

# A New Approach to the Assessment of the Treatment Effects of Somatoform Disorders

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*A new 53-item instrument for the evaluation of treatment effects in somatoform disorders, the Screening for Somatoform Symptoms—7 (SOMS-7), is presented. It covers all somatic symptoms mentioned as occurring in somatization disorder, according to DSM-IV and ICD-10. A group of 325 patients was assessed at the beginning and end of treatment to compute scores of reliability and validity. The new scale showed high internal consistency ( $\alpha = 0.92$ ) and revealed two composite indices: somatization symptom count and somatization severity index. These indices discriminated patients fulfilling complete criteria for somatoform disorders, patients with somatization syndrome, and patients with other mental and psychosomatic disorders. The instrument confirmed symptom reductions between admission and discharge, while in another group composed of wait-listed patients, no significant decrease in symptoms was observed. In sum, the SOMS-7 seems to be a comprehensive, reliable, and valid instrument for the evaluation of treatment effects in patients with somatoform disorders.* (Psychosomatics 2003; 44:492–498)

Physical complaints not fully explained by organic reasons are a common phenomenon. About 10% of the general population report multiple and persisting physical symptoms, with subsequent visits to physicians not finding an organic explanation for the complaints.<sup>1</sup> Multiple somatic symptoms are a predictor of persistency and bad outcome.<sup>2</sup> These patients represent about one-fifth of the patients defined as high users of health care services.<sup>3</sup> Therefore, effective management and treatment strategies are needed that may help reduce the symptoms, the disability, and the treatment costs for patients in the health care system.

Treatment studies of patients with somatoform disorders should use evaluation instruments that allow assess-

ment of the different aspects of outcome. However, to date, an adequate instrument to assess outcome of somatoform symptoms is lacking. There are some scales that assess trait aspects of somatization, such as the Screening for Somatoform Symptoms (SOMS)<sup>4,5</sup> or the WHO screening scales.<sup>6,7</sup> However, these instruments were not developed to assess change but to define groups at high risk for somatoform disorders. Other instruments, such as the somatization scale of the symptom checklist SCL-90-R<sup>8</sup> and the hypochondriasis scale of the MMPI,<sup>9</sup> contain questions regarding a few physical symptoms; however, their suitability for assessing changes in somatoform disorders is questionable. The lists of somatoform symptoms in somatization disorder according to ICD-10 and DSM-IV as well as in somatoform autonomic dysfunction comprise 53 physical complaints; therefore, SCL-90-R and MMPI exclude the majority of these symptoms. Moreover, for the assessment of somatoform disorders, patients should be instructed not to endorse symptoms that have evaluated organic causes. Other measures with comparable shortcom-

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ings are the Symptom Questionnaire<sup>10</sup> and the Bradford Somatic Inventory.<sup>11</sup>

Studies of patients with unexplained physical symptoms have frequently used symptom counts, according to standardized interviews.<sup>12</sup> Other groups used self-developed rating scales for the assessment of change or symptom diaries.<sup>13</sup> In a pharmacological treatment trial,<sup>14</sup> the somatic items of the Hamilton Anxiety Rating Scale have been used. Hiller and Janca<sup>15</sup> summarized different ways of assessing multiple somatoform symptoms by using interviewing and self-rating strategies and emphasizing that there is a need for instruments assessing syndrome severity. Suitable scales for the assessment of hypochondriasis exist,<sup>16,17</sup> but for somatization syndrome, most of the instruments mentioned do not assess the intensity of symptoms, and validity data are still missing.

A psychometric instrument used to measure symptoms of somatoform disorders should fulfill the following criteria:

1. Objectivity: Most self-rating scales fulfill this criterion.
2. Comprehensiveness: All 53 physical symptoms mentioned in DSM-IV and ICD-10 for somatization should be covered.
3. Reliability: The instrument should have sufficient internal consistency to allow the aggregation of symptoms to form total scores.
4. Validity: 1) Associations of total somatization scores should be higher with other somatization scores than with other psychopathology indices. 2) Somatization scores should be higher in patients with somatization disorder than in patients with other psychological disorders. 3) The instrument should reveal no differences in patient groups without treatment (on a waiting list) but significant differences in patient groups receiving an effective treatment. 4) Not only total scores but also scores for single items should be sufficiently sensitive to demonstrate treatment changes. 5) Difference scores of somatization, indicating treatment success, should be associated with other difference scores of psychopathology and well-being.

We tested whether a newly developed scale for the assessment of somatoform disorders could fulfill these criteria. The basis of our new scale was the symptom list of the SOMS, which includes all 53 physical symptoms mentioned in the somatoform disorders categories of DSM-IV and ICD-10 (items or symptoms of the SOMS-7). To im-

prove the sensitivity to change, the answer categories were modified from dichotomy to a 5-point Likert scale, ranging from 0 (not at all) to 4 (very severe). Furthermore, the time frame that should be considered for the answers was reduced to 7 days, which should give a good basis for the assessment of treatment effects.

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## METHOD

### Subjects

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Subjects were patients applying for treatment at the behavioral medicine treatment center in Prien, Germany. We included 325 subsequently admitted patients. Patient characteristics are shown in Table 1. Data were obtained from most patients at discharge (N = 285). For the analyses of temporal stability during periods of no intervention, we used another group of patients (N = 34) who filled out the self-rating scale about 4 months before admission and at admission. This group had elevated scores for somatization and was therefore acquired for another study. Other characteristics of that second group were comparable to those of the main group.

### Treatment

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For all these patients, an intensive treatment program was administered, including individual and group cognitive behavior therapies, relaxation training, symptom-specific interventions, such as panic management or depression management in group therapy or psychopharmacotherapy, if indicated, and other medical and psychological interventions. Since this treatment is covered by all health care insurance companies in Germany, a socioeconomic selection bias was not present. However, persistence of the symptoms as well as comorbidity of multiple disorders are common features of the patients referred to the center.

### Psychological Assessment

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All patients were interviewed after admission with a structured interview (the International Diagnostic Check Lists for ICD-10 and DSM-IV<sup>18</sup>) to obtain valid diagnoses according to DSM-IV, then the SOMS-7 was administered. This instrument reveals two variables. The somatization symptom count is the number of all items that have been confirmed from the patients, even in a mild form. This score should allow estimations of the number of symptoms, which may be relevant for classification. The other variable

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is the sum of all item answers and is termed the “somatization severity index.” This variable should be more sensitive to assess change, since it includes not only aspects of the existence of symptoms but also aspects of the severity of symptoms. Furthermore, we used the symptom checklist SCL-90-R<sup>8</sup> and focused on the somatization subscale as well as on the general psychopathology scales. Since somatoform disorders are frequently comorbid with depression and hypochondriacal fears, we also used the Beck Depression Inventory<sup>19</sup> and the Whiteley Index<sup>20</sup> to assess health anxiety. As a general measure of disability, Mark’s 3-item scale for the assessment of disabling effects of the symptoms on three areas of life was used.

### Statistical Analysis

Psychometric criteria of assessment instruments are typically analyzed by parametrical approaches, despite deviations of the normal distribution assumption, since the analyses are quite robust against violation of this assumption. Therefore, we used Pearson’s *r* for correlation coefficients, one-way analysis of variance for the cross-sectional comparison of group means, and paired sample *t* tests for comparisons across different time points.

## RESULTS

### Characteristics

Gender, age, and mean scores on the scales at admission can be found in Table 1. The items of the SOMS-7

combined to form a highly internally consistent instrument (Cronbach’s alpha of all gender-unspecific items = 0.92). All items except items 43–47 had item total correlations of  $\geq 0.30$ .

### Other Variables

One step in the validation of a new instrument is to correlate its results with those of comparable instruments (termed “convergent validity”). Table 2 shows the correlation coefficients between the two SOMS-7 variables and other variables of somatization and psychopathology. The high association between the questionnaire results and interview somatization scores confirmed the validity of the scale. Moreover, the SOMS-7 variables revealed higher associations with somatization scores (such as SCL-90-R) than with depression or anxiety scores. SOMS-7 scores were also associated with aspects of disability.

### Discrimination Between Patients

An aspect of external validity is the ability of an instrument to discriminate among different clinical groups. The total group included 57 patients who fulfilled complete criteria for somatization disorders, 181 patients who fulfilled Escobar’s criteria for somatization syndrome on the Somatic Symptom Index<sup>21</sup> but not the full criteria for somatization disorder, and 78 patients with other mental dis-

**TABLE 1. Rating on the Screening for Somatoform Symptoms–7 for 325 Patients Who Applied for Treatment at a Behavioral Medicine Center**

Variable	SOMS-7 Score					
	Admission			Discharge		
	N	Mean	SD	N	Mean	SD
Female sex	215					
Age (years)	324	46.0	11.0			
Beck Depression Inventory score	304	20.5	10.8	281	11.8	9.4
Disability score	280	9.9	3.2	259	7.9	3.7
SCL-90-R						
General symptomatic	307	1.1	0.7	285	0.8	0.6
Stress index	307	1.8	0.5	285	1.6	0.5
Number of symptoms	307	52.1	20.0	285	43.9	20.9
Somatization	307	1.2	0.8	285	0.9	0.7
Depression	307	1.4	0.9	285	1.0	0.8
Anxiety	307	1.2	0.8	285	0.9	0.7
Phobia	307	0.8	0.8	285	0.5	0.7
Number of somatoform symptoms in last 2 years on SOMS-2	313	15.0	7.6			
Whiteley Index						
Total for hypochondriasis	303	6.3	3.6	279	4.6	3.4
Health anxiety	280	4.0	2.3	265	2.9	2.2
Somatic complaints	280	2.6	1.5	265	2.0	1.5
Disease conviction	280	1.9	1.4	265	1.4	1.4

orders but not somatization syndrome. Both SOMS-7 somatization scores differed significantly between the three groups (somatization symptom count: mean = 23.7, SD = 10.1; mean = 17.2, SD = 8.4; mean = 10.3, SD = 7.1, respectively) ( $F = 42.4$ ,  $df = 2$ , 315,  $p < 0.001$ ) (somatization severity index: mean = 52.1, SD = 26.7; mean = 33.1, SD = 19.1; mean = 18.9, SD = 15.5) ( $F = 45.6$ ,  $df = 2$ , 315,  $p < 0.001$ ).

We tested whether single items of the SOMS-7 could discriminate between patients with complete somatization disorder and patients with subsyndromal and other disorders. Significant F scores for the following 40 items indicated different item answers for patients with somatization disorder, somatization syndrome, and other disorders: items 1–12, 14–20, 22–30, 32–36, 39–42, 45, 46, and 53.

#### Changes During Waiting Period

Concerning further validity aspects, we expected no changes during waiting periods but decreases in scores during treatment. In the subgroup of 34 patients who were assessed during the waiting period before admission, we found a slight increase of SOMS-7 scores (somatization symptom count: mean = 17.7, SD = 8.7, versus mean = 20.1, SD = 8.9; somatization severity index from mean = 36.6, SD = 22, to mean = 39.3, SD = 22). Test-retest reliability was  $r_{tt} = 0.76$  (symptom count) and  $r_{tt} = 0.71$  (severity index), which is within a reasonable range for an instrument developed to assess change over 4-month interval.

#### Changes During Treatment

Sensitivity to change was tested in the original total group of more than 300 patients. Both somatization indices of the SOMS-7 differed significantly between admission and discharge. The somatization symptom count decreased from mean = 16.8 (SD = 9.5) to mean = 13.5 (SD = 9.0) ( $t = 7.7$ ;  $df = 272$ ;  $p < 0.001$ ), and the somatization severity index decreased from mean = 33.3 (SD = 22.9) to mean = 23.8 (SD = 19.4) ( $t = 9.7$ ;  $df = 273$ ,  $p < 0.001$ ). Thus, the somatization severity index revealed higher t scores for the treatment changes and seemed to be slightly more sensitive to change than the somatization symptom count.

#### Item Sensitivity of Change

We hypothesized that the somatization symptoms suggested in DSM-IV and ICD-10 and assessed with the SOMS-7 would differ in terms of sensitivity to change, which may be partly because some symptoms easily change and others are more treatment resistant. Therefore, we present a list of items that showed differences between admission and discharge (Table 3).

Forty-two of the 53 symptoms revealed significant differences between admission and discharge. With the exception of item 10, most items that did not reveal significant change between admission and discharge were symptoms with low base rates (mean score  $< 0.55$ ).

**TABLE 2. Correlations of Psychological Measures With Screening for Somatoform Symptoms-7 (SOMS-7) for Patients Who Applied for Treatment at a Behavioral Medicine Clinic<sup>a</sup>**

Measure	Correlation (r) with SOMS-7	
	Symptom Count	Severity Index
Somatization index		
All symptoms (by interview)	0.68	0.70
According to DSM-IV (by interview)	0.63	0.66
SCL-90-R		
Somatization	0.67	0.76
Depression	0.41	0.48
Anxiety	0.53	0.60
Phobic anxiety	0.45	0.53
Beck Depression Inventory depression subscale	0.39	0.46
Whiteley Index		
Total score	0.45	0.46
Health anxiety	0.42	0.41
Somatic complaints	0.43	0.43
Disease conviction	0.38	0.42
Disability	0.33	0.40

<sup>a</sup>All scores from admission.  $N \geq 275$ ; for all coefficients,  $p < 0.001$ .

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### Correlations of Change

To assess the convergent validity of the change scores, we computed correlation coefficients between change scores of the SOMS-7 and other change scores for psycho-

pathology (Table 4). The change score of the SOMS-7 somatization severity index correlated somewhat higher with change scores for somatization (SCL-90-R), depression, and general psychopathology than the change scores for somatization symptom count.

**TABLE 3. Sensitivity of Single Items on the Screening for Somatoform Symptoms—7 to Assess Change<sup>a</sup> for Patients Who Applied for Treatment at a Behavioral Medicine Clinic**

Item Number	Symptom	Mean Score on SOMS-7		
		Admission	Discharge	Analysis of Difference (t)
For all				
1	Headache	1.73	1.34	6.01
2	Abdominal pain	1.22	0.96	3.37
3	Back pain	1.64	1.23	5.55
4	Joint pain	1.14	0.76	5.58
5	Pain in legs and/or arms	1.21	0.89	4.34
6	Chest pain	0.67	0.51	2.98
7	Anal pain	0.32	0.23	2.15
8	Pain during sexual intercourse	0.14	0.02	3.53
9	Pain during urination	0.18	0.11	1.92 <sup>b</sup>
10	Nausea	0.83	0.74	1.34 <sup>b</sup>
11	Bloating	1.22	0.91	3.97
12	Discomfort in and around the precordium	1.23	0.99	3.12
13	Vomiting (excluding pregnancy)	0.20	0.22	0.36 <sup>b</sup>
14	Regurgitation of food	0.69	0.49	3.27
15	Hiccoughing or burning sensation in chest or stomach	0.65	0.42	4.18
16	Food intolerance	0.71	0.52	3.22
17	Loss of appetite	0.55	0.35	3.31
18	Bad taste in mouth or excessively coated tongue	0.80	0.54	4.33
19	Dry mouth	0.86	0.69	2.50
20	Frequent diarrhea	0.59	0.32	4.61
21	Discharge of fluid from anus	0.22	0.11	3.19
22	Frequent urination	0.81	0.62	3.31
23	Frequent bowel movements	0.63	0.42	3.49
24	Heart palpitations	1.00	0.87	2.20
25	Stomach discomfort or churning feeling in stomach	0.90	0.65	4.30
26	Sweating	1.28	0.93	5.06
27	Flushing or blushing	0.93	0.70	3.94
28	Breathlessness without exertion	0.66	0.51	2.73
29	Painful breathing or hyperventilation	0.54	0.48	1.0 <sup>b</sup>
30	Excessive tiredness upon mild exertion	1.54	0.98	7.35
31	Blotchiness or discoloration of the skin	0.50	0.27	3.71
32	Sexual indifference (loss of libido)	1.30	0.77	6.75
33	Unpleasant sensations in or around the genitalia	0.24	0.17	1.4 <sup>b</sup>
34	Impaired coordination or balance	0.80	0.50	5.03
35	Paralysis or localized weakness	0.35	0.26	2.27
36	Difficulty swallowing or lump in the throat	0.69	0.54	2.99
37	Aphonia (loss of voice)	0.29	0.19	2.13
38	Urinary retention	0.28	0.19	2.46
39	Hallucinations	0.18	0.09	2.94
40	Loss of touch or pain sensations	0.25	0.13	3.40
41	Unpleasant numbness or tingling sensations	0.74	0.52	3.87
42	Double vision	0.18	0.09	2.42
43	Blindness	0.04	0.04	0.0 <sup>b</sup>
44	Deafness	0.31	0.24	1.59
45	Seizures	0.24	0.14	2.60
46	Amnesia (loss of memory)	0.57	0.33	4.51
47	Loss of consciousness	0.05	0.02	1.24 <sup>b</sup>

**TABLE 3. Sensitivity of Single Items on the Screening for Somatoform Symptoms—7 to Assess Change<sup>a</sup> for Patients Who Applied for Treatment at a Behavioral Medicine Clinic (continued)**

For women only				
48	Painful menstruation	0.74	0.47	2.94
49	Irregular menstruation	0.55	0.43	1.29 <sup>b</sup>
50	Excessive menstrual bleeding	0.46	0.40	0.91 <sup>b</sup>
51	Continuous or frequent vomiting during pregnancy	0.25	0.18	1.07 <sup>b</sup>
52	Unusual or copious vaginal discharge	0.35	0.23	2.22
For men only				
53	Erectile or ejaculatory dysfunction	0.61	0.31	3.31

<sup>a</sup>Range: 0 = not at all, 4 = very severe. Unless otherwise specified, scores indicate significant differences (at least  $p < 0.05$ ). Patients were given the following instructions: "A number of different bodily complaints are listed below. Please indicate whether you have suffered from these symptoms within the last 7 days. Consider only symptoms for which no clear causes have been found by physicians and which have affected your well-being."

<sup>b</sup>n.s.

## DISCUSSION

Somatoform disorders are a frequent and costly illness for our health care systems. Recent studies have demonstrated that these disorders are not only characterized by cognitive and behavioral features but also by psychophysiological and immunological variations.<sup>22,23</sup> Psychopharmacological and psychological interventions considering these aspects of the syndrome have to be developed and evaluated. However, adequate assessment instruments for treatment evaluation are lacking. Therefore, we present reliability and validity scores of a new self-rating scale to assess intervention effects in somatoform disorders. This new SOMS-7 asks for the existence and intensity of 53 somatoform symptoms that are mentioned in DSM-IV and ICD-10 criteria for somatization disorder and ICD-10 somatoform autonomic dysfunction. The instrument reveals two composite indi-

ces: one representing the number of existing symptoms during the last 7 days (SOMS-7 somatization symptom count), the other considering the intensity of symptoms (SOMS-7 somatization severity index). Since the scale asks not only for the frequency, but also for the intensity of symptoms, the instrument should be a useful tool for assessing change and investigating patients with smaller number of symptoms.

The reliability of the instrument is confirmed by high internal consistency and reasonable retest coefficients (0.71–0.76) for an instrument assessing change. The validity of the SOMS-7 is confirmed by high associations with a number of somatoform symptoms, according to a standardized interview and with associations with other scales assessing somatization, depression, and other features of psychopathology. Moreover, SOMS-7 scores were highest for patients fulfilling complete criteria for somatization disorder, medium for patients with somatization syndrome who did not fulfill complete criteria for somatization disorder, and low for patients with other mental disorders. This is an important finding since our comparison group in this case was not symptom free but had a high number of symptoms, although not as high as the patients with somatization disorder. The SOMS-7 was also able to demonstrate significant symptom decreases between the beginning and end of an inpatient treatment program. Most items of the SOMS-7 were sufficiently sensitive to assess change. These differences were significantly associated with other improvements in psychopathological features.

In comparisons of the two composite indices of the SOMS-7, the somatization severity index seems to have some advantages over the somatization symptom count. It not only better discriminated between patients with high and low somatization symptom load but also was more sensitive for the assessment of change. The SOMS-7 can

**TABLE 4. Differences in Scores Between Admission and Discharge<sup>a</sup> for Patients Who Applied for Treatment at a Behavioral Medicine Clinic**

Difference in Score	Difference in Screening for Somatoform Symptoms—7 Scores Between Admission and Discharge	
	Symptom Count	Severity Index
SCL-90-R		
Somatization	0.21	0.41
General psychopathology	0.30	0.42
Number of symptoms	0.37	0.30
Beck Depression Inventory depression subscale	0.43	0.49
Whiteley Index hypochondriasis subscale	0.29	0.31

<sup>a</sup>All correlation coefficients were statistically significant.

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be used as a measure of change of specific somatization symptom profiles; in outcome studies, this approach should be expanded by instruments assessing disability, general psychopathology, illness behavior, and illness attribution.

In sum, the SOMS-7 seems to be a reliable and valid instrument for the assessment of treatment effects. This makes it suitable as an evaluation instrument in pharma-

cology trials as well as in psychological intervention studies. One limitation of the present investigation is the inclusion of disabled inpatients and, consequently, an underrepresentation of mildly to moderately disabled patients more frequently found in outpatient settings. Further methodological investigations of the SOMS-7 should therefore focus on its application in other settings and on a shortened version.

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