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Development of a Type 2 Diabetes Symptom Checklist: a Measure of Symptom Severity

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The aim of the present study was to develop a Type 2 diabetes symptom checklist for use in clinical and epidemiological research, which can measure differences in symptom severity between patients and detect changes over time within patients. Face and content validity of items and dimension structure were based on literature and experiences of diabetologists. Two Likert scales were used to measure symptom frequency and perceived burden. Reliability, responsiveness and validity were studied in 185 Type 2 diabetic patients. Factor-analysis confirmed the predesigned dimension structure with 34 items, distributed over 6 dimensions. The internal consistency with Cronbach α coefficients between 0.76 and 0.95 and test-retest reliability with Pearson product-moment correlation coefficients between 0.79 and 0.94 were satisfactory. The ability to detect change over time (responsiveness) was estimated in stable subjects, using sample size calculations. A minimal detectable mean change of 0.07–0.58 points in total score on the 10-point scale within a group of 100 subjects suggests an impressive responsiveness. Significant differences in symptom severity score were found between patients with different co-morbidity status and treatment modes, indicating satisfactory construct validity of the dimension structure. The Type 2 Diabetes Symptom Checklist was found to be a useful diabetes-specific symptom severity assessment method for clinical and epidemiological studies.

KEY WORDS Type 2 diabetes mellitus Quality of life
Diabetes symptoms Questionnaire

Introduction

In clinical and epidemiological research metabolic parameters such as blood glucose and HbA_{1c} levels are often used to describe the disease status and the efficacy of treatment in Type 2 diabetic patients. Other frequently used objective outcome measures include long-term complications of diabetes, such as cardiovascular disease, neuropathy and retinopathy. Additionally, subjective measures are needed to describe the perceived disease severity and to assess the treatment effects in terms of changes in disease-burden over time. Several health-related 'quality of life' assessment methods are available for this purpose.¹ Most of these measures were originally developed for use in a general population² and may be not optimally discriminative in a diabetic population and may be relatively insensitive for clinically important changes over time among diabetic patients.^{3,4} To meet these shortcomings disease-specific 'quality of life' measures have been developed.^{5–7} However, none of these instruments contains a well-established measure for symptom severity. Diabetes-related symptoms are disease-specific manifestations mainly due to hypergly-

caemic and/or long-term complications. A measure of symptom severity is clinically relevant, particularly as treatment strategies which may affect symptom-burden are available.

We developed a self-administered Type 2 Diabetes Symptom Checklist (DSC-Type 2), which measures both the occurrence and the perceived burden of physical and psychological symptoms related to Type 2 diabetes and its possible complications. Our aim was to design an instrument that could both measure differences in symptom severity between patients and detect changes over time within patients. This article presents data on the reliability, responsiveness, and validity of the DSC-Type 2 for use in clinical and epidemiological research.

Patients and Methods

Initial Item Selection

Physical and psychological symptoms, related to diabetes mellitus Type 2 or associated complications, were derived from a literature review and from discussions with experienced diabetologists. Seventy-eight eligible items were identified and distributed over six symptom dimensions (hyperglycaemic, hypoglycaemic, psychological, cardiovascular, neuropathic, ophthalmological).

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Initial Item Reduction

The initial item-list was sent to 20 experienced clinicians, including diabetologists, general practitioners and diabetes educators. They were asked to consider whether any symptom occurs more frequently in diabetic patients than in non-diabetic subjects. Additional items could be proposed. The item-list was returned by 85 % of the clinicians and 42 additional items were mentioned. In a second evaluation, the respondents were confronted with the extended list, and information was given about the distribution of answers during the first round. Again, they scored the list but were also asked to consider the additional information.

Initial item reduction was based on the following criteria: items with less than 50 % scores on 'Yes, more or less associated with diabetes' or more than 25 % scores on 'No, not associated'. Sixty-nine of the 120 items met these criteria and were excluded. The remaining 51 items, described in the Appendix, were distributed over the 6 dimensions as follows: 7 hyperglycaemic items (1–7), 6 hypoglycaemic items (8–13), 10 psychological items (14–23), 8 cardiovascular items (24–31), 10 neuropathic items (32–41), 5 ophthalmological items (42–46), and a rest group of 5 items (47–51).

Questionnaire Construction

The 51 items described above were listed in random order. The self-administered questionnaire consists of two scales. Firstly, the subject is asked about the frequency of a symptom during the preceding 4 weeks. Secondly, if a symptom occurs, the subject is asked to quantify the perceived discomfort from that symptom. Both the frequency and the discomfort scales consist of a 4-point Likert scale. (Frequency scale: 0 = not at all, 1 = one or more times a month, 2 = one or more times a week, and 3 = daily; discomfort scale: 1 = not at all, 2 = a little, 3 = quite a bit, and 4 = very much). The scoring algorithm is as follows: frequency scores are simple summations of item-frequency scores (range: 0–3) within one (sub)dimension; weighted scores are calculated for each (sub)dimension by summation after multiplying the frequency of an item with the corresponding discomfort score (range: 1–4). To permit mutual comparison of (sub)dimensions with different numbers of items, the frequency and weighted scores for each (sub)dimension are standardized, i.e. scores (range 0–10) are calculated as the proportion of the total possible score for the (sub)dimension at issue multiplied by 10.

Study Population

For the assessment of the perceived symptom severity within various subjects with Type 2 diabetes, we invited:

1. patients ($n = 175$) visiting the diabetes out-patient clinic of the Vrije Universiteit Hospital in Amsterdam;

2. patients ($n = 29$) referred to the neurologist of this hospital because of suspected polyneuropathy;
3. patients ($n = 60$) from a general practice.

The patients completed the self-administered questionnaire at home and gave additional information about age, gender, duration of known diabetes, diabetes treatment and coexisting chronic disease (co-morbidity). Three weeks after returning the first questionnaire, the participating patients from the diabetic outpatient clinic and the general practice were asked to fill in the questionnaire once more. Additionally, they were asked whether major symptoms had changed.

Data Analysis

A first evaluation of the data was performed with respect to 'homogeneity' and internal consistency of the predesigned dimensions. Final item reduction was accomplished according to the following criteria:

1. exclusion of signs (as opposed to symptoms) and items which were considered to be too abstract;
2. exclusion of items allocated to a dimension with an item-total correlation < 0.35 .⁸

Principal component factor-analysis, with varimax rotation for the responses on the frequency scale, was used to confirm the predesigned dimension structure of the questionnaire and to explore the distribution of the rest items over the dimensions.⁹ Distribution of standardized frequency and weighted scores is given by means (standard deviations) and percentiles.

To study the influence of missing values on the distribution of scores on the questionnaire, we substituted in the case of one missing value within a (sub)dimension the mean of the remaining items. Reliability of frequency and weighted scores was assessed using Cronbach's α coefficient of internal consistency, and test-retest reliability was assessed using Pearson product-moment correlations.¹⁰ Responsiveness, operationalized as the minimal detectable mean change in standardized weighted scores over time within a group of 100 patients, was investigated by means of the estimated variance in test-retest differences, obtained from stable subjects with symptom scores greater than 0 for at least one of the administrations. Non-stable subjects who reported lessening or worsening of major symptoms were excluded from this analysis. Responsiveness was calculated using a sample-size formula (see Table 4) with the assumption that $\alpha = 0.05$ (two-tailed), $\beta = 0.10$, and group size = 100.¹¹ Construct validity of the final dimension structure is evaluated by comparison of Mann-Whitney U test of means of scores in patients with different co-morbidity status, stratified for treatment mode.

Results

Characteristics of Study Population

One hundred and sixteen Type 2 diabetes patients from the hospital outpatient clinic (66 % of the invited patients), 29 Type 2 diabetic patients referred to the neurologist because of suspected polyneuropathy (100 % of the invited patients) and 46 general practice patients (77 % of the invited patients) participated in the study (Table 1). Six participants were excluded (four left the questionnaire blank, two responded with written answers to every item). The administration of the questionnaire took about 10 min. The second questionnaire was filled in by 116 (74 %) of the 156 participating patients. A major change in perceived symptoms was reported by 16 patients.

Final Item Reduction

Three items (30, 31, and 50) were excluded because they represented signs rather than symptoms and three items (22, 23, and 51) were eliminated because they were considered to be too abstract. Eleven items did not meet the criterion of internal consistency and were, therefore, omitted, including three hyperglycaemic (5–7), three autonomic manifestations of hypoglycaemia (11–13), one peripheral cardiovascular (29) and four autonomic neuropathic symptoms (38–41). As a consequence, the predesigned neuropathic dimension consisted of only peripheral polyneuropathic symptoms (32–37) and the hypoglycaemic dimension included only neuroglycopenic symptoms (8–10).

Factor Analysis

Responses to the 34 remaining items were factor analysed in order to explore and confirm statistically the predesigned dimension structure. The principal component analyses produced eight factors with a cumulative explained variance of 71.1 %. As expected, the first

principal component was general in nature and had moderate to high positive loadings for all symptoms and accounted for 34.3 % of the variance. After varimax rotation, eight factors with loadings between 0.51 and 0.87 confirmed statistically the distinctiveness of an ophthalmological (Vision: 42–46), a cardiovascular (Cardiac: 24–28), a hyperglycaemic (Hyper: 1–4), a hypoglycaemic (Hypo: 8–9 and 21) dimension, two neuropathic subdimensions ('polyneuropathic pain symptoms' (N-pain: 28, 32, 47, and 48) and 'polyneuropathic sensory symptoms' (N-sens.: 33–37)) and two psychological subdimensions ('fatigue' (P-fatigue: 10, 14–16) and 'cognitive distress' (P-cogn.: 17–20)). These eight factors accounted for 34.3, 3.4, 3.7, 3.2, 9.4, 5.2, 7.3, and 4.5 % of the variance, respectively. Two rest-items (47, 48) loaded on the N-pain subdimension and one (49) on the N-sens. subdimension with loadings of 0.74, 0.79 and 0.52, respectively. One cardiovascular item (28) loaded 0.74 on the N-pain subdimension. The hypoglycaemic item *lack of energy* (10) was allocated with a loading of 0.81 on the P-fatigue subdimension and the psychological item *moodiness* (21) was allocated to the hypoglycaemic dimension with a loading of 0.62. An analysis with a forced six-factor solution was used to explore the statistical support of unique significance of the predesigned six-dimension structure and accounted for a total of 64.5 % of the variance. The N-pain and N-sens. subdimensions and the P-cogn. and Hypo (sub)dimension were combined in one factor, whereas the P-fatigue subdimension remained separated.

In summary, the 34 items were finally distributed over 6 dimensions (including 4 subdimensions, see Appendix), consisting of Hyper (4 hyperglycaemic items: 1–4), Hypo (3 hypoglycaemic items: 8, 9 and 21), Cardiac (4 cardiovascular items: 24–27), N-total (including N-pain (4 polyneuropathic pain items: 28, 32, 47 and 48), and N-sens. (6 polyneuropathic sensory items: 33–37 and 49)), P-total (including P-fatigue (4 psychological fatigue items: 10 and 14–17 and P-cogn. (4 psychological cognitive distress items: 18–22)) and Vision (5 ophthalmological items: 42–47). A copy of the final version of the DSC-Type 2 is available on request from the first author.

Table 1. Characteristics of study population

	Diabetic clinic	Polyneuropathy patients	General practice	Total
<i>n</i>	112	29	44	185
Age (yr)	66 ± 10	56 ± 6	66 ± 13	65 ± 11
Gender (M/F ratio)	55/57	23/6	19/25	97/88
Diabetes duration (yr)	12.8 ± 7.0	11.2 ± 6.1	9.7 ± 7.5	11.8 ± 7.1
Treatment status				
Diet	3	2	8	13
OHA ^a	19	—	24	43
Insulin	74	26	12	112
Insulin and OHA ^a	15	1	—	16

Results as number or mean ± SD. For one patient treatment status was unknown.

^aOHA, oral hypoglycaemic agent

Distribution of Standardized Questionnaire Score

The mean standardized frequency scores vary from 2.0 for the hypo and cardiovascular dimension to 4.5 for the psychological fatigue subdimension (Table 2). The mean standardized weighted scores ranged from 1.4 to 3.4. Eleven to forty-four percent of the subjects reported no symptoms on the (sub)dimensions and in 4 % of the cases there were no symptoms at all. Because of this substantial proportion of zero-scores, the distribution is positively skewed. Therefore, the 20th, 50th, and 80th percentile scores are also presented in Table 2.

There were 2.2–5.4 % missing values per item, except in the case of *deteriorating vision* (43) with 7.6 %. One hundred and forty-three subjects, 77 % of the study population, completed the questionnaire without missing values and in 10 % of all cases only one answer was missing. When one value within a (sub)dimension was missing, substitution by the mean of the remaining items did not change the score distribution of the questionnaire (data not shown).

Reliability and Responsiveness

Table 3 shows the results of the analyses of internal consistency for the frequency and weighted scores in the total study population ($n = 185$). This table also shows data on test–retest reliability, calculated for patients of the outpatient clinic and general practice only ($n = 116$). The Cronbach's α coefficients ranged from 0.76 to 0.95 and the Pearson product-moment

correlation coefficients were between 0.79 and 0.94 for both frequency and weighted scores.

Table 4 deals with responsiveness and presents data regarding stable patients (no change in major symptoms in 86 % of all subjects with two questionnaire administrations) divided into two groups, separated by the median standardized weighted score. Responsiveness is calculated on the basis of standard deviations of within-subject differences between the first and second questionnaire administration. The mean standardized weighted scores for groups A (scores < median) and B (scores $\geq$ median) vary from 0.3 to 0.9 and 2.7 to 5.4, respectively. The standard deviations of test–retest differences are 1.5 to 5 times lower for group A than for group B. The calculated minimal detectable mean change in score over time (responsiveness) in a group of 100 patients, ranges in situations A and B from 0.07 to 0.25 and 0.14 to 0.58, respectively. If responsiveness is expressed as percentage of change for the corresponding mean (sub)dimension score in situation A and B, the ranges are 16–77 percent and 5–14 percent, respectively.

Cross-sectional Construct Validity

Our assumption was that subjects with comorbidity would score higher on particular dimensions related to diabetic complications. Therefore, the subjects were grouped by their co-morbidity status. Co-morbidity was defined by the presence of at least one of the following diabetes-related conditions: history of cardiovascular disease (myocardial infarction, hypertension or consequences of cerebrovascular disease), renal disease or

Table 2. Distribution of percentage zero-score, mean (SD) and percentile of standardized frequency and weighted scores for (sub)dimensions for the total study population

	<i>n</i> ^a	%- Zero score	Frequency score	Weighted score	Frequency score 20th 50th 80th percentiles			Weighted score 20th 50th 80th percentiles		
Hyper	167	37	2.6 ± 3.0	1.7 ± 2.3	0.0	1.7	5.3	0.0	0.6	3.1
Hypo	170	44	2.0 ± 2.4	1.4 ± 2.0	0.0	1.1	4.2	0.0	0.6	2.3
Cardiac	167	40	2.0 ± 3.4	1.4 ± 2.0	0.0	0.8	4.1	0.0	0.4	2.6
N-sens.	168	31	2.8 ± 3.0	2.0 ± 2.5	0.0	1.7	5.5	0.0	0.8	4.0
N-pain	166	44	2.4 ± 3.0	1.8 ± 2.7	0.0	0.8	5.0	0.0	0.4	3.8
N-total	161	25	2.6 ± 2.8	1.9 ± 2.4	0.0	1.7	5.0	0.0	0.9	3.5
P-fatigue	172	15	4.5 ± 3.6	3.4 ± 3.3	0.8	4.2	8.3	0.4	2.3	7.0
P-cogn.	174	33	2.5 ± 2.8	1.8 ± 2.5	0.0	1.7	5.0	0.0	0.6	3.4
P-total	168	11	3.6 ± 2.9	2.6 ± 2.6	0.8	3.1	6.3	0.4	1.7	4.7
Vision	160	43	2.1 ± 2.9	1.5 ± 2.5	0.0	0.7	3.3	0.0	0.3	2.2
Total	143	4	2.6 ± 2.0	1.9 ± 1.8	0.7	2.1	4.4	0.3	1.2	3.4

Results as number, mean $\pm$ SD or percentiles. Standardized scores are calculated by dividing the real score by the corresponding maximal (sub)dimension score and multiplying by 10 (range: 0–10). ^aSubjects without missing values for (sub)dimension scores on 1st questionnaire administration.

Hyper, hyperglycaemic symptoms; Hypo, hypoglycaemic symptoms; Cardiac, cardiovascular symptoms; N-sens., polyneuropathic sensory symptoms; N-pain, polyneuropathic pain symptoms; N-total, all polyneuropathic symptoms; P-fatigue, psychological fatigue symptoms; P-cogn., psychological cognitive distress symptoms; P-total, all psychological fatigue and cognitive distress symptoms; Vision, ophthalmological symptoms; Total, total DSC-Type 2 symptom severity score.

Table 3. Internal consistency and test-retest reliability for frequency and weighted scores

	Number of items	<i>n</i> ^c	Cronbach's α ^a		<i>n</i> ^d	Test-retest correlation ^b	
			Frequency score	Weighted score		Frequency score	Weighted score
Hyper	4	167	0.84	0.83	110	0.79	0.84
Hypo	3	170	0.77	0.76	110	0.83	0.80
Cardiac	4	167	0.79	0.80	108	0.84	0.86
N-sens.	6	168	0.85	0.86	106	0.88	0.87
N-pain	4	166	0.88	0.89	108	0.88	0.83
N-total	10	161	0.91	0.92	104	0.93	0.91
P-fatigue	4	172	0.90	0.93	110	0.86	0.89
P-cogn.	4	174	0.84	0.86	110	0.82	0.85
P-total	8	168	0.90	0.92	107	0.87	0.88
Vision	5	160	0.90	0.91	103	0.89	0.88
Total	34	143	0.94	0.95	93	0.94	0.92

^aCronbach's α studied in total study population. ^bPearson product-moment correlation coefficient, studied in patients from the diabetic out-patient clinic and general practice with a time-interval of 3 weeks. ^cNumber of subjects without missing values for (sub)dimension scores on the 1st questionnaire administration. ^dNumber of subjects without missing values for (sub)dimension scores on both questionnaire administrations.

Table 4. Means and standard deviations of within-subject differences between the 1st and the 2nd questionnaire administration for standardized weighted scores and responsiveness

Dimension	<i>n</i> ^a	A Scores < median			B Scores $\geq$ median		
		Mean ^b	SD _{dif}	R (%)	Mean ^b	SD _{dif}	R (%)
Hyper	67	0.4	0.74	0.24 (60)	3.5	1.46	0.47 (13)
Hypo	52	0.9	0.71	0.23 (26)	4.6	1.78	0.58 (13)
Cardiac	58	0.5	0.72	0.23 (46)	2.9	1.25	0.41 (14)
N-sens.	60	0.3	0.22	0.07 (23)	2.8	1.16	0.38 (14)
N-pain	47	0.6	0.56	0.18 (30)	4.6	1.77	0.57 (12)
N-total	65	0.4	0.42	0.14 (35)	3.2	1.00	0.32 (10)
P-fatigue	80	0.9	0.76	0.25 (28)	5.4	1.67	0.54 (10)
P-cogn.	72	0.4	0.63	0.20 (50)	3.7	1.57	0.51 (14)
P-total	82	0.8	0.57	0.19 (24)	4.5	1.38	0.45 (10)
Vision	49	0.3	0.70	0.23 (77)	3.3	1.09	0.35 (11)
Total	70	0.5	0.24	0.08 (16)	2.7	0.44	0.14 (5)

^aNumber of stable patients (= no change in major symptoms) from the hospital out-patient clinic and general practice with scores > 0 for at least one of the administrations. ^bMeans are standardized weighted scores. This population is subsequently divided into two groups as follows: A: (sub)dimension scores < median score and B: (sub)dimension scores $\geq$ median score (according to the 1st administration).

Sample size formula: $R = \sqrt{(Z\alpha + Z\beta)^2 \times \sigma^2 / N_t}$.

R (responsiveness) = minimal detectable mean change in standardized weighted score over time in groups; σ^2 = variance of intra-person change over time between subjects, estimated by SD_{dif}^2 ; SD_{dif} = calculated standard deviation of intra-person differences in scores between stable subjects based on two DSC-Type 2 administrations; $\alpha = 0.05$ ($Z\alpha = 1.96$); $\beta = 0.10$ ($Z\beta = 1.282$); $N_t = 100$ (group size). Responsiveness expressed as percentage of change for corresponding mean (sub)dimension score between parentheses.

ocular disease. For patients with suspected polyneuropathy no co-morbidity data were available and excluded from this analysis and the prevalences for these conditions were 21 %, 37 %, 9 %, 5 % and 20 %, respectively. The prevalence of any co-morbidity was 61 %. We also assumed that insulin-treated patients, as an objective measure of 'diabetes severity', would show high scores compared to patients treated with oral hypoglycaemic agents (OHA). For all dimensions significant differences with 1.4–3.2 fold higher scores were found in subjects with co-morbidity compared to patients without co-morbidity, except for the polyneuropathic (sub)dimension scores (Table 5). After stratification for mode of treatment, the (sub)dimension scores were 1.3–2.0 fold higher in OHA or insulin-treated patients with co-morbidity compared to patients without co-morbidity. Most (sub)dimension scores were 1.5–2.0 fold higher in the insulin-treated subjects (stratified for co-morbidity) than OHA-treated patients, except for the hyperglycaemic dimension, whereas a major significant difference was found for the hypoglycaemic dimension (Table 5). When we compared the (sub)dimension scores of insulin-treated patients with suspected polyneuropathy to the other insulin-treated outpatient clinic patients, the former scored significantly higher on the polyneuropathic sensory and the polyneuropathic total (sub)dimensions (3.3 vs 1.7, $p < 0.001$ and 2.2 vs 1.7, $p < 0.001$, respectively), whereas a tendency toward higher scores for the polyneuropathic pain subdimension (2.9 vs 1.8, $p = 0.227$) and

no significant differences of less than 0.3 were found for the other dimensions (data not shown).

Discussion

The distribution of 34 diabetes-related symptoms over six predefined dimensions has been examined and confirmed by factor-analysis. Although there was no strong statistical support for the unique significance of two polyneuropathic subdimensions (N-sens. and N-pain), the plausibility of existence is confirmed by clinical observations in which painful diabetic neuropathy can be distinguished from sensory manifestations.^{12,13} Manifestations, such as pain and temperature-related sensations, are predominantly caused by small fibre loss, whereas large fibre loss results in sensory disturbance symptoms. The allocation of *aching calves when walking* [28] to the domain of polyneuropathic pain is open to some criticism. Distinguishing polyneuropathic from peripheral vascular pain symptoms can be very difficult and it is debatable whether one item can differentiate between neuropathic pain and peripheral vascular pain. Based on content, and also for statistical reasons, the allocation of this (initially classified as peripheral vascular) item to the polyneuropathic pain dimension seems, therefore, plausible. The existence of fatigue and cognitive distress related entities, operationalized by the two subdimensions (P-fatigue and P-cogn.) are also described in the literature.^{14,15} Seventy-seven percent of the patients

Table 5. Mean standardized weighted scores for (sub)dimensions in subjects with and without co-morbidity, obtained from patients of the diabetic outpatient clinic and general practice and stratified for treatment mode

	Co-morbidity ^a (All treatment modes)			Co-morbidity ^a (OHA) ^b			Co-morbidity ^a (Insulin) ^c		
	No (n = 58)	Yes (n = 94)	p-value ^d	No (n = 19)	Yes (n = 24)	p-value ^d	No (n = 30)	Yes (n = 54)	p-value ^d
Age ^e	65 ± 11	67 ± 11	0.280	64 ± 12	67 ± 12	0.397	64 ± 9	67 ± 10	0.215
Age at diagnosis ^e	53 ± 10	55 ± 11	0.230	53 ± 9	59 ± 11	0.061	52 ± 9	53 ± 11	0.831
DM-duration ^e	12 ± 7	12 ± 7	0.858	12 ± 8	9 ± 6	0.167	12 ± 6	14 ± 8	0.160
Hyper	1.3	2.0	0.041	1.5	2.0	0.763	1.4	1.9	0.133
Hypo	1.0	1.6	0.012	0.2	0.5	0.123	1.4	2.1	0.105
Cardiac	0.7	1.9	< 0.001	0.7	1.3	0.125	0.8	2.4	< 0.001
N-sens.	1.4	1.9	0.236	0.8	1.0	0.528	1.7	2.3	0.496
N-pain	1.3	2.0	0.245	1.1	1.0	0.794	1.5	2.4	0.573
N-total	1.4	1.9	0.126	0.9	1.0	0.630	1.6	2.4	0.420
P-fatigue	2.3	4.0	0.001	1.6	2.8	0.101	2.5	4.4	0.008
P-cogn.	1.1	2.2	0.012	0.8	1.6	0.096	1.2	2.5	0.291
P-total	1.7	3.2	< 0.001	1.3	2.2	0.053	1.8	3.5	0.004
Vision	0.7	2.2	< 0.001	0.7	1.4	0.049	0.8	2.6	0.045
Total	1.1	2.3	< 0.001	1.0	1.4	0.187	1.1	2.7	0.005

^aFor subjects with suspected polyneuropathy no co-morbidity data are available.

^bOnly subjects treated with oral hypoglycaemic agent (OHA) included.

^cOnly subjects with insulin-treatment included; co-morbidity was defined by the presence of cardiovascular disease (myocardial infarction, hypertension or consequences of cerebrovascular disease), renal disease or ocular disease; information about co-morbidity was missing for 4 patients.

^dp-Value of Student's *t*-test for differences in age, age at diagnosis and DM-duration, p-Value of Mann-Whitney U test for differences in (sub)dimension score.

^eMeans ± SD in years.

completed the questionnaire without leaving any item unanswered. The number of omissions was approximately equally distributed across the various items.

In order to reduce random error, considerable attention was paid to the questionnaire format, including item formulation and scale construction.^{16–18} The item formulation was carefully chosen, in order to be also applicable to persons with a low reading level. The 4-point frequency scale, rather than a simple dichotomic scale, provides information on the symptom occurrence, and the discomfort scale enables weighting of the frequency scores by means of the subject's own judgement. The standardized weighted score is, by virtue of its wide range, high internal consistency and satisfactory test–retest reliability, probably also sensitive for longitudinal change in symptom severity. Our calculation of responsiveness clearly demonstrates that very small changes in mean symptom severity can be detected by the DSC-Type 2 (on the aggregated level). We assumed that subjects with higher scores would have greater variance in test differences, thus, influencing the precision and the minimal detectable effect. Therefore, the subjects were divided into two groups by their median (sub)dimension score. As expected, the variability in test differences in diabetic patients with a high symptom score was found to be larger than in those with a low score. Although the former group consequently demonstrated a two-fold lower responsiveness on individual (sub)dimensions level, the possibility of measuring this minimal detectable change (expressed as percentage of mean corresponding (sub)dimension score) was remarkably better in this patient category. The smallest minimal detectable change was calculated for the standardized total score (all (sub)dimensions included). A change of 0.08 and 0.14 points on the 10-point scale (16 % and 5 % of the corresponding mean scores of 0.5 and 2.7) demonstrates an impressive responsiveness on the aggregated level (group size of 100) for the total score.

The calculation of responsiveness has some limitations. The time-interval of 3 weeks between the first and second questionnaire administration probably differs from the time-period in which the instrument will be used during an intervention study. The intra-person variability will probably be higher when the repeated measurement is performed within a longer time-interval which consequently diminishes the responsiveness. Formal longitudinal construct validity, i.e. correlates between change in symptom score and change in observed metabolic control (e.g. as measured by HbA_{1c}), will be evaluated in future studies.

The cross-sectional construct validity of the (sub)dimension structure was examined by comparison of Mann-Whitney U test of means of scores in patients with different comorbidity status, stratified for treatment mode. Both our hypotheses, that patients with co-morbidity compared to subjects without co-morbidity and insulin-treated patients compared to oral hypoglycaemic agent (OHA) treated patients would score higher, were

confirmed in our data. The differences between OHA-treated patients with and without co-morbidity were less frequent statistically significant compared to the insulin group. This may be attributed to the shorter diabetes duration, possibly due to later 'onset' of diabetes in the co-morbidity category. Alternatively, this may be seen as the result of a selection process favouring insulin therapy for patients with co-morbidity. Further evidence for construct validity of the dimension structure was found when the (sub)dimension scores in patients with suspected polyneuropathy were compared to the other diabetic patients from the outpatient clinic and showed significantly higher scores on the polyneuropathic sensory and the polyneuropathic total (sub)dimensions in the former group. Since only insulin-treated patients were compared, the differences were not explained by disproportional insulin-treatment between both patients groups. In conclusion, the Diabetes Symptom Checklist (DSC-Type 2) is a reliable Type 2 diabetes-specific symptom severity assessment method. The ability to measure differences in symptom severity between patients and to detect change over time on the aggregated level, suggest that the DSC-Type 2 is a useful subjective outcome measure for use in clinical and epidemiological studies. The satisfactory psychometric properties and attributes of the DSC-Type 2 warrant further study with regard to the associations of the (sub)dimension scores with objective clinical outcome measures, such as glycaemic level and presence and severity of diabetic complications. In future studies, we will also study the change in DSC-Type 2 scores in response to therapeutic interventions.

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(continued with Appendix on next page)

Appendix. Initial and Final Item Content of the Dimensions of the Type 2 Diabetes Symptom Checklist

Predefined dimension	Initial item content ^a	Final item content of (sub)dimension
Hyperglycaemic	1 Very thirsty	1–4: Hyper
	2 Dry mouth	
	3 Drink a lot (all sorts of drinks)	
	4 Frequent voiding	
	5 Headache	5–7: excluded
	6 Itching 'below'	
	7 Itching skin	
Hypoglycaemic	8 Easily irritated or annoyed	8–9: Hypo
	9 Irritability just before a meal	
	10 Lack of energy	–10: allocated to P-fatigue
	11 Excessive hunger	11–13: excluded
	12 Trembling	
	13 Sweating at night or sweating when waking up	
Psychological	14 Overall sense of fatigue	14–16: P-fatigue
	15 Fatigue in the morning when getting up	
	16 Increasing fatigue in the course of the day	
	17 Dull head	
	18 Sleepiness or drowsiness	18–20: P-cogn.
	19 Difficulty concentrating	
	20 Difficulty staying attentive	
	21 Moodiness	
	22 Being concerned about the future	22, 23: excluded
	23 Being concerned about health	
Cardiovascular	24 Shortness of breath during exercise	24–28: Cardiac
	25 Shortness of breath at night	
	26 Palpitations	
	27 Pains in the breast or heart region	
	28 Aching calves when walking	
	29 Sensation of cold feet, also when it is not cold	29–31: excluded
	30 Swollen feet or ankles	
	31 Slow wound-healing	
Neuropathy	32 Shooting pains in the legs	–32: allocated to N-pain
	33 Numbness (loss of sensation) in the hands	33–37: N-sens.
	34 Numbness (loss of sensation) in the feet	
	35 Tingling or prickling in the hands or fingers	
	36 Tingling or prickling in the legs or feet	
	37 Queer feeling in the legs or feet when touching	
	38 Sensation of a full stomach after meals	38–41: excluded
	39 Sweating or clammy skin, also when it is not hot	
	40 Dizzy or light-headed	
	41 Trouble finishing voiding	
Ophthalmological	42 Persistently blurred vision (also with glasses)	42–46: Vision
	43 Deteriorating vision	
	44 Flashes or black spots in the field of vision	
	45 Fluctuating clear and blurred vision	
	46 Sudden deterioration in vision	
Rest group	47 Burning pain in the calves at night	47,48: allocated to N-pain
	48 Burning pain in the legs during the day	
	49 Tingling in the limbs at night	–49: allocated to N-sens.
	50 Inflamed toe(s) or toenail(s)	50, 51: excluded
	51 Being concerned about the diet	

^a Abbreviated form; not the original formulation.