35	7.3 (6.1); 1-19	8.8 (6.3); 0-25
IEQ (0-48)	8.7 (9.6); 0-46	11.5 (11.0); 0-44	5.8 (7.0); 0-24	10.2 (10.3); 0-37	8.8 (14.1); 0-46	6.6 (6.6); 0-31

n=number of participants, SD=standard deviation, FACS=Fear-Avoidance Components Scale, NPRS=Numeric Pain Rating Scale, ODI=Oswestry Disability Index, NDI=Neck Disability Index, HOOS=Hip Osteoarthritis Outcome Scale, KOOS=Knee Osteoarthritis Outcome Scale, DASH=Disability of the Arm, Shoulder and Hand Questionnaire, FABQ-PA=Fear Avoidance Beliefs Questionnaire Physical Activity Subscale, TSK=Tampa Scale for Kinesiophobia, PCS=Pain Catastrophizing Scale, HADS=Hospital Anxiety and Depression Scale, IEQ=Injustice Experience Questionnaire.

Structural validity

The inter-item correlation matrix of the total group indicated a correlation of <0.2 between item 12 and 15 other items. Item 10 had a correlation of <0.2 with 4 other items. Item 1 and item 15 had a correlation of <0.2 with 3 other items. The other items correlated >0.2 with at least 18 out of 19 items. Exploratory factor analysis was performed on the total group of participants. Four factors with an Eigenvalue >1 were found, explaining 40.2%, 11.0%, 6.4% and 5.3% of the variance, respectively. The cumulative percentage variance indicated that more than 50% of variance was explained following the second factor (51.1%). Also, the scree plot showed that after the second factor, the slope flattened substantially (Fig. 2). Therefore, both the eigenvalues and the scree plot indicated a 2-factor model.

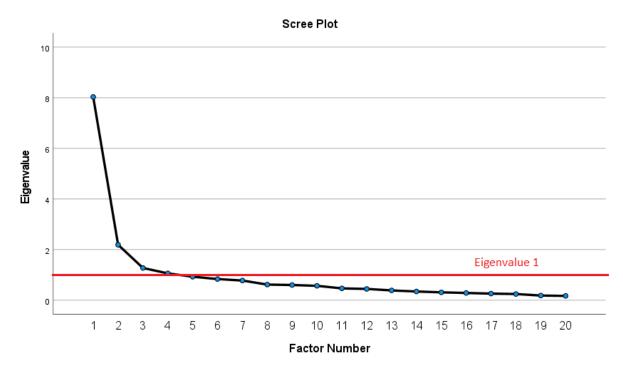


Fig. 2 Scree plot for exploratory factor analysis of FACS-D.

Through parallel analysis, [62] it was found that the first two eigenvalues were larger than their corresponding random eigenvalue, suggesting that two factors should be retained. After repeating the principle axis factoring with a two-factor model with Varimax rotation, the

factor loadings illustrated in Table 3 appeared. Only item 12 showed a factor loading <0.32, which is considered as a feasible cut-off point.[63] Items in Factor one (items 2-4, 6-10 and 12-14) represented "pain-related cognitions and emotions". Items in Factor two (items 1, 5, 11, and 15-20), represented "avoidance behaviour". When applying the same statistics on the FACS-D excluding item 12, similar results were found.

ltem	Factor 1	Factor 2	
#2	.659	.317	
#3	.624	<u>.256</u>	
#4	.730	.345	
#6	.526	.242	
#7	.726	<u>.202</u>	
#8	.670	<u>.162</u>	
#9	.735	.274	
#10	.536	<u>.157</u>	
#13	.622	<u>.190</u>	
#14	.696	<u>.269</u>	
#12	<u>.280</u>		
#1	<u>.140</u>	.629	
#5	<u>.244</u>	.623	
#11	.210	.656	
#15	<u>.192</u>	.663	
#16	<u>.233</u>	.711	
#17	.335	.440	
#18	<u>.280</u>	.640	
#19	<u>.299</u>	.540	
#20	<u>.168</u>	.796	

Table 3. Factor loadings for the two-factor model of the FACS-D.

Extraction Method: Principal Axis Factoring. Factor loadings <0.32 are underlined.

Measurement properties

Lambda 2 was 0.89 for factor 1 and 0.90 for factor 2, Cronbach's alpha was 0.88 for factor 1 and 0.90 for factor 2. The ICC (95% confidence interval) was 0.92 (0.80–0.96), indicating very good reliability. A SEM of 5.6 points and an SDC of 15.5 points were calculated.

Hypotheses testing

Spearman correlation coefficients were calculated among the patient-reported instruments (Table 4). Seven of the eight a priori formulated hypotheses were confirmed, indicating sufficient construct validity. In accordance to the hypotheses, the FACS-D showed moderate relationships with the TSK, PCS, and IEQ; weak relationships with the HADS-D, HADS-A and NPRS; and moderate to high relationships with the ODI, NDI, KOOS, HOOS and DASH. The FABQ-PA showed a weak relationship with the FACS-D, which did not match the corresponding hypothesis. Interestingly, the FACS-D showed mostly higher correlations with measures of perceived disability, pain intensity, HADS-A, HADS-D and IEQ than the other fear-avoidance scales (TSK, FABQ-PA, PCS)(AppendixS4).

п	FACS-D	TSK-17	FABQ-PA	PCS
56	.70** (.53, .81)	.55** (.32, .71)	.24 (04, .48)	.60** (.39, .75)
24	.53* (.11, .79)	.21 (27, .61)	.07 (40, .51)	.31 (16, .66)
80	.57** (.39, .70)	.54** (.35, .68)	.46** (.26, .62)	.44** (.23, .60)
47	73** (85,56)	62** (77,40)	41** (64,14)	47** (67,21)
17	59* (84,14)	45 (77,06)	55* (82,08)	54* (82,06)
224	<u>.49**</u> (.38, .58)	/	/	/
224	.64** (.57, .73)	/	/	/
224	.59** (.50, .67)	/	/	/
224	.69** (.60, .75)	.55** (.44, .64)	.31** (.19, .43)	.59** (.49, .67)
224	.37** (.24, .48)	.21** (.07, .33)	.14* (.00, .27)	.39** (.27, .50)
224	.48** (.37, .58)	.37** (.25, .48)	.29** (.16, .41)	.35** (.23, .47)
224	.41** (.29, .51)	.30** (.17, .42)	.16** (.03, .29)	.33** (.20, .45)
	56 24 80 47 17 224	56 .70** (.53, .81) 24 .53* (.11, .79) 80 .57** (.39, .70) 47 73** (85,56) 17 59* (84,14) 224 .49** (.38, .58) 224 .64** (.57, .73) 224 .69** (.60, .75) 224 .37** (.24, .48) 224 .48** (.37, .58)	56 $.70^{**}(.53, .81)$ $.55^{**}(.32, .71)$ 24 $.53^{*}(.11, .79)$ $.21(27, .61)$ 80 $.57^{**}(.39, .70)$ $.54^{**}(.35, .68)$ 47 $73^{**}(85,56)$ $62^{**}(77,40)$ 17 $.59^{*}(84,14)$ $.45(77,06)$ 224 $.49^{**}(.38, .58)$ /224 $.64^{**}(.57, .73)$ /224 $.69^{**}(.60, .75)$ $.55^{**}(.44, .64)$ 224 $.37^{**}(.24, .48)$ $.21^{**}(.07, .33)$ 224 $.48^{**}(.37, .58)$ $.37^{**}(.25, .48)$	56.70** (.53, .81).55** (.32, .71).24 (04, .48)24.53* (.11, .79).21 (27, .61).07 (40, .51)80.57** (.39, .70).54** (.35, .68).46** (.26, .62)4773** (85,56)62** (77,40)41** (64,14)17.59* (84,14)45 (77,06).55* (82,08)224.49** (.38, .58)//224.64** (.57, .73)//224.69** (.50, .67)//224.69** (.60, .75).55** (.44, .64).31** (.19, .43)224.37** (.24, .48).21** (.07, .33).14* (.00, .27)224.48** (.37, .58).37** (.25, .48).29** (.16, .41)

Table 4. Spearman correlation coefficients (95% CI) between FACS-D and other patient-reported instruments

**correlation is significant at the 0.01 level(2-tailed);*correlation is significant at the 0.05 level(2-tailed). Correlations coefficients not confirming corresponding hypothesis are underlined.

CI=confidence interval, NPRS=Numeric Pain Rating Scale, ODI=Oswestry Disability Index, NDI=Neck Disability Index, HOOS=Hip Osteoarthritis Outcome Scale, KOOS=Knee Osteoarthritis Outcome Scale, DASH=Disability of the Arm, Shoulder and Hand Questionnaire, FABQ-PA=Fear Avoidance Beliefs Questionnaire Physical Activity Subscale, TSK=Tampa Scale for Kinesiophobia, PCS=Pain Catastrophizing Scale, HADS=Hospital Anxiety and Depression Scale, IEQ=Injustice Experience Questionnaire.

DISCUSSION

The FACS claims to offer a more comprehensive assessment of fear-avoidance than previous fear-avoidance-related instruments that were used in the present study (i.e. TSK, FABQ-PA, and PCS). The FACS-D was more strongly associated with fear-avoidance-related constructs of pain intensity, perceived disability, feelings of injustice, and depressive/anxiety symptoms than these other fear-avoidance-related scales. These results suggest that the FACS-D may be more effective in evaluating the cognitive, emotional and behavioural constructs of pain-related fear-avoidance.

In addition, a key finding emerged from the exploratory factor analysis. Though the English[24], Spanish[27], Serbian[26], and Dutch FACS have all been determined to be twodimensional scales, the item distribution of the FACS-D was found to be different than these previous versions. FACS-D factor one (items 2-4, 6-10 and 13-14) represents "pain-related cognitions and emotions" and factor two (item 1,5,11 and 15-20) represents "avoidance behaviour", including the types of activities that are avoided. We believe the item distribution of the two factors in the FACS-D provide more face validity than the two-factor solution found in the English, Spanish, and Serbian versions[24, 26, 27]. It is assumed that the differences in the item distribution between the different translated versions may be due to slight differences in the assessed population, rather than due to the cross-cultural translation process, since this was done in a rigorous manner following the guidelines of Beaton,[29] and face validity was considered appropriate (Appendix S2 Part A).

The internal consistency of the FACS-D was found to be very high. However, item 12 ("It is someone else's fault that I have this painful medical condition"), which is related to the

concept of perceived injustice, had low correlations with multiple other items, low factor loading for the two-factor model, and was unable to differentiate participants with high fearavoidance from participants with low fear-avoidance (i.e. item 12 was scored zero by 78% of the participants and one by another 12%). This finding suggested that item #12 was not useful for the current study sample. It should be noted that almost all participants in the original psychometric evaluation study of the English FACS were being treated for chronic pain conditions that developed from work-related injuries.[24] It is likely that many subjects in this population might have held feelings of blame towards their employer, colleagues or the workers compensation insurance company. In fact, factor loadings for item 12 in the English version were reported to be 0.488 for factor one and 0.103 for factor two.[24] In contrast, no subjects in the present study presented with pain related to a work-related injury, motor vehicle accident, unsuccessful surgery, etc. which would likely have generated feelings of blame. Results of the present study suggest that the usefulness of item 12 is dependent on the population under investigation, i.e., item 12 is useful in case the assessed population holds feelings of blame towards someone else. This result is in line with the results of the Spanish and Serbian studies.[26, 27]

The FACS-D showed sufficient internal consistency, test-retest reliability and construct validity. Internal consistency has been found to be sufficient in all the other language versions of the FACS, [23, 26, 27] with similar Cronbach's alpha values as the FACS-D. Also the values for test-retest reliability found by Bid et al. (2020), Knezevic et al. (2018), and Neblett et al. (2016) were sufficient and nearly equal to the value in the current study. [23, 26, 28] Regarding the SEMs and SDCs, the results indicated that the minimum amount of change in a patient's score that ensures the change is not the result of measurement error is 15.5/100 points on

the FACS-D. Results regarding the association between the FACS-D and other self-reported outcomes were similar to the reported associations of Knezevic et al. (2018) and Bid et al. (2020). The correlation coefficients reported by Knezevic et al. (2018) between the FACS and ODI and between the FACS and pain intensity were very close to the correlation coefficients found in the current study. Bid et al. (2020) reported similar correlation coefficients between the FACS and pain intensity, and FACS and perceived level of disability, though they used the Roland-Morris Disability Questionnaire instead of the ODI or NDI, as in the present study.[64] One previous study reported a somewhat higher moderate correlation between the FACS and FABQ total scores.[64] However, when looking at the correlation between their FABQ-PA score and the FACS, they also found a weak correlation of .32 (p<.001), which is lower that the weak (approaching moderate) correlation of .49 (p<.05) between the FABQ-PA and FACS-D reported in this study.

As with other similar studies, several considerations should be made. Importantly, we did not include a behavioural movement assessment in our protocol. It is known that other fearavoidance-related measures (e.g. TSK) have not been shown to consistently predict actual (avoidance) behaviour in people with nonspecific low back pain,[65] and are only very weakly associated with it in musculoskeletal conditions in general.[5, 66] However, higher FACS severity scores have been shown to be associated with worse lifting performance in subjects with chronic musculoskeletal pain[24]. Therefore, it is of high interest to study whether the identified 'activity avoidance' dimension of the FACS-D would be able to predict actual avoidance behaviour. Concerning test-retest reliability and measurement error, the test setting was not completely similar between the test sessions, since the retest was completed

at home. However, a potential recall bias was minimized by applying an appropriate time interval between the two test periods. We specifically chose to exclude patients who received physiotherapy for their current pain within the previous 6 months, since it is known that treatments like pain neuroscience education can influence fear-avoidance but do not necessarily have an immediate impact on pain or disability[67, 68]. Therefore, if these patients would not have been excluded, it is possible that correlations between the FACS-D and pain or disability measures may have been lower. This implies that current results only apply to these patients who did not receive physiotherapy. Responsiveness, defined as "the ability of a patient-reported instrument to detect change over time in the construct to be measured",[69] was also not investigated in this study, and should be considered in future studies. Studies should also focus on performing a confirmatory factor analyses for the twofactor model of the FACS-D within a new sample and with a representation of the fit indices. Another topic of investigation could be the development of a short version of the FACS. Items that do not perform well should be deleted, potentially resulting in better measurement properties and less time needed to complete the FACS.

CONCLUSION

The FACS-D demonstrated adequate measurement properties for assessing fear-avoidance in Dutch speaking patients with chronic musculoskeletal pain. Two clinically relevant factors, with a different item distribution than the original FACS, were identified. Factor one represented "pain-related cognitions and emotions" and factor two "avoidance behaviour". The stronger association between FACS-D and fear-avoidance related constructs suggests that the FACS-D may be more effective in evaluating the cognitive, emotional and behavioural

constructs of pain-related fear-avoidance than the other fear-avoidance-related scales studied here.

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this study.

Ethical approval: Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as amended in 2013), and has been approved by the ethical committee of Jessa Hospital (18.61/reva18.02).

Figures:

- Fig. 1 Distribution of total scores of the Dutch version of the Fear Avoidance Component Scale (FACS-D).
- Fig. 2 Scree plot for exploratory factor analysis of FACS-D.

Tables:

- Table 1. Participants' characteristics
- Table 2. Outcomes (presented as mean (SD); range) on patient-reported instruments
- Table 3. Factor loadings for the two-factor model of the FACS-D.
- **Table 4.** Spearman correlation coefficients between FACS-D and other patient-reported instruments

Supplementary files:

- AppendixS1. English FACS
- AppendixS2. Methodology and results translation

- AppendixS3. FACS-D
- AppendixS4. Scatterplots of FACS-D and other patient-reported instruments colored per region

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