The content and construct validity of the modified patient specific functional scale (PSFS 2.0) in individuals with neck pain

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ABSTRACT

Study design: Clinical measurement study.

Background: The Patient Specific Functional Scale (PSFS) is a commonly used outcome measure, however answering options differ and content validity has yet to be assessed.

Objective: To assess the content validity of the PSFS in patients with neck pain presenting to a physical therapist. And secondly, to assess the construct validity of the PSFS using the preferred version identified in the content validity study.

Methods: The target population consisted of patients with neck pain presenting to physical therapy. First, content validity was assessed through semi structured interviews and content thematic analysis. Second, construct validity was assessed on the PSFS 2.0 by examining its correlation with the Neck Disability Index (NDI).

Results: Eleven patients were interviewed. Patients indicated the concept of 'activity limitations' is very important to them. The PSFS is considered to be relevant and easy to understand. Patients had an explicit preference for the PSFS 2.0 version (using a different answering option and example list) and indicated they preferred to answer the PSFS 2.0 together with a clinician. One hundred patients participated in the construct validity study on the PSFS 2.0. The median PSFS 2.0 score was 4.5 and the correlation with the NDI was substantial (0.54).

Conclusion: The results of this study indicate that in individuals with neck pain, the PSFS is appropriate however; PSFS 2.0 is the preferred version. The PSFS 2.0 is considered to be valid in terms of content validity and construct validity for patients with neck pain.

KEYWORDS

Neck; activities of daily living; disability; psychometrics; patient outcome assessment; patient specific functional scale

Introduction

Neck pain is a common musculoskeletal disorder which affects approximately two-thirds of individuals at some point in their lives [1–3]. Many people with neck pain never experience a complete resolution of symptoms and proceed to chronicity [4,5]. Neck pain is ranked 4th highest in terms of associated disability [5,6]. Neck pain results in a substantial economic burden to society and can result in major individual suffering due to a change in functional health status (substantial disability and functional limitations) [7]. The International Classification of Functioning, Disability and Health (ICF) has described the widely accepted definition of functional health status in terms of 'impairments', 'activity limitations', and 'participation restrictions' [8–10].

One measurement that can potentially be used to measure 'activity limitations' is the 'Patient Specific Functional Scale' (PSFS) [11]. The PSFS was originally designed to allow individual patients to identify activities that they were having difficulty with compared to preinjury state. The PSFS has been shown to exhibit good validity and reliability and been shown to be a responsive instrument for patients with variety of musculoskeletal problems (e.g. acute low back pain,

knee dysfunction, etc.) [12]. Additionally, an international survey reported about approximately 40% of physical therapists (PTs) reported they routinely used the PSFS on patients with neck pain [13], which is in accordance with a recent Delphi study among known experts in the management of cervical spine disorders [14]. However, the psychometric properties of the PSFS on patients with neck pain is conflicting and previous studies have often used small sample sizes [12,15,16]. Additionally, a great deal of research has been performed on patients with cervical radiculopathy, which has a clinically different presentation than patients with non-specific neck pain.

According to a systematic review, moderate evidence exists supporting a high test-retest reliability for the PSFS when used with patients with cervical radiculopathy [12], however this conclusion was based on one small study using only 38 patients [17]. A more recent study on 165 patients with cervical radiculopathy found poor reliability [15]. There exists low quality evidence of strong concurrent associations between the PSFS and the Neck Disability Index (NDI) in a small cohort of 31 patients [16], and test-retest reliability in patients with a neck dysfunction [12].

Answering options for the PSFS vary in the literature. The original PSFS has a response option where 0 represents 'the inability to perform an activity' and 10 represents 'the ability to perform the activity at the same level as before the injury or condition' [11]. The PSFS-Dutch version, which recently has been shown to have good validity for patients with shoulder pain, uses a slightly different answering option [18] and provides patients with an example list of activities. Patients are asked to rate their 'activity limitations', where 0 represents 'no difficulty' and 10 represents 'impossible to perform the activity' [18,19]. Originally this scale was called the 'patient specific approach' and was designed for patients with low back pain [19]. A higher score indicates a greater disability. It is unknown if this version (PSFS 2.0) possesses adequate validity for patients with neck pain.

The PSFS 2.0 does not reflect on a pre-injury level (such as the PSFS) but on a reference endpoint ('no difficulty'); scores on the PSFS 2.0 therefore do not have to be interchangeable with scores on the PSFS when corrected for the opposite direction. This could potentially have an impact on patient scores, especially on patients with a history of recurrent neck pain (as most patients do not completely recover) [4].

Furthermore, the content-validity of the PSFS (2.0) has not been assessed, despite the fact that content validity is considered to be the most important measurement property [20]. Although content validity using qualitative interviews with patients has not been assessed, content validity has been examined using a different method. Mapping strategies were used, to assess if the answers of patients on the PSFS could be labelled into 'activity limitations' following ICF criteria [21–23], of which one study was performed on patients with neck pain (including patients with structural pathology) [23]. Although these studies revealed useful information, this does not reflect the complete spectrum of content validity and the relevance, comprehensiveness that requires further examination [24]. Additionally, it is of great clinical relevance to examine the preference of both answering options (PSFS 2.0 or PSFS).

Therefore, the aim of the current study was to assess the content validity of the PSFS and PSFS 2.0. Additionally, we sought to examine if scores on the originally designed PSFS differ from those on the PSFS 2.0 and which of these methods is preferred by patients with neck pain. Moreover, construct validity (using hypotheses testing with the NDI) of the preferred version of the PSFS on patients with neck pain was examined.

Methods

Design

This is a validation study, which was designed *a priori* as part of a cohort study (CROMM-study), including

patients with neck pain treated by physical therapists. The Medical Ethic Center in Rotterdam approved the study (MEC-2018–129), the study was registered in the Dutch Trial Register (NTR7463). Informed consent was obtained from all subjects prior to their participation.

Participants

Consecutive patients were recruited from a primary care physical therapy clinic between July 2018 and January 2019. Patients with neck pain were eligible if they were over 18 years of age and adequately understood the Dutch language and were classified as Grade I or II as described by the Neck Pain Task Force [25]. Patients were excluded in the presence of serious pathology (such as infection, cancer, fracture or rheumatoid arthritis) and previous surgery. Ten subjects were recruited for the content validity study and a minimum number of 100 patients were recruited for the construct validity study similar to previous studies [24,26].

Individual interviews

The first ten patients who agreed to participate completed the content validity portion of the study as well as in the complete study [24]. We checked to be certain there was variety within this sample in terms of gender, duration of complaints, education level, ethnicity, as variety is considered essential in qualitative research. In cases where an important aspect of variety was not included (such as being male), we invited extra participants selected specifically on this variable. Individual interviews with patients were conducted in-person and followed semi-structured discussion/interview guides with a trained interviewer [24]. Participants were informed about the concept of 'activity limitations' using the ICF definition: an 'activity is the execution of a task or action by an individual' and 'activity limitations are difficulties an individual may have in executing activities' [27].

All patients completed the PSFS and the PSFS 2.0. Patients identified important activities specific to themselves and indicated the amount of difficulty using both answering options. After formulating their important activity limitations, an example list was provided (addendum 1). This example list was created using 19 activities, as they are the most commonly mentioned by patients with neck pain according to the Neck Pain Guidelines [23,28] or were commonly used in an electronic patient record filing system (FysioRoadMap). The example list is in accordance with the PSFS-D used on patients with low back pain and shoulder pain [18,19]. The example list could be used to check if their formulated activities were indeed the most important or could be

used to assist formulating activities in case this proved difficult.

The interview guide contained a topic list including e.g. the patient's understanding of the instructions, the recall period, the intended meaning and relevance of the items and response options and missing concepts. Participants were asked if they had a preference regarding the answering options of either the PSFS and PSFS 2.0 and if the example list was useful. All sessions were audio-recorded and later transcribed for analysis.

Baseline measurement

Content validity sample

All participating patients in the content validity study ($N = \pm 10$) received a questionnaire that collected demographic characteristics, the NRS and the NDI in Dutch. Both the PSFS and PSFS 2.0 were completed together with the PT at the same visit, starting with the original PSFS and followed by the PSFS 2.0 including the example list.

Construct validity sample

Participating patients included in the validity study ($N = 100$) received a questionnaire that collected demographic characteristics, the NRS, NDI and the version of the PSFS derived from the content validity study.

NRS

Neck pain was measured using a Numeric Rating Scale (NRS), where 0 represents 'no pain' and 10 'the worst pain possible' in the past 24 hours [29,30]. The minimal detectable change has been reported to be approximately 4 points [29,30]. The NRS is an appropriate measure to assess the amount of pain [31,32] and is recommended in the clinical practical guidelines for the management of neck pain [28]. We were unable to identify any evidence regarding the content validity, construct validity, reliability and responsiveness of the NRS on patients with neck pain from systematic reviews. However, one study found the reliability ($ICC = 0.76$) and the responsiveness ($AUC = 0.85$) to be good in patients with non-specific neck pain [33].

NDI

The NDI was designed to measure 'activity limitations' (activities of daily living (ADL)) in patients with neck pain and was derived from the Oswestry Disability Index (ODI) [34,35]. The 10 items each have 6 response categories (range 0–5, total score range 0–50) [35]. No floor or ceiling effects have been detected [35–38] and there exists limited evidence for the content validity of the NDI [35,39], a follow-up study stated the content validity is doubtful [40].

Hypothesis testing shows that the NDI has a positive correlation with instruments measuring pain and/or physical functioning ($r = 0.53$ – 0.70) [35,37,41,42] and can detect differences in scores between subgroups (e.g. same work status vs. altered work status) [37,43]. There exists moderate evidence for responsiveness of the NDI ($AUC = 0.79$) [43]. The NDI is recommended in English [28,39] and in Dutch (as it was shown to exhibit good reliability, validity and responsiveness) [44,45].

PSFS

The PSFS was designed as a functional outcome scale to measure 'activity limitations' [11]. The PSFS is based on the concept of generating a list of problems specific for each patient rather than having patients check a general list of their most commonly encountered problems. The PSFS allows each patient to nominate any activity that he or she may currently be having difficulty with. Patients were asked to identify 3 important activities they were unable to perform or were having difficulty with as a result of their neck problem [16]. Patients were asked to score their 'activity limitations', where 0 represents 'the inability to perform an activity' and 10 represents 'the ability to perform the activity at the same level as before the injury or condition' [11,16]. The final score is determined by averaging the 3 activity scores. Lower scores represent a greater level of activity limitation.

There is no evidence available for the content validity and low-level evidence of construct validity, as hypothesis testing shows a strong correlation between the PSFS and the NDI. There is conflicting evidence regarding the reliability of the PSFS as most studies identified reasonable reliability but the number of included patients was generally low which makes it difficult to generalize the findings [12,15–17,46]. The PSFS is recommended in the clinical practical guideline for neck pain [28].

PSFS 2.0

The PSFS 2.0 is considered similar to the PSFS and is also focused on 'activity limitations' [18]. Patients were asked to identify three important activities they were unable to perform or were having difficulty with because of their neck problem. An example list was provided to assist in either formulating activities or checking if the mentioned activities were indeed the most important ones. Patients were asked to score their 'activity limitations', where 0 represents 'no difficulty' and 10 represents 'impossible to perform the activity' [18,19]. An average PSFS 2.0 score was calculated. Higher scores indicate a higher level of activity limitation.

All forms were available online, using Limesurvey software. The PSFS (2.0) was answered together with the PT.

Analyses

All statistical analyses were performed with SPSS version 24 (Inc, Chicago, Ill, USA. Qualitative data were analyzed using ATLAS.ti software (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany). Handling of missing items on the NDI was performed as described by the original author: if a patient did not complete one question or another, the average of all other items is then added to the completed items [47]. All data were checked for normality, using a Stem-and-leaf Plot, Q-Plot and Whisker box. Non-parametric tests were used if data was not normally distributed. Descriptive statistics were used to calculate frequencies.

Interchangeability of the PSFS and PSFS 2.0

A Wilcoxon signed rank test was used to calculate if there was a significant difference between the scores on the PSFS (corrected for direction) and the PSFS 2.0. Moreover, a Spearman correlation coefficient was calculated between the PSFS score and the PSFS 2.0 score. A correlation above 0.80 was expected [26] and could indicate the PSFS and PSFS 2.0 scores are comparable/interchangeable in research and clinical practice.

Content validity

Interview transcripts were systematically analyzed, coded, and compared using ATLAS.ti by two researchers. First, verbatim transcripts were coded. We used thematic content analysis [48]. Codes were smaller units and identifying concepts, themes, or recurring regularities that appeared within each interview were created. Emerging themes were discussed within the research team and credibility of the findings was established by seeking agreement among co-researchers. Second, codes were tallied, and trends were identified. A list of the mentioned problems with frequencies was provided and if possible, the items were coded according to the ICF. Established linking rules were used to guide the linking of functional problems to the ICF [49].

Construct validity

Convergent validity relates to the extent to which a particular instrument corresponds to the construct (theoretical concept) of neck pain and 'activity limitations' [26,50]. Therefore, the correlation between the total score of the PSFS (2.0) and the total score of the NDI was evaluated as both questionnaires aim to measure the same construct. Convergent validity was quantified by the Pearson correlation coefficient in case of a normal distribution of the data, otherwise a Spearman correlation coefficient was used. Correlations were rated as follows: $r < 0.30$ as low/insignificant; $0.30 \leq r < 0.45$ as moderate; $0.45 \leq r < 0.60$ as substantial and $r \geq 0.60$ as high [51]. Therefore, hypothesis one was a high

correlation ($r \geq 0.60$) was expected between the PSFS (2.0) and the NDI, as these instruments are based on a similar construct [26,50].

Construct validation by extreme groups (known group validity) is a type of validation where the instrument is assessed on two extreme groups, which should score significantly different on the instrument [26,50]. Extreme groups were defined on initial pain levels. We assumed that patients with high initial pain (>7 on the NRS in the preceding 24 h) would have a higher level of perceived disability [52]. The independent Samples Whitney U test was used to test the difference between known groups. For hypothesis two, we expected a significant difference between both groups (high and low pain).

Results

The first ten consecutive patients agreed to participate, after which we decided to ask one extra male patient to increase gender variety. The median age of the patients was 46.0 (Interquartile range (IQR) 25.0–55.0) years and 81% were female. Demographic characteristics of the eleven patients are reported in Table 1. The median total score on the PSFS was 5.3 (IQR 4.3–7.0) versus 4.3 (IQR 3.0–6.3) on the PSFS 2.0.

Interchangeability of the PSFS and PSFS 2.0 score

The spearman correlation between the PSFS (corrected for direction) and the PSFS 2.0 was found to be high (0.92). The difference between both median total scores was non-significant on the Wilcoxon signed rank test (0.776). This provides an indication the PSFS and the PSFS 2.0 score could potentially be interchangeable. Figure 1 visually illustrates the mean PSFS (uncorrected) and PSFS 2.0 total score per patient.

Content validity

Relevance and understandability

All patients indicated the concept was relevant to them, most patients felt it was one of the most important issues they had to deal with, along with pain. Some patients stated their pain and activity limitations were interrelated and others said they could not perform an activity as they were just unable to, not as a result of their pain.

'To me "activity limitation" is very important as it really impacts my daily life and what I'm able to do. I think it is actually more important to me than the pain itself, although I feel my pain and disabilities are related. Some activities I am unable to perform due to the pain.'

According to participants the PSFS (2.0) question was appropriate (e.g. in terms of measuring 'activity limitations' and duration) and easy to understand. One patient indicated the PSFS (2.0) is about 'the most important

Table 1. Demographic characteristics of the patients included in the content validity study.

	N = 11
Gender (male) (%)	2 (18.2)
Age	46.0 (25.0–55.0)
Median (IQR)	
Duration of neck pain in weeks	
Median (IQR)	45.0 (16.0–100.0)
Acute/subacute	2 (18.2)
Chronic	9 (81.8)
Previous history with neck pain (yes) (%)	9 (81.8)
Ability to work despite neck pain:	
No, completely unable	0 (0.0)
No, but I do not work at all	1 (9.1)
Yes, it's possible to perform my ordinary work activities	7 (63.6)
Yes, but I have to adjust my work	3 (27.3)
Initial pain (NRS)	7.0 (2.0–7.0)
Median (IQR)	
PSFS total score	5.3 (4.3–7.0)
Median (IQR)	
PSFS score per item	1. 6.0 (4.0–8.0)
Median (IQR)	2. 5.0 (4.0–7.0)
	3. 5.3 (4.3–7.0)
PSFS 2.0 total score	4.3 (3.0–6.3)
Median (IQR)	
PSFS 2.0 score per item	1. 4.0 (2.0–6.0)
Median (IQR)	2. 4.0 (3.0–5.0)
	3. 4.0 (2.0–7.0)

Abbreviations: NRS; Numeric Rating Scale, IQR; Inter quartile range.

activity limitations' and not about 'activity limitations in general'. All other patients indicated the three activities they mentioned were a complete indication of their 'activity limitations' and according to them no missing items or concepts could be detected.

Activities

Even though patients stated they completely understood the question and felt the assignment itself was 'easy', a small majority of patients (54.5%) reported it was quite difficult to mention the three most important activities. Although most patients eventually came up with three activities (72.7%) themselves, some patients could not mention three activities. They most often mentioned two activities and stated they could not come up with a third activity at that time. 'I feel it is difficult to come up

with activities I am restricted in, as I am so used to having difficulties. I am living with it every day for a long time and it became ordinary for me to be restricted.'

Despite the difficulty level in coming up with three activities, the number of requested activities was deemed appropriate according to all patients (no need to report more activities).

Example list

Patients that mentioned two activities added an activity after seeing the example list and felt the activity forgotten was important to them. Reasons for not mentioning this activity initially were: 'I'm so used to it, I'm unaware', 'I forgot I am actually really restricted in this activity', 'I wasn't thinking about this as an activity, I thought it had to be active such as sports'. All these patients felt the example list was really important and of great assistance when identifying their personal activity limitations.

After seeing the example list, 36.4% of all patients added an activity, 18.2% changed an activity (as they felt the activity on the list was more important than the one mentioned) and on 45.5% of patients the example list did not impact their PSFS-activities. Patients that were perfectly capable of formulating three important activities and felt this covered the entire scope of important 'activity limitations' indicated the example list was mostly used as a tool to check if the formulated activities indeed were most important.

All patients indicated the example list was useful, either to assist in formulating activities or to be of assistance as a reference tool. Patients were unanimous regarding the timing of the example list: it should be provided after formulating the three activities themselves, as they felt it would otherwise guide them too much and they would not be capable to come up with their own specific 'problems'.

'I feel it is useful to use the example list as a facilitator to verify if I missed anything important and to check if I mentioned my most important activities. You probably

Figure 1. Distribution of scores. Mean patient specific functional scale per patient.

recognize multiple activities that apply, but you have to think about how important it is to you.'

Preference of answering option (PSFS/PSFS 2.0)

The great majority of patients (90,9%) indicated the answering option of the PSFS 2.0 (0 being 'no difficulty' and 10 represents 'impossible to perform the activity') was preferred or more appropriate. About seventy percent (66,7%) of patients having recurrent or chronic neck pain indicated they had a difficult time thinking back to 'before the injury'. A significant proportion of patients felt it was unclear which reference was required, 'before this episode' or 'before having neck pain for the first time'.

The answering option using "before..." was really hard to interpret, probably because I do have neck complaints for a while now. and yes. well it is hard to remember what it was like. It is tough to approach it like this'.

The only patient preferring the original PSFS answering option indicated this was in accordance with her school grading, 0 being bad and 10 being good. This patient did not have recurrent or chronic neck pain and only had neck pain for 2 months.

The PSFS 2.0 response option was well understood, clear, intuitive and 'logical'.

To me this answering option is easier. It is familiar and I can understand it immediately as I feel this is used in other settings in a similar way'.

Self-administered or conversation orientated. Some patients stated they preferred to fill out the PSFS (2.0) with the clinician together (although they understood the PSFS question perfectly), as they felt it 'helped them to talk about it', 'it had more meaning' and 'it invited them to think about in depth, instead of just writing down a quick answer'. Moreover, they felt it could be quite difficult to come up with restricted activities. Patients explicitly stated that even though they could not immediately come up with the

activities themselves, it impacted their lives and was important to objectify.

Talking about my restricted activities helped me to continue to think about it. On my own I would have stopped after thinking about it for one second. Together feels more comfortable and helps me to really think about it.'

Mapping activities to the ICF

PSFS-activities most mentioned were lying in bed, driving, having a conversation, reading, sitting behind the computer and remunerative employment. The activities provided by patients all fell into the category activity and participation of the ICF. Lying in bed was coded under d4150 ('staying in a lying position for some time as required, such as remaining in a prone position in a bed'), although other studies labelled this as b134, however this regards the mental component of sleep disturbance. Table 2 presents the activities mapped to ICF codes.

On the basis of our content validity study we chose to use the PSFS 2.0 answering option during this project and to provide patients with the example list after they formulated important activities.

Construct validity

A total of 100 patients participated in the validity study. We did not exclude any patients due to missing data. The mean age of the patients was 52.6 (14.5) years and 75% were female. Demographic characteristics of the 100 patients are reported in Table 3.

Hypothesis one was not confirmed, as the spearman correlation between the PSFS 2.0 total score and the NDI was 0.54, indicating a substantial correlation, instead of a high correlation (>0.60). Hypothesis two was confirmed as differences between "known groups" were statistically significant. The mean was 4.0 (1.8) in the low pain group, compared to 5.7 (1.6) in the high pain group ($p = 0.00$).

Table 2. Activities mapped to ICF codes.

Activities	ICF-code	ICF label
Lying in bed (6)	d4150	Activities and participation
Driving (6)	d4751	Activities and participation
Reading (4)	d9202	Activities and participation
Having a conversation (3)	d3501	Activities and participation
Sitting behind the computer (3)	d3601/*d920	Activities and participation
Remunerative employment (2)	d850	Activities and participation
Doing housework	d640	Activities and participation
Carrying a bag doing groceries	d4301/**d620	Activities and participation
Eating	d550	Activities and participation
Watching television	d920	Activities and participation
Doing sports	d9201	Activities and participation
Riding a bicycle	d4750	Activities and participation
Horse-riding	d9201	Activities and participation
Swimming	d9201	Activities and participation
Shaving	d5205	Activities and participation

* Depending on the intended purpose, this item could either be labelled as d3601; using communication devices and techniques such as the computer or d920; recreation and leisure.

** Carrying in the hands versus acquisition of goods and services

Table 3. Demographic characteristics of the patients included in the construct validity study.

	N = 100
Gender (male) (%)	25 (25.0)
Age	52.6 (14.5)
Mean (SD)	
Duration of neck pain in weeks	
Median (IQR)	18.0 (8.0–100.0)
Acute/subacute	45 (45.0)
Chronic	55 (55.0)
Prior history with neck pain (yes) (%)	79 (79.0)
Ability to work despite neck pain:	
No, completely unable	1 (1.0)
No, but I do not work at all	22 (22.0)
Yes, it's possible to perform my ordinary work activities	60 (60.0)
Yes, but I have to adjust my work	17 (17.0)
NDI baseline score	12.1 (6.1)
Mean (SD)	
NDI baseline score percentage	24.1 (12.2)
Mean (SD)	
Initial pain (NRS)	4.7 (2.4)
Mean (SD)	
PSFS 2.0 total score	4.5 (3.3–6.0)
Median (IQR)	

Abbreviations: NDI; Neck Disability Index, NRS; Numeric Rating Scale, IQR; Inter quartile range, SD: Standard deviation.

Discussion

This study found 'activity limitations' is a very important concept by patients with neck pain. According to the patients in this study, the PSFS 2.0 is appropriate and easy to understand. Patients had an explicit preference for the PSFS 2.0 version and indicated it made more sense to them and they had difficulties recalling using the original PSFS. Additionally, patients indicated they preferred answering the question face to face with a clinician (as opposed to answering it themselves digitally) as this provided them more depth to the question. We found a substantial correlation between the PSFS 2.0 and the NDI and a significant difference between 'known groups'. Based on our findings, the PSFS 2.0 is considered to possess adequate validity in terms of content validity and construct validity seems to be acceptable for patients with non-specific neck pain.

Comparison to the literature

This study was the first to assess the content validity of the PSFS 2.0 and therefore we are unable to directly compare our results to other studies reported in the literature. The relationship between pain and 'activity limitations' however, has been observed before using quantitative data [17,18,53,54]. Our study indicates, several patients indeed experience pain and activity limitations to be interrelated. However, this differed per patient and although the concepts can influence each other, some patients stated they do not always feel pain but were restricted in performing an activity. Therefore, we consider it to be important to measure both concepts separately and to discuss the answers of the PSFS 2.0 with the patient. The PSFS has been described as a tool to use at the end of history taking, with the

clinician and patient together [16] our interviews revealed patients actively prefer this compared to filling in the question themselves. We found a substantial (0.54) correlation between the PSFS 2.0 and the NDI. We anticipated finding a correlation above 0.60. Westaway and Stratford investigated concurrent validity and found a high correlation between the average PSFS activity score and the NDI score in 31 individuals with neck dysfunctions ($r = 0.82$) which differs from our findings [16]. They found a similar PSFS score, however their average NDI score was higher. Moderate correlations have been found between the PSFS and the Physical Disability Index score and SF-36 (bodily part) in individuals with knee pain [55] and with the Roland Morris Low Back Pain and Disability Questionnaire for individuals with low back pain [56]. A possible explanation for a substantial correlation might be that patients stated the PSFS gives them the opportunity to specify their personal problems regarding activity limitations as opposed to the NDI. Some patients did not have problems with general activities as listed on the NDI but did with very specific problems. Moreover, the content validity of the NDI has been rated as doubtful [40]. Another study concluded the content validity of the NDI was good, however this study did not include a patient's perspective. Content validity was assessed by comparing the items of the NDI with problems identified from problem elicitation technique. Eleven common problems were identified, of which six were included in the NDI [36].

A significant difference between known groups had not been assessed in this manner previously, however, Cleland et.al. found a high correlation between the change score of the PSFS and the NRS (0.80) [17].

Strengths and limitations

This study has some limitations. Our study sample for mapping ICF activities and assessing the interchangeability was small. Therefore, the results regarding interchangeability should be interpreted with caution. We chose to only assess both versions on the content validity sample, due to practical reasons. Patients in this part of the study were informed and interviewed and we therefore were able to take the time to explain the purpose and to answer their questions. As the preferred version (PSFS 2.0) was clear, we felt it was not necessary to expose all patients to both versions. Moreover, our total sample consisted of a high number of females and patients with non-acute neck pain. This however is in accordance with the literature [25]. We tested only two hypothesis and did not assess divergent validity; future studies could potentially assess construct validity more extensively.

One of the strengths of this study is that we were the first to assess the content validity of the PSFS 2.0. Moreover, our population consisted of patients

visiting a physical therapist, as the PSFS is frequently used by physical therapists and pain/activity limitations are important outcome measures, it is important to assess the measurement properties in this population. We registered our trial *a priori*, increasing transparency.

Implications for clinical practice

We advise clinicians to use the PSFS 2.0 in the future and to discuss the findings with the patient. We also suggest further studies should continue to examine other psychometric properties (such as responsiveness) of the PSFS 2.0 in patients with neck pain and other musculoskeletal disorders.

Key points

Findings: The results of the current study provide preliminary evidence for the content validity of the PSFS (2.0). The PSFS 2.0 is preferred in patients with neck pain. The construct validity of the PSFS 2.0 seems to be good.

Implications: Clinicians should consider using the PSFS 2.0 instead of the original PSFS.

Caution: The reliability, measurement error and responsiveness of the PSFS 2.0 on patients with neck pain is unknown and requires further investigation.

Recommendations

The reliability, measurement error, interpretability and responsiveness should also be assessed on patients with neck pain visiting a physical therapist.

Disclosure statement

No potential conflict of interest was reported by the authors.

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Notes on contributors

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References

- [1] Fejer R, Kyvik KO, Hartvigsen J. The prevalence of neck pain in the world population: a systematic critical review of the literature. *Eur Spine J.* 2006 Jun;15(6):834–848. PubMed PMID: 15999284; eng.
- [2] Cote P, Cassidy JD, Carroll L. The Saskatchewan health and back pain survey. The prevalence of neck pain and related disability in Saskatchewan adults. *Spine (Phila Pa 1976).* 1998 Aug 1;23(15):1689–1698. PubMed PMID: 9704377; eng.
- [3] Guez M, Hildingsson C, Nilsson M, et al. The prevalence of neck pain: a population-based study from northern Sweden. *Acta Orthop Scand.* 2002;73(4):455–459. PubMed PMID: 612.
- [4] Haldeman S, Carroll L, Cassidy JD, et al. The bone and joint decade 2000-2010 task force on neck pain and its associated disorders: executive summary. *Spine (Phila Pa 1976).* 2008 Feb 15;33(4 Suppl):S5–7. PubMed PMID: 18204400; eng.

- [5] Cohen SD. Epidemiology, diagnosis, and treatment of neck pain. *Mayo Clin Proc.* 2015 Feb;90(2):284–299.
- [6] Hoy D, March L, Woolf A, et al. The global burden of neck pain: estimates from the global burden of disease 2010 study. *Ann Rheum Dis.* 2014 Jul;73(7):1309–1315. PubMed PMID: 24482302.
- [7] Hurwitz EL, Randhawa K, Yu H, et al. The global spine care initiative: a summary of the global burden of low back and neck pain studies. *Eur Spine J.* 2018 Feb 26. DOI:10.1007/s00586-017-5432-9. PubMed PMID: 29480409.
- [8] Stucki G, Kostanjsek N, Ustun B, et al. ICF-based classification and measurement of functioning [Review]. *Eur J Phys Rehabil Med.* 2008 Sep;44(3):315–328. PubMed PMID: 18762741; eng.
- [9] Cieza A, Stucki G. The international classification of functioning disability and health: its development process and content validity [Review]. *Eur J Phys Rehabil Med.* 2008 Sep;44(3):303–313. PubMed PMID: 18762740; eng.
- [10] Jelsma J. Use of the international classification of functioning, disability and health: a literature survey. *J Rehabil Med.* 2009 Jan;41(1):1–12. PubMed PMID: 19197563; eng.
- [11] Stratford P, Gill C, Westaway M, et al. Assessing disability and change on individual patients: A report of a patient-specific measure. *Physiother Can.* 1995;47:258–263.
- [12] Horn KK, Jennings S, Richardson G, et al. The patient-specific functional scale: psychometrics, clinimetrics, and application as a clinical outcome measure. *J Orthop Sports Phys Ther.* 2012 Jan;42(1):30–42. PubMed PMID: 22031594.
- [13] Macdermid JC, Walton DM, Cote P, et al. Use of outcome measures in managing neck pain: an international multidisciplinary survey. *Open Orthop J.* 2013;7:506–520. PubMed PMID: 24115972; PubMed Central PMCID: PMC3793628.
- [14] Maissan F, Pool J, Stutterheim E, et al. Clinical reasoning in unimodal interventions in patients with non-specific neck pain in daily physiotherapy practice, a Delphi study. *Musculoskelet Sci Pract.* 2018 Jun;2(37):8–16. PubMed PMID: 29908493.
- [15] Young IA, Cleland JA, Michener LA, et al. Reliability, construct validity, and responsiveness of the neck disability index, patient-specific functional scale, and numeric pain rating scale in patients with cervical radiculopathy. *Am J Phys Med Rehabil.* 2010 Oct;89(10):831–839. PubMed PMID: 20657263.
- [16] Westaway MD, Stratford PW, Binkley JM. The patient-specific functional scale: validation of its use in persons with neck dysfunction. *J Orthop Sports Phys Ther.* 1998 May;27(5):331–338. PubMed PMID: 9580892.
- [17] Cleland JA, Fritz JM, Whitman JM, et al. The reliability and construct validity of the neck disability index and patient specific functional scale in patients with cervical radiculopathy. *Spine (Phila Pa 1976).* 2006 Mar 1;31(5):598–602. PubMed PMID: 16508559.
- [18] Koehorst ML, van Trijffel E, Lindeboom R. Evaluative measurement properties of the patient-specific functional scale for primary shoulder complaints in physical therapy practice. *J Orthop Sports Phys Ther.* 2014 Aug;44(8):595–603. PubMed PMID: 25029915.
- [19] Beurskens AJ, de Vet HC, Koke AJ. Responsiveness of functional status in low back pain: a comparison of different instruments. *Pain.* 1996 Apr;65(1):71–76. PubMed PMID: 8826492.
- [20] Reeve BB, Wyrwich KW, Wu AW, et al. ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research. *Qual Life Res.* 2013 Oct;22(8):1889–1905. PubMed PMID: 23288613.
- [21] Fairbairn K, May K, Yang Y, et al. Mapping patient-specific functional scale (PSFS) items to the international classification of functioning, disability and health (ICF). *Phys Ther.* 2012 Feb;92(2):310–317. PubMed PMID: 22074939.
- [22] Bagraith KS, Hayes J, Strong J. Mapping patient goals to the International classification of functioning, disability and health (ICF): examining the content validity of the low back pain core sets. *J Rehabil Med.* 2013 May;45(5):481–487. PubMed PMID: 23538737.
- [23] Andelic N, Johansen JB, Bautz-Holter E, et al. Linking self-determined functional problems of patients with neck pain to the international classification of functioning, disability, and health (ICF). *Patient Prefer Adherence.* 2012;6:749–755. PubMed PMID: 23118531; PubMed Central PMCID: PMC3484528.
- [24] Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Qual Life Res.* 2018 May;27(5):1159–1170. PubMed PMID: 29550964; PubMed Central PMCID: PMC5891557.
- [25] Guzman J, Hurwitz EL, Carroll LJ, et al. A new conceptual model of neck pain: linking onset, course, and care: the bone and joint decade 2000–2010 task force on neck pain and its associated disorders. *J Manipulative Physiol Ther.* 2009 Feb;32(2 Suppl): S17–28. PubMed PMID: 19251062.
- [26] Mokkink LB, Terwee CB, Knol DL, et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol.* 2010;10:22. PubMed PMID: 20298572; PubMed Central PMCID: PMC2848183. eng.
- [27] CHECKLIST. Version 2.1a, Clinician form for international classification of functioning, disability and health. [cited 2018 May 1]. Available from: <http://www.who.int/classifications/icf/en/ICF>
- [28] Blanpied PR, Gross AR, Elliott JM, et al. Neck pain: revision 2017. *J Orthop Sports Phys Ther.* 2017 Jul;47(7):A1–A83. PubMed PMID: 28666405.
- [29] Pool JJ, Ostelo RW, Hoving JL, et al. Minimal clinically important change of the neck disability index and the numerical rating scale for patients with neck pain. *Spine (Phila Pa 1976).* 2007 Dec 15;32(26):3047–3051. PubMed PMID: 18091500.
- [30] Kovacs FM, Abaira V, Royuela A, et al. Minimum detectable and minimal clinically important changes for pain in patients with nonspecific neck pain. *BMC Musculoskelet Disord.* 2008;9:43. PubMed PMID: 18402665; eng.
- [31] Jensen MP, Karoly P, Braver S. The measurement of clinical pain intensity: a comparison of six methods. *Pain.* 1986 Oct;27(1):117–126. PubMed PMID: 3785962.
- [32] Hjermstad MJ, Fayers PM, Haugen DF, et al. Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *J Pain Symptom Manage.* 2011 Jun;41(6):1073–1093. PubMed PMID: 21621130.
- [33] Cleland JA, Childs JD, Whitman JM. Psychometric properties of the neck disability index and numeric

- pain rating scale in patients with mechanical neck pain. *Arch Phys Med Rehabil.* 2008 Jan;89(1):69–74. PubMed PMID: 18164333.
- [34] Fairbank JC, Couper J, Davies JB, et al. The Oswestry low back pain disability questionnaire. *Physiotherapy.* 1980 Aug;66(8):271–273. PubMed PMID: 6450426.
- [35] Vernon H, Mior S. The neck disability index: a study of reliability and validity. *J Manipulative Physiol Ther.* 1991 Sep;14(7):409–415. PubMed PMID: 1834753.
- [36] En MC, Clair DA, Edmondston SJ. Validity of the neck disability index and neck pain and disability scale for measuring disability associated with chronic, non-traumatic neck pain. *Man Ther.* 2009 Aug;14(4):433–438. PubMed PMID: 18824393.
- [37] Riddle DL, Stratford PW. Use of generic versus region-specific functional status measures on patients with cervical spine disorders. *Phys Ther.* 1998 Sep;78(9):951–963. PubMed PMID: 9736893.
- [38] Stratford P, Riddle D, Binkley J, et al. Using the neck disability index to make decisions concerning individual patients. *Physiother Can.* 1999;51(2):107. 1999/04/1999 Spring.
- [39] Schellingerhout JM, Verhagen AP, Heymans MW, et al. Measurement properties of disease-specific questionnaires in patients with neck pain: a systematic review. *Qual Life Res.* 2012 May;21(4):659–670. PubMed PMID: 21735306; PubMed Central PMCID: PMC3323817. eng.
- [40] Ailliet L, Knol DL, Rubinstein SM, et al. Definition of the construct to be measured is a prerequisite for the assessment of validity. The neck disability index as an example. *J Clin Epidemiol.* 2013 Jul;66(7):775–782. quiz 782 e1-2. PubMed PMID: 23618795.
- [41] Hains F, Waalen J, Mior S. Psychometric properties of the neck disability index. *J Manipulative Physiol Ther.* 1998 Feb;21(2):75–80. PubMed PMID: 9502061.
- [42] Hoving JL, O’Leary EF, Niere KR, et al. Validity of the neck disability index, Northwick Park neck pain questionnaire, and problem elicitation technique for measuring disability associated with whiplash-associated disorders. *Pain.* 2003 Apr;102(3):273–281. PubMed PMID: 12670669.
- [43] Young BA, Walker MJ, Strunce JB, et al. Responsiveness of the neck disability index in patients with mechanical neck disorders. *Spine J.* 2009 Oct;9(10):802–808. PubMed PMID: 19632904.
- [44] Schellingerhout JM, Heymans MW, Verhagen AP, et al. Measurement properties of translated versions of neck-specific questionnaires: a systematic review [Review]. *BMC Med Res Methodol.* 2011;11:87. PubMed PMID: 21645355; PubMed Central PMCID: PMC3118950. eng.
- [45] Jorritsma W, de Vries GE, Dijkstra PU, et al. Neck pain and disability scale and neck disability index: validity of Dutch language versions. *Eur Spine J.* 2012 Jan;21(1):93–100. PubMed PMID: 21814745; PubMed Central PMCID: PMC3252449.
- [46] Abelin-Genevois K, Idjeroudene A, Roussouly P. Cervical spine alignment in the pediatric population: a radiographic normative study of 150 asymptomatic patients. *European Spine.* 2014 Jul;23(7):1442–1448. Springer 2014.
- [47] Vernon DC. The neck disability index (NDI). An informal “blurb” from the author. [cited 2018 May 1]. Available from: http://www.chiro.org/forms/NDI_Explains.shtml
- [48] Braun VCV. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):2–16.
- [49] Cieza A, Geyh S, Chatterji S, et al. ICF linking rules: an update based on lessons learned. *J Rehabil Med.* 2005 Jul;37(4):212–218. PubMed PMID: 16024476.
- [50] de Vet HCTC, Mokkink LB, Knol DL. Practical guides to biostatistics and epidemiology. Cambridge: Measurement in medicine. UK; 2011.
- [51] Burnand B, Kernan WN, Feinstein AR. Indexes and boundaries for “quantitative significance” in statistical decisions. *J Clin Epidemiol.* 1990;43(12):1273–1284. PubMed PMID: 2254764.
- [52] Thoomes-de Graaf M, Scholten-Peeters GG, Duijn E, et al. The Dutch shoulder pain and disability index (SPADI): a reliability and validation study. *Qual Life Res.* 2015 Jun;24(6):1515–1519. PubMed PMID: 25471288.
- [53] Cook CE, Hegedus EJ, Stefancin JJ, et al. An investigation of the relationship between measures of pain intensity, pain affect, and disability, in patients with shoulder dysfunction. *J Man Manip Ther.* 2011 May;19(2):71–75. PubMed PMID: 22547916; PubMed Central PMCID: PMC3172941.
- [54] Stratford PW, Kennedy DM. Does parallel item content on WOMAC’s pain and function subscales limit its ability to detect change in functional status? *BMC Musculoskelet Disord.* 2004 Jun 9;5:17. PubMed PMID: 15189563; PubMed Central PMCID: PMC3172941.
- [55] Gross DP, Battie MC, Asante AK. The patient-specific functional scale: validity in workers’ compensation claimants. *Arch Phys Med Rehabil.* 2008 Jul;89(7):1294–1299. PubMed PMID: 18534550.
- [56] Costa LO, Maher CG, Latimer J, et al. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: which one is the best? *Spine (Phila Pa 1976).* 2008 Oct 15;33(22):2459–2463. PubMed PMID: 18923324.

Appendix. PSFS 2.0

I'm going to ask you to identify up to three important activities that you are unable to do or having difficulty with as a result of your problem?

For example: were there any activities that you were unable to do or have difficulty with because of your problem today or in the last week?

0	1	2	3	4	5	6	7	8	9	10
No difficulty at all									Impossible to perform the activity	

Self reported activities:

1.....

0	1	2	3	4	5	6	7	8	9	10
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2.....

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

3.....

0	1	2	3	4	5	6	7	8	9	10
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If you are having difficulty with reporting activities you are restricted in or you want to check if your self-reported activities are indeed the most important ones, you can use the example list below (you can add or change activities if you feel they are important to you):

Renumorative employment Doing housework Making dinner Recreation and leisure Gardening Lifting and carrying objects Changing body position Lying in bed Maintaining a body position	Reading Reaching Looking behind you Activities above shoulder height Driving Riding a bicycle Using communication devices and techniques Sitting behind the computer Using your telephone
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